DURECT CORP
Form 10-K
March 10, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 000-31615

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3297098**

(State or other jurisdiction of incorporation or organization) **(I.R.S. Employer Identification No.)**

2 Results Way

Cupertino, CA 95014

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: (408) 777-1417

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.0001 par value

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 of the Act. YES ¨ NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ¨ NO x

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $282,473,859 as of June 30, 2008 based upon the closing sale price on the NASDAQ Global Market reported for such date. Shares of Common Stock held by each officer and director and by each person who may be deemed to be an affiliate have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 82,025,921 shares of the registrant s Common Stock issued and outstanding as of February 27, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the definitive Proxy Statement for the 2009 annual meeting of stockholders, which is expected to be filed not later than 120 days after the Registrant s fiscal year ended December 31, 2008.

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DURECT CORPORATION

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

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PART I

Item 1. Business.

Overview

We are an emerging specialty pharmaceutical company focused on the development of pharmaceutical products based on our proprietary drug delivery technology platforms. We are developing pharmaceutical systems that will deliver the right drug to the right place in the right amount at the right time to treat chronic or episodic diseases and conditions. By integrating chemistry and engineering advancements, we can achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration as well as, for certain applications, placement of the drug at the intended site of action. Our proprietary drug delivery technology platforms include:

SABER Delivery System a patented and versatile depot injectable useful for delivery of small molecules and biologics that can be formulated for systemic or local administration. The advantages of SABER may include reduced side effects, longer duration and smaller injection volume. Our first application is for controlled delivery of bupivacaine for post-operative pain relief (POSIDUR), for which we have licensed commercialization rights in Europe and certain other countries to Nycomed Danmark APS (Nycomed) while retaining commercialization rights in the United States, Canada, Asia and other countries. A successful Phase IIb clinical trial in hernia surgery was completed and an end-of-Phase II meeting has been held with the FDA. We are currently in dialogue with the FDA regarding our Phase III program. In parallel with these discussions, we are conducting a 60-patient Phase IIb study in Australia using a 5 mL dose in shoulder surgery in order to confirm aspects of our clinical study design. Additionally, Nycomed is commencing Phase IIb studies in surgical procedures in Europe.

ORADUR® Delivery System an oral sustained release gel-cap technology. We believe that ORADUR can transform short-acting oral capsule forms into oral sustained release technology products with the added benefit of being less prone to abuse. Our first application is Remoxy , a novel long-acting, abuse deterrent oral formulation of the opioid oxycodone, for which we have licensed worldwide rights to Pain Therapeutics, Inc. (Pain Therapeutics), which has in turn sublicensed the commercialization rights to King Pharmaceuticals, Inc. (King). In December 2007, Pain Therapeutics and King reported positive results from the pivotal Phase III trial submitted under an approved Special Protocol Assessment (SPA) with the FDA. The NDA was submitted to the FDA in June 2008, and in August 2008 the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics has indicated that they plan to meet with the FDA in the second quarter of 2009 regarding the NDA for Remoxy, and that they believe this FDA meeting will provide them with a more reliable context in which to make projections about Remoxy.

TRANSDUR Delivery System a proprietary transdermal patch technology. The advantages of TRANSDUR may include, depending on the application, less potential for abuse, longer use per patch and smaller patch size. Our first application is for a transdermal sufentanil patch (TRANSDUR-Sufentanil) which we have licensed to Endo Pharmaceuticals for the U.S. and Canada. An end-of-Phase II meeting with the FDA for TRANSDUR-Sufentanil was held on February 19, 2009. As a result of that meeting, we believe we understand the anticipated regulatory pathway for the Phase III

NOTE: POSIDUR , SABER , TRANSDUR , ORADUR®, ELADUR , DURIN , CHRONOGESIC®, MICRODUR , ALZET® and LACTEL® are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners.

