Mallinckrodt plc
Form 424B3
March 05, 2014
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Registration No. 333-193395

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 April 2, 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 17 for a discussion of the factors you should consider in connection with the exchange offer.

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

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

The date of this prospectus is March 5, 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 consolidated subsidiaries. Unless the context otherwise requires, references to Mallinckrodt s historical business and operations prior to the completion of the separation on June 28, 2013 refer to the business and operations of Covidien s Pharmaceuticals business as it was historically managed as part of Covidien and its subsidiaries. Unless the context otherwise requires, references in this prospectus to Covidien refer to Covidien plc, an Irish public limited company, and its consolidated subsidiaries, including the Pharmaceuticals business prior to completion of the separation. References to the distribution refer to the dividend on Covidien ordinary shares that was satisfied by Mallinckrodt s issuance of its ordinary shares to the persons entitled to receive the dividend on June 28, 2013. References to the initial purchasers refer to J.P. Morgan Securities LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., Deutsche Bank Securities Inc., Barclays Capital Inc., BMO Capital Markets Corp., Mizuho Securities USA Inc., PNC Capital Markets LLC, The Williams Capital Group, L.P. and Wells Fargo Securities, LLC. Except as otherwise indicated, references in this prospectus to fiscal 2014, fiscal 2013, fiscal 2012, fiscal 2011, fiscal 2010 and fiscal 2009 are to Mallinckrodt s fiscal years ended September 26, 2014, September 27, 2013, September 28, 2012, September 30, 2011, September 24, 2010 and September 25, 2009, respectively. References to dollars or $ refer to United States dollars.

Trademarks and Trade Names

Mallinckrodt owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this prospectus is Mallinckrodt, which is a registered trademark or the subject of pending trademark applications in the United States and other jurisdictions. Solely for convenience, the Company only uses the 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. 333-193395) under the Securities Act with respect to the exchange notes. This prospectus is a part of the registration statement and does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information about us and the exchange notes, you should refer to the registration statement, including its exhibits and schedules. This prospectus summarizes material provisions of contracts and other documents to which we refer you. Since the prospectus may not contain all of the information that you may find important, you should review the full text of these contracts and other documents. We have included or incorporated by reference copies of these documents as exhibits to our registration statement.

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

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

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

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

The Company has made forward-looking statements in this prospectus that are based on management s beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning the Company s possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words believe, expect, 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 17.

Our Company

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

We conduct our business in the following two segments:

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

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

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

Our Competitive Strengths

We believe we have the following strengths:

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

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

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

Formulation and manufacturing expertise in controlled substances and complex generics;

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

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

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

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

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

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

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

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

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

Our Strategy

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

We are committed to the following goals:

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

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

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

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

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Risk Factors

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

Risks related to the exchange offer, such as:

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

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

Risks related to the notes, such as:

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

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

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

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

Risks related to our business, such as:

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

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

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

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

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

Risks related to the separation.

Risks related to tax matters.

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

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The Separation

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

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

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

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

Recent Developments Our Pending Acquisition of Cadence Pharmaceuticals, Inc.

The Offer and the Merger

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

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

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

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

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

Conditions to the Offer and the Merger

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

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

Representations and Warranties; Covenants

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

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

Termination and Termination Fees

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

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

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

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Debt Financing

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

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

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

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

Corporate Information

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

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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 April 2, 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 the three months ended December 27, 2013 and December 28, 2012 and the summary balance sheet data at December 27, 2013 have been derived from our unaudited condensed consolidated and combined financial statements included elsewhere in this prospectus. The summary income statement data for each of the fiscal years in the three-year period ended September 27, 2013 and the summary balance sheet data as of September 27, 2013 and September 28, 2012 have been derived from our audited consolidated and combined financial statements, which are included elsewhere in this prospectus. The summary balance sheet data as of September 30, 2011 has been derived from our audited combined financial statements that are not included in this prospectus. The summary balance sheet data as of December 28, 2012 has been derived from our unaudited combined financial statements that are not included in this prospectus. The summary financial data should be read in conjunction with our consolidated and combined financial statements and accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

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

Non-GAAP Financial Measures

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

Adjusted EBITDA has the following limitations:

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

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

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

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

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

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

(Dollars in Millions)	Three Months Ended December 27, 2013[2]	Three Months Ended December 28, 2012[3]	Fiscal Year[1] 2013[4]	Fiscal Year[1] 2012[5]	Fiscal Year[1] 2011[6]
Consolidated and Combined Statement of Income Data:					
Net sales	$540.2	$504.0	$ 2,204.5	$ 2,056.2	$ 2,021.8
Gross profit	255.6	233.5	1,024.9	964.8	914.9
Operating income[7]	73.1	36.8	144.8	235.2	240.7
Income from continuing operations before income taxes	63.0	36.9	126.4	236.1	243.2
Income from continuing operations	46.4	19.8	57.8	141.3	157.0
Other Financial Data:					
Adjusted EBITDA[8]	N/A	N/A	$ 396.7	$ 402.8	$ 371.8

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

(1) Fiscal 2011 includes 53 weeks, while fiscal 2013 and 2012 each includes 52 weeks.
(2) The three months ended December 27, 2013 includes $2.2 million of separation costs and $8.1 million of restructuring and related charges, net, of which $0.1 million related to accelerated depreciation.
(3) The three months ended December 28, 2012 includes $12.0 million of separation costs and $1.0 million of restructuring and related charges, net, of which $0.8 million related to accelerated depreciation.
(4) Fiscal 2013 includes $74.2 million of separation costs and $35.8 million of restructuring and related charges, net, of which $2.6 million related to accelerated depreciation.
(5) Fiscal 2012 includes $25.5 million of separation costs and $19.2 million of restructuring and related charges, net, of which $8.0 million related to accelerated depreciation.
(6) Fiscal 2011 includes $2.9 million of separation costs and $10.0 million of restructuring and related charges, net, of which $1.6 million related to accelerated depreciation.
(7) During fiscal 2013, 2012 and 2011, Covidien allocated general corporate expenses to us in the amount of $39.6 million, $49.2 million and $56.3 million respectively. The three months ended December 28, 2012 includes $11.9 million of allocated general corporate expenses. General corporate expenses include, but are not limited to, costs related to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and stock-based compensation. Effective upon completion of the separation, we assumed

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

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

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

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RISK FACTORS

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

Risks Related to the Exchange Offer

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

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

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

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

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

- the number of holders of exchange notes;
- our operating performance and financial condition;

the market for similar securities;

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

prevailing interest rates.

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

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

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

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

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

Risks Related to the Notes

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

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

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

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

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

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

increasing our vulnerability to general adverse economic and industry conditions;

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

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

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

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

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

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

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

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

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

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

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

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

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

- incur additional non-guarantor indebtedness;
- pay dividends or make other distributions on or repurchase or redeem our capital stock;
- incur liens;
- enter into transactions with affiliates;
- enter into agreements restricting the Issuer s subsidiaries ability to pay dividends;
- enter into sale and leaseback transactions; and
- consolidate, merge or sell all or substantially all of our assets or all or substantially all of the assets of the Specialty Pharmaceuticals segment or the Global Medical Imaging segment.

As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

In addition, the restrictive covenants in the credit agreement that govern the credit facility require us to maintain specified financial ratios. Our ability to meet those financial ratios can be affected by events beyond our control.

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

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

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

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

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

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

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

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

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

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

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

Upon the occurrence of specific change of control events, we are required to offer to repurchase all outstanding notes at 101% of their principal amount, plus accrued and unpaid interest to, but not including, the date of repurchase. Additionally, under the credit facility, the occurrence of one or more certain change of control events may constitute an event of default that permits the lenders to accelerate the obligations under the credit facility and terminate their commitments to lend thereunder. The source of funds for any repurchase of the notes and repayment of borrowings under the credit facility would be MIFSA s available cash or cash generated from Mallinckrodt s operations or other sources, including borrowings, sales of assets or sales of equity. MIFSA may not be able to repurchase the notes upon a change of control 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

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

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

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

- the Issuer or any of the guarantors, as applicable, were insolvent or rendered insolvent by reason of the issuance of the notes or the incurrence of the guarantees;
- the issuance of the notes or the incurrence of the guarantees left the Issuer or any of the guarantors, as applicable, with an unreasonably small amount of capital or assets to carry on the business;
- the Issuer or any of the guarantors intended to, or believed that the Issuer or such guarantor would, incur debts beyond the Issuer s or the guarantor s ability to pay as they mature; or
- the Issuer or any of the guarantors were a defendant in an action for money damages, or had a judgment for money damages docketed against the Issuer or the guarantor if, in either case, the judgment is unsatisfied after final judgment.