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program and approval, which will follow a 505(b)2 pathway as discussed with the FDA. This pathway allows referencing of third-party data, potentially reducing time and expense. On February 26, 2009, Endo notified us that it was terminating its license agreement for TRANSDUR-Sufentanil and thereby returning to us Endo s rights to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada effective August 26, 2009. Endo has committed to assist us in an orderly and rapid transition of this program back to us. Our second application of TRANSDUR is for a transdermal bupivacaine patch (TRANSDUR-Bupivacaine or ELADUR), which we have licensed to Alpharma Ireland Limited, an affiliate of Alpharma Inc. (Alpharma) (now owned by King). We successfully completed a Phase IIa clinical trial with ELADUR in the fourth quarter of 2007.

DURIN Biodegradable Implant a proprietary biodegradable drug-loaded implant that is absorbed into the body. DURIN enables parenteral (injectable) delivery over a period of weeks or months of both large and small molecules using our proprietary polymers. The advantages of DURIN may include small size, longer duration and constant rate of delivery. Our first application is Memryte , a novel long-acting potential therapy for the treatment of Alzheimer s disease using leuprolide, for which we have licensed worldwide rights to Voyager Pharmaceutical Corporation (Voyager). Voyager has conducted clinical studies for Memryte but future development is pending Voyager s ability to obtain additional financing and is not assured.

DUROS® System an osmotic implant technology licensed to us for specified fields from ALZA Corporation, a Johnson & Johnson Company (ALZA). DUROS is a miniature drug-dispensing subcutaneous pump which can be as small as a matchstick that can be used for therapies requiring systemic or site-specific administration of drug. The advantages of DUROS may include precise constant drug delivery of potent molecules.

MICRODUR Biodegradable Microparticulates a patented biodegradable microparticulate depot injectable. Sustained release from a few days to many months can be achieved through suitable choice of polymers and processing.

Our pharmaceutical systems combine engineering with proprietary small molecule pharmaceutical and biotechnology drug formulation to yield proprietary delivery technologies and products. Through this combination, we are able to control the rate and duration of drug administration, as well as, when desired, target the delivery of the drug to its intended site of action, allowing our pharmaceutical systems to meet the special challenges associated with treating medical conditions over an extended period of time. Our pharmaceutical systems can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biologics such as proteins, peptides and genes.

Our pharmaceutical systems are suitable for providing long-term drug therapy because they store highly concentrated, stabilized drugs in a small volume and can protect the drug from degradation by the body. This, in combination with our ability to continuously deliver precise and accurate doses of a drug, allows us to extend the therapeutic value of a wide variety of drugs, including those which would otherwise be ineffective, too unstable, too potent or cause adverse side effects. In some cases, delivering the drug directly to the intended site of action can improve efficacy while minimizing unwanted side effects elsewhere in the body, which often limit the long-term use of many drugs. Our pharmaceutical systems can thus provide better therapy for chronic diseases or conditions, or for certain acute conditions where longer drug dosing is required or advantageous, by replacing multiple injection therapy or oral dosing, improving drug efficacy, reducing side effects and ensuring dosing compliance. Our pharmaceutical systems can improve patients quality of life by eliminating more repetitive treatments, reducing dependence on caregivers and allowing patients to lead more independent lives.

In addition to developing our own proprietary products, we also collaborate with pharmaceutical and biotechnology companies to develop and commercialize proprietary and enhanced pharmaceutical products based on our technologies.

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Product Research and Development Programs

Our development efforts are focused on the application of our pharmaceutical systems technologies to potential products in a variety of chronic and episodic disease areas including pain, central nervous system, or CNS, disorders, cardiovascular disease and other chronic diseases. Our ongoing product research and development efforts in these areas are set forth in the following table:

Disease/Indication	Product Candidate	Collaborator	Technology Platform	Stage
Post Operative Pain	POSIDUR (Controlled release injection of bupivacaine)	Nycomed (Europe and certain other territories); DURECT retains rights in U.S., Canada, Asia and other countries	SABER	Phase II
Neuropathic Pain associated with Post-Herpetic Neuralgia (PHN)	ELADUR (Transdermal bupivacaine)	King (worldwide)	TRANSDUR	Phase II
Chronic Pain	Remoxy (Oral controlled release oxycodone)	King/Pain Therapeutics (worldwide)	ORADUR	NDA accepted but not approved/ Complete Response Letter received
Pain	Oral controlled release opioid (active agent undisclosed)	King/Pain Therapeutics (worldwide)	ORADUR	Phase I
Pain	Oral controlled release opioid (active agent undisclosed)	King/Pain Therapeutics (worldwide)	ORADUR	Phase I
Chronic Pain	TRANSDUR-Sufentanil (Transdermal sufentanil)	Endo (U.S. & Canada) until August 2009; DURECT retains rights in Europe, Asia and other countries, and worldwide rights as of August 2009	TRANSDUR	Phase II
Alzheimer s Disease	Memryte (Controlled release Leuprolide implant)	Voyager (worldwide)	DURIN	Further development pending financing/ partnering by Voyager
Central Nervous System Disorders/Cardiovascular Disorders/Biologics Programs	Various	DURECT retains worldwide rights	SABER/ DUROS/ DURIN	Preclinical/ Research Stage

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Local Post-Operative Pain

POSIDUR

Market Opportunity. According to data published by the Center for Disease Control and Prevention, there are approximately 72 million ambulatory and inpatient procedures performed in the United States. Epidemiological studies indicate that up to 100% of surgical patients experience postoperative pain, with 50-75% reporting inadequate pain relief. The current standard of care for post-surgical pain includes oral opiate and non-opiate analgesics, transdermal opiate patches and muscle relaxants. While oral analgesics can effectively control post-surgical pain, they commonly cause side effects including drowsiness, constipation, cognitive impairment. Effective pain management can be compromised if patients fail to adhere to recommended dosing regimens because they are sleeping or disoriented. Post-surgical pain can be treated effectively with local anesthetics; however, the usefulness of current conventional medications is limited by their short duration of action.

Development Strategy. We are developing POSIDUR, a sustained-release formulation of bupivacaine, using our SABER delivery system for the treatment of post-surgical pain. Bupivacaine is a local anesthetic agent currently used in the hospital for anesthesia and analgesia and for which the patent covering the chemical entity has expired. The physician would administer POSIDUR at the time of surgery to the surgical site. This formulation is designed to provide sustained regional analgesia from a single dose. We believe that by delivering effective amounts of a potent analgesic to the location from which the pain originates, adequate pain control can be achieved with minimal exposure to the remainder of the body, thus minimizing side effects. POSIDUR is intended to provide local analgesia for up to 3 days, which we believe coincides with the time period of greatest need for post-surgical pain control in most patients. In November 2006, we entered into a collaboration agreement with Nycomed Danmark, APS. Under the terms of the agreement, we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. Nycomed paid us an upfront license fee of $14.0 million in 2006 and an $8.0 million milestone payment in 2007, with future potential additional milestone payments of up to $180.0 million upon achievement of defined development, regulatory and sales milestones. We will jointly direct and equally fund with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. In addition, we will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay us blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. We retain full commercial rights to POSIDUR in the U.S., Canada, Asia and certain other countries.

Clinical Program. In 2007, we successfully completed a 122 patient Phase IIb clinical trial of POSIDUR for treatment of post-operative pain in patients undergoing inguinal hernia repair, thereby triggered the $8.0 million milestone payment from Nycomed. In the Phase IIb trial, POSIDUR at a dose of 5 mL demonstrated statistically significant reductions in pain and in total consumption of supplemental opioid analgesic medications versus placebo. These successful results triggered the $8.0 million milestone payment by Nycomed to us under our agreement with Nycomed.

Phase IIb Inguinal Hernia Trial

Design

The POSIDUR Phase IIb clinical trial was designed to evaluate the tolerability, activity, dose response and pharmacokinetics of POSIDUR in patients undergoing open inguinal hernia repair. The study was conducted in Australia and New Zealand as a multi-center, randomized, double blind, placebo-controlled study in 122 patients. Study patients were randomized into three treatment groups: patients that were treated with POSIDUR 2.5 mL (n=43), POSIDUR 5 mL (n=47) and placebo (n=32). The co-primary efficacy endpoints for the study were Mean Pain Intensity on Movement area under the curve (AUC), a measure of pain over a period of 1-72 hours post-surgery, and the proportion of patients requiring supplemental opioid analgesic medication during the study. Secondary efficacy endpoints included Mean Pain Intensity on Movement AUC over the period 1-48 hours post-surgery, mean total consumption of supplemental opioid analgesic medication, and time to first use of supplemental opioid analgesic medication. The threshold for statistical significance was considered to be at the $p<0.05$ level.

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Results

Pain Control

In relation to the co-primary endpoint of pain reduction as measured by Mean Pain Intensity on Movement AUC 1-72 hours post-surgery, the patient group treated with POSIDUR 5 mL reported thirty-one percent (31%) less pain versus placebo (p=0.0033). A secondary endpoint measure reported a thirty-five percent (35%) reduction of pain as measured by Mean Pain Intensity on Movement AUC for the period 1-48 hours post-surgery between the POSIDUR 5 mL treatment group versus placebo (p=0.0007).

Consumption of Supplemental Opioid Analgesic Medication

Fifty-three percent (53%) of the study patients in the POSIDUR 5 mL group took supplemental opioid analgesic medications versus seventy-two percent (72%) of the placebo patients (p=0.0909). Although this positive trend for this co-primary endpoint in favor of the POSIDUR 5 mL group was not statistically significant, both secondary endpoints measuring opioid analgesic medication consumption were met at a statistically significant level. During the periods of 1-24 hours, 24-48 hours and 48-72 hours after surgery, placebo patients consumed approximately 3.5 (p=0.0009), 2.9 (p=0.0190) and 3.6 (p=0.0172) times more supplemental opioid analgesic medications (mean total daily consumption of opioid analgesic medication in morphine equivalents), respectively, than the POSIDUR 5 mL treatment group. In addition, the median time to first use of supplemental opioid analgesic medication after surgery for the placebo patients was 2.7 hours versus >72 hours for the POSIDUR 5 mL treatment group (p=0.0197).

Dose Finding

POSIDUR administered at the dose of 5 mL showed statistically significant activity relative to placebo whereas POSIDUR administered at 2.5 mL showed a positive trend relative to placebo on certain parameters but the results were not statistically significant.

Safety

The patient groups treated with POSIDUR 5 mL and POSIDUR 2.5 mL showed comparable safety profiles as the patient groups treated with placebo, and the drug administration appeared well tolerated. The side effects commonly observed with opioid medication use were less frequent in the POSIDUR 5 mL and 2.5 mL treatment groups compared to placebo.

Other Exploratory Phase II studies

In addition to the Phase IIb study described above, we have also been conducting smaller exploratory Phase II studies in hernia, shoulder arthroscopy and appendectomy surgeries to evaluate different application techniques, clinical design and conduct as well as other investigational factors. These trials have been conducted in multiple cohorts, generally consisting of approximately 6 to 21 patients in each treatment group. Hernia, shoulder and appendectomy studies have been completed. In all the exploratory studies, patient groups treated with POSIDUR 5 mL and POSIDUR 2.5 mL showed comparable safety profiles as the patient groups treated with placebo, and the drug administration appeared well tolerated. Some treatment groups from these exploratory studies utilizing POSIDUR have shown positive activity as measured by reduction of pain or consumption of supplemental opioid analgesic medication versus placebo, while other treatment groups have not. We have evaluated these studies to understand the different results observed, and intend to apply our learnings in the design of our Phase III program.

We have held an end-of-Phase II meeting with the FDA and are in dialogue with the FDA regarding our POSIDUR Phase III program. In parallel with these discussions, we are conducting a 60-patient Phase IIb study in Australia using a 5 mL dose in shoulder surgery in order to confirm aspects of our clinical study design. Additionally, Nycomed is commencing Phase IIb studies in surgical procedures in Europe.

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Local Pain

ELADUR

Market Opportunity. Neuropathic pain is pain resulting from a disturbance of the central nervous system (brain and spinal cord) or peripheral nervous system (nerves outside the brain and spinal cord). There are a variety of conditions and diseases that produce neuropathic pain, including trauma and diseases such as multiple sclerosis and stroke. One form of neuropathic pain is a debilitating complication of herpes zoster referred to as Post-Herpetic Neuralgia (PHN or post-shingles pain), which is usually defined as the presence of pain at the site of eruption that lasts more than a month after the onset of zoster eruption. Within the affected skin supplied by the nerve root, patients have a variety of sensory abnormalities in addition to neuropathic pain. Pain can persist for months and occasionally years. The prevalence of PHN (including PHN lasting more than one year) is estimated to be approximately 144,000 people in the U.S.

Development Strategy. We are developing a transdermal bupivacaine patch (ELADUR) based on our proprietary TRANSDUR transdermal technology intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches. We anticipate that ELADUR will have several potential differentiating attributes compared with currently marketed lidocaine patches, including extended duration of action and better wearability. During 2008, we received Orphan Drug Designation for bupivacaine for relief of persistent pain associated with post-herpetic neuralgia, such that if ELADUR is the first bupivacaine product approved for PHN, ELADUR will receive seven years of market exclusivity following its approval by the FDA. Effective October 2008, we licensed the worldwide development and commercialization rights for ELADUR to Alpharma Ireland, Ltd. (which was acquired by King Pharmaceuticals in December 2008).

Clinical Program. In 2007, we successfully completed a 60 patient Phase IIa clinical trial for ELADUR. In this study of patients suffering from PHN, ELADUR showed improved pain control versus placebo during the 3-day continuous treatment period. In addition, ELADUR appeared well tolerated overall, and patients treated with ELADUR and placebo exhibited similar safety profiles. In 2008, we conducted manufacturing scale-up and processing studies to secure additional Phase II and Phase III supplies, and developed our clinical and regulatory strategy for further development of this program.

Chronic Pain (Systemic)

Market Opportunity. Chronic pain, defined as lasting six months or longer, is usually the result of an ongoing condition or significant problem associated with chronic diseases, including cancer, various neurological and skeletal disorders and other ailments such as severe arthritis or a debilitating back injury. As the condition gets worse, the pain often gets worse. Also, long-lasting pain can affect the nervous system to the point where pain persists even if the condition that originally caused the pain is stabilized or improved. This is one reason patients often need stronger pain medication even if their underlying condition has been treated. Chronic pain affects as many as 50 million Americans annually. OxyContin®, a brand name extended-release oral oxycodone-based painkiller, accounted for approximately $1.6 billion in worldwide sales in 2007, and Duragesic®, a leading transdermal fentanyl product, accounted for approximately $1.0 billion in worldwide sales in 2008.

Development Strategy. We are developing several products for the chronic pain market:

ORADUR-based oral sustained release, abuse deterrent opioid products, including Remoxy, licensed to Pain Therapeutics, which has in turn sublicensed the commercialization rights of these products to King;

TRANSDUR-Sufentanil, our proprietary transdermal patch that is intended to provide sufentanil for a period of up to seven days from a single application. The rights to develop and commercialize this drug candidate in the U.S. and Canada were licensed to Endo, but Endo has notified us that it is returning the rights to us effective August 26, 2009, after which we will hold worldwide development and commercialization rights.

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ORADUR-Opioid Products In Development

Remoxy (ORADUR-Oxycodone)

Remoxy is an oral, long-acting oxycodone gelatin capsule under development with Pain Therapeutics, to which we have licensed exclusive, worldwide, development and commercialization rights under a development and license agreement entered into in December 2002. Subsequently, Pain Therapeutics has sublicensed the commercialization rights of Remoxy to King. Remoxy is formulated with our ORADUR technology and incorporates several abuse-deterrent properties with the convenience of twice-a-day dosing. Oxycodone is also the active drug ingredient in OxyContin®, a brand name extended-release oral painkiller, which achieved annual worldwide sales of approximately $1.6 billion in 2007. Under the agreement with Pain Therapeutics, we are eligible to receive milestone payments of up to $9.3 million in the aggregate upon the achievement of predetermined development and regulatory milestones. As of December 31, 2008, we have received $1.7 million in milestone payments. We also receive reimbursement for our research and development efforts on Remoxy and a manufacturing profit on our supply of key product excipients for use in Remoxy. In addition, if Remoxy is commercialized, we will receive royalties for Remoxy of between 6.0% to 11.5% of net sales depending on the sales volumes.

Clinical Program. In December 2007, Pain Therapeutics and King Pharmaceuticals announced that the pivotal Phase III trial for Remoxy successfully met its primary endpoint ($p<0.01$) that was prospectively defined by the FDA during the Special Protocol Assessment process. In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia ($p<0.01$) and Global Assessment ($p<0.01$).

Pain Therapeutics submitted an NDA for Remoxy to the FDA in June 2008, and in August 2008 the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy, but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics has indicated that they plan to meet with the FDA in the second quarter of 2009 regarding the NDA for Remoxy, and they believe this FDA meeting will provide them with a more reliable context in which to make projections about Remoxy.

Additional ORADUR-Opioid Products in Development

During 2006, 2007 and 2008, we also worked with Pain Therapeutics and King on the development of additional ORADUR abuse-resistant opioid drug candidates. Phase I clinical trials have been completed for two of these ORADUR-based product. According to Pain Therapeutics, the data from these Phase I trials indicate that these drug candidates are safe and well-tolerated with release profiles that appear well suited to use with a chronic pain population. The active ingredients in these two drug candidates are opioids whose identities have not been publicly disclosed.

TRANSDUR-Sufentanil Patch

Our transdermal sufentanil patch (TRANSDUR-Sufentanil) under development is based on our proprietary TRANSDUR transdermal technology and is intended to provide continuous delivery of sufentanil for up to seven days from a single application, as compared to the two to three days of relief provided by currently available opioid patches. Sufentanil is a highly potent opioid that is currently used in hospitals as an analgesic for which the patent covering the chemical entity has expired. We anticipate that the small size of our sufentanil patch (potentially as small as 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) and longer duration of delivery may offer improved convenience and compliance for patients. Worldwide sales for Duragesic®, a leading transdermal fentanyl product, were approximately $1.0 billion in 2008.

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In March 2005, we entered into an agreement with Endo granting Endo exclusive rights to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. We have received an initial payment of $10.0 million in connection with the execution of the Agreement. In February 2009, Endo notified us that it was terminating the license agreement with us, and thereby returning Endo s rights to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada to us effective August 26, 2009. Endo has committed to assist in an orderly and rapid transition of this program back to us. Effective August 26, 2009, we will hold worldwide commercialization rights for TRANSDUR-Sufentanil. During 2008, we continued to perform development activities for Endo with respect to TRANSDUR-Sufentanil.

Clinical Program. Endo recently successfully completed a Phase II program for TRANSDUR- Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. The most recent Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. As a result of that meeting, we believe we understand the anticipated regulatory pathway for the Phase III program and approval, which will follow a 505(b)2 pathway as discussed with FDA. This pathway would allow us to reference third-party data, potentially reducing time and expense.

Alzheimer s Disease

Market Opportunity. Alzheimer s disease is a progressive, degenerative and ultimately terminal brain disorder that gradually destroys a person s memory and ability to learn, reason, make judgments, communicate and carry out daily activities. There is currently no treatment that stops or materially slows the progression of Alzheimer s disease. It is estimated that Alzheimer s patients and their families spend more than $200,000 on health care per patient and employers lose approximately $60 billion per year on lost productivity as adult caregivers are forced to leave their jobs either permanently or temporarily to care for a family member with the disease. As a result, it is one of the world s largest unmet medical needs. The global market for currently available Alzheimer s disease drugs is growing rapidly and has been estimated to be over $3.5 billion in 2006. It is estimated that over five million Americans suffer from Alzheimer s disease and this number could more than triple by mid-century.

Development Strategy. In July 2002, we entered into a development and commercialization agreement with Voyager under which we granted Voyager the exclusive, worldwide rights to develop and commercialize a product, Memryte, using the DURIN implant system to deliver the peptide leuprolide acetate to treat Alzheimer s disease based on Voyager s patented method of treatment. Under the agreement, as amended, we are eligible to receive milestone payments from Voyager of up to $3.0 million in the aggregate upon the achievement of predetermined development and regulatory milestones. As of December 31, 2008, we have received $500,000 in milestone payments. Additionally, if the product candidate is commercialized, we will receive royalties of between 10% to 14% of net sales depending on the sales volumes, and we will receive 10% of any upfront, milestone and other fees received by Voyager in the event that the product candidate is sublicensed to a third party.

Clinical Program. In October 2005, Voyager initiated a Phase III clinical trial for Memryte, which was truncated by Voyager in order to get an earlier look at potential efficacy. In the second quarter of 2007, Voyager informed its shareholders that it had observed positive outcome trends among women, but no positive effect among men in this truncated Phase III clinical trial. Based on these results, Voyager has stated that it intends to focus its efforts on developing Memryte for the treatment of Alzheimer s disease in women and on seeking a potential collaborative partner for the program. There can be no assurance that Voyager or any other party will continue development of Memryte.

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Biologics Programs

The proteins and genes identified by the biotechnology industry are large, complex, intricate molecules, and many are unsuitable as drugs. If these molecules are given orally, they are often digested before they can have an effect; if given by injection, they may be destroyed by the body s natural processes before they can reach their intended sites of action. The body s natural elimination processes require frequent, high dose injections that may result in unwanted side effects. As a result, the development of biotechnology molecules for the treatment of human diseases has been limited, and advanced drug delivery systems such as we possess are required to realize the full potential of many of these protein and peptide drugs. We have active programs underway to apply our drug delivery systems to various biotechnology drugs and drug candidates, and have entered into a number of feasibility studies with biotechnology and pharmaceutical companies to test their products in our systems.

Research Programs in other Therapeutic Categories

We have underway a number of research programs covering medical diseases and conditions other than pain. Such programs include various diseases and disorders of the central nervous system (CNS), including schizophrenia and attention deficit/hyperactivity disorder. Another area of focus includes cardiovascular disease, including congestive heart failure. In conducting our research programs and determining which particular efforts to prioritize for formal development, we employ a rigorous opportunity assessment process that takes into account the unmet medical need, commercial opportunity, technical feasibility, clinical viability, intellectual property considerations, and the development path including costs to achieve various critical milestones.

Industry Background

Chronic Diseases and Conditions

Although the pharmaceutical, biotechnology and medical device industries have played key roles in increasing life expectancy and improving health, many chronic, debilitating diseases continue to be inadequately addressed with current drugs or medical devices. Cardiovascular disease, cancer, neurodegenerative diseases, diabetes, arthritis, epilepsy and other chronic diseases claim the lives of millions of Americans each year. These illnesses are prolonged, are rarely cured completely, and pose a significant societal burden in mortality, morbidity and cost. The Centers for Disease Control estimates that the major chronic diseases are responsible for approximately 1.7 million deaths, or 70% of all deaths in the U.S. Chronic diseases cause major limitations in daily living for more than 25 million Americans. These diseases account for more than 70% of the $1 trillion spent on health care each year in America. Demographic trends suggest that, as the U.S. population ages, the cost of treating chronic diseases will increase.

Current Approaches to Treatment

Drugs are available to treat many chronic diseases, but harmful side effects can limit prolonged treatment. In addition, patients with chronic diseases commonly take multiple medications, often several times a day, for the remainder of their lives. If patients fail to take drugs as prescribed, they often do not receive the intended benefits or may experience side effects, which are harmful or decrease quality of life. These problems become more common as the number of drugs being taken increases, the regimen of dosing becomes more complicated, or the patient ages or becomes cognitively impaired. It is estimated that only half of prescribed medicines are taken correctly.

The Pharmaceutical Industry. The pharmaceutical industry has traditionally focused on the chemical structure of small molecules to create drugs that can treat diseases and medical conditions. The ability to use these molecules as drugs is based on their potency, safety and efficacy. Therapeutic outcome and ultimately the suitability of a molecule as a drug depends to a large extent on how it gets into the body, distributes throughout the body, reacts with its intended site of action and is eliminated from the body. However, small molecules can act in diverse tissues throughout the body resulting in unwanted side effects.

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Most drugs require a minimum level in blood and tissues to have significant therapeutic effects. Above a maximum level, however, the drug becomes toxic or has some unwanted