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

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

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

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

it could not pay its debts as they became due.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

potential difficulties integrating and harmonizing financial reporting systems;

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the loss of key employees; and

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

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

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

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

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

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

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

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

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

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

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

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

increasing our vulnerability to general adverse economic and industry conditions;

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

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

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

increasing our cost of borrowing.

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

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

- incur additional indebtedness;
- pay dividends or make other distributions on or repurchase or redeem our capital stock;
- prepay, redeem or repurchase certain debt;
- make loans and investments;
- sell assets;
- incur liens;
- enter into transactions with affiliates;
- enter into agreements restricting the ability of the subsidiaries of Mallinckrodt plc to pay dividends; and
- consolidate, merge or sell all or substantially all of our assets.

As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively, execute our growth strategy or take advantage of new business opportunities.

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

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

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

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

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

- our ability to increase market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product we may later establish;
- our ability to maintain and defend the patent protection and regulatory exclusivity of OFIRMEV;
- our ability to continue to procure a supply of OFIRMEV from its sole source third-party manufacturer in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- the performance of Cadence s third-party manufacturer and our ability to ensure that the supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;
- our ability to deploy and support a qualified sales force;
- our ability to maintain fees and discounts payable to the wholesalers and distributors who distribute OFIRMEV, as well as to group purchasing organizations, at commercially reasonable levels;
- whether the Federal Trade Commission (FTC), Department of Justice (DOJ) or third parties seek to challenge and are successful in challenging Cadence s settlement agreement with Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC (collectively, Perrigo) or its settlement agreement with Sandoz, Inc., Sandoz AG, Neogen International N.V. and APC Pharmaceuticals, LLC;
- warnings or limitations that may be required to be added to OFIRMEV s FDA-approved labeling;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and
- our ability to achieve hospital formulary acceptance for OFIRMEV, and to the extent third-party payors separately cover and reimburse for OFIRMEV, the availability of adequate levels of reimbursement for OFIRMEV from third-party payors.

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

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

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

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

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

For example, in August 2011, Cadence and Pharmatop filed suit in the United States District Court for the District of Delaware against Perrigo and Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, Exela). The lawsuit followed the notices that Cadence received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, Cadence alleged that Perrigo and Exela each infringed the 222 patent and the 218 patent by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The 222 and the 218 patents are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Perrigo ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the 222 and 218 patents, the entry of a settlement order or consent decree stating that the 222 and 218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case that asserted, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Cadence s licensors might not have been the first to make the inventions covered by each of its pending patent applications and issued patents;
- Cadence s licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of Cadence s products, product candidates or technologies;

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

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

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

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

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

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

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

Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;
- receiving requisite regulatory approvals for such products in a timely manner, or at all;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;

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

unanticipated costs;

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

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

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

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

effective execution of the planned launch in a manner that is consistent with anticipated costs.

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

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

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

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

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

which would limit our growth and future revenue.

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

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

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

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

The industries in which we operate are highly competitive. Competition takes many forms, such as price reductions on products that are comparable to our own, development, acquisition or in-licensing of new products that may be more cost-effective than or have performance superior to our products, and the introduction of generic versions when our proprietary products lose their patent protection or market exclusivity. For further discussion on the competitive nature of our business, as well as intellectual property rights and market exclusivity, refer to the section entitled Business. Our current or future products could be rendered obsolete or uneconomical as a result of this competition. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

We regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Moreover, the due diligence that we conduct in conjunction with an acquisition may not sufficiently discover risks and contingent liabilities associated with the acquisition target and, consequently, we may consummate an acquisition for which the risks and contingent liabilities are greater than were projected. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, and our customer or employee base, including diversion of management s attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies which we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. Additionally, the time between our expenditures to acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses (or the timing of revenue recognition related to licensing agreements and/or strategic collaborations) could cause fluctuations in our financial performance from period 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 issued its formal recommendation to the DHHS, who in turn issued a similar recommendation to the DEA in December 2013. In February 2014, the DEA issued its proposal to reschedule hydrocodone combination products from Schedule III to Schedule II. The DEA proposal is open for comment through April 28, 2014. At this time, it is too early to determine the degree of impact the hydrocodone rescheduling, if adopted, will have on our business.

Global economic conditions could harm us.

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

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 December 27, 2013, it was probable that we would incur remedial costs in the range of $44.5 million to $80.3 million. We also concluded that, as of December 27, 2013, the best estimate within this range was $44.5 million. For further information on our environmental obligations, refer to Business Legal Proceedings and Note 18 of the notes to our annual consolidated and combined financial statements included

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

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

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical, regulatory and commercial personnel. The loss of key scientific, technical, regulatory and commercial personnel, 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.

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

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

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

- money owed to Luxembourg tax authorities, for example, in respect of income tax deducted at the source;
- value-added tax and certain other taxes and duties owed to Luxembourg Customs and Excise;
- social security contributions; and
- remuneration owed to employees.

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

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

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

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

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

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

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

Irish law imposes restrictions on certain aspects of capital management.

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

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USE OF PROCEEDS

We will not receive any proceeds from the issuance of the exchange notes in the exchange offer. The exchange offer is intended to satisfy MIFSA s obligations under the registration rights agreement that MIFSA entered into in connection with the private offering of the outstanding notes. As consideration for issuing the exchange notes as contemplated in this prospectus, we will receive in exchange a like principal amount of outstanding notes, the terms of which are substantially identical in all material respects to the exchange notes, except that the exchange notes will not contain terms with respect to transfer restrictions or additional interest upon a failure to fulfill certain of our obligations under the registration rights agreement. The outstanding notes that are surrendered in exchange for the exchange notes will be retired and 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 December 27, 2013. Completion of the exchange offer will not result in any change to our capitalization. The historical information below is not necessarily indicative of our future capitalization. This table should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated and combined financial statements and accompanying notes included elsewhere in this prospectus.

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

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RATIO OF EARNINGS TO FIXED CHARGES

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

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

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

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SELECTED FINANCIAL DATA

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

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

(in millions, except per share data)	Three Months Ended		Fiscal Year[1]				
	December 27, 2013	December 28, 2012	2013	2012	2011	2010	2009
Consolidated and Combined Statement of Income Data:							
Net sales[2]	$ 540.2	$ 504.0	$ 2,204.5	$ 2,056.2	$ 2,021.8	$ 2,047.6	$ 2,429.5
Gross profit	255.6	233.5	1,024.9	964.8	914.9	932.4	1,296.3
Research and development expenses[3]	39.0	38.4	165.7	144.1	141.5	119.1	155.2
Operating income[4][5]	73.1	36.8	144.8	235.2	240.7	240.4	508.5
Income from continuing operations before income taxes	63.0	36.9	126.4	236.1	243.2	243.2	512.0
Income from continuing operations	46.4	19.8	57.8	141.3	157.0	145.9	315.5
Share Data:[6]							
Basic income from continuing operations per share	$ 0.80	$ 0.34	$ 1.00	$ 2.45	$ 2.72	$ 2.53	$ 5.47
Diluted income from continuing operations per share	0.79	0.34	1.00	2.45	2.72	2.53	5.47

Cash dividends per ordinary share							

	December 27, 2013	December 28, 2012	September 27, 2013	September 28, 2012	September 30, 2011	September 24, 2010	September 25, 2009
Consolidated and Combined Balance Sheet Data:							
Total assets	$ 3,569.4	$ 3,083.2	$ 3,556.6	$ 2,898.9	$ 2,832.2	$ 2,892.6	$ 3,167.4
Long-term debt	918.0	2.8	918.3	8.9	10.4	11.6	13.6
Shareholders equity	1,309.3	2,113.7	1,255.6	1,891.9	1,788.7	1,835.9	2,016.4

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

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(2) Fiscal 2009 includes $354.5 million of sales of oxycodone hydrocodone extended-release tablets, which were sold under a license agreement that began in the fourth quarter of fiscal 2008 and ended in the second quarter of fiscal 2009.

(3) Fiscal 2013 includes a $5.0 million charge related to milestone payments related to the acceptance of our Xartemis XR NDA for filing with the FDA. Fiscal 2009 includes a $35.3 million charge related to upfront fees and milestone payments related to a product acquisition and licensing agreements.

(4) Fiscal 2013 and 2012 include costs related to the build-out of our corporate infrastructure of $70.6 million and $10.7 million, respectively. The three months ended December 27, 2013 and December 28, 2012 include separation related costs of $2.2 million and $12.0 million, respectively. Fiscal 2013, 2012 and 2011 include separation related costs of $74.2 million, $25.5 million and $2.9 million, respectively. The three months ended December 27, 2013 and December 28, 2012 include restructuring and related charges, net of $8.0 million and $0.2 million, respectively. Fiscal 2013, 2012, 2011, 2010 and 2009 include restructuring charges, net, of $33.2 million, $11.2 million, $8.4 million, $11.5 million and $26.7 million, respectively. Fiscal 2010 and 2009 include product liability charges of $31.3 million and $27.8 million, respectively. Fiscal 2009 also includes a $71.2 million charge for the estimated additional cost to remediate environmental matters at a site located in Orrington, Maine, the liability for which was retained by Covidien pursuant to the separation and distribution agreement.

(5) Fiscal 2013, 2012, 2011, 2010 and 2009 include expense allocations from Covidien of $39.6 million, $49.2 million, $56.3 million, $60.8 million and $60.6 million, respectively, which relate to finance, legal, information technology, human resources, communications, employee benefits and incentives, insurance and share-based compensation. The three months ended December 28, 2012 include expense allocations from Covidien of $11.9 million. Effective with the legal separation from Covidien on June 28, 2013, we have assumed responsibility for all of these functions and related costs and anticipate our costs as an independent, publicly-traded company will be higher than those allocated to us from Covidien.

(6) The computation of basic and diluted earnings per share assumes that the number of shares outstanding for periods prior to June 28, 2013 was equal to the number of ordinary shares of Mallinckrodt outstanding on June 28, 2013, immediately following the distribution of one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien.

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

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

Overview

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

We conduct our business in the following two segments:

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

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

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

Significant Events

Separation from Covidien

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

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

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

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

Acquisitions

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

In August 2012, we paid $13.2 million under an agreement to acquire all of the rights to Roxicodone® 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 Petten, the Netherlands also experienced a shutdown. The HFR resumed production in late February. Our Mo-99 processing facility remains shut down. Until it resumes production, we expect to fulfill customer orders through processing of Mo-99 from alternative sources at higher costs. Ongoing increased raw material and manufacturing costs will limit our ability to return the Global Medical Imaging segment to historical operating margins.

Business Factors Influencing the Results of Operations

New Products

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

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

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

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

Restructuring Initiatives

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

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

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

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

Research and Development Investment

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

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

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

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

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

Results of Operations

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

Net Sales

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

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

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

Operating Income

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

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

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

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

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

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

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

Non-Operating Items

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

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

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

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

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

Net Sales

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

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

Net Sales

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

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

(1) Represents products that were sold to Covidien.

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

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

	Three Months Ended		
	December 27, 2013	December 28, 2012	Percentage Change
U.S.	$ 281.9	$ 233.6	20.7%
Europe, Middle East and Africa	24.8	22.5	10.2
Other	2.8	4.1	(31.7)
Net sales	$ 309.5	$ 260.2	18.9

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

	Three Months Ended

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

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

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

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

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

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

Operating Income

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

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

Unallocated amounts:		
Corporate and allocated expenses	(25.2)	(25.4)
Intangible asset amortization	(8.8)	(8.9)
Restructuring and related charges, net[1]	(8.1)	(1.0)
Separation costs	(2.2)	(12.0)
Total operating income	$ 73.1	$ 36.8

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

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

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

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

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

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

Net Sales

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

	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

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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

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)

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Operating Income

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

	Fiscal Year			
	2013		2012	
Specialty Pharmaceuticals	$ 311.7	25.6%	$ 162.8	16.2%
Global Medical Imaging	112.3	12.0	214.3	21.5
Segment operating income	424.0	19.7	377.1	18.8
Unallocated amounts:				
Corporate and allocated expenses	(133.8)		(69.9)	
Intangible asset amortization	(35.4)		(27.3)	
Restructuring and related charges, net[(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.

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

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(1) Represents products that were sold to Covidien.

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

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

	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

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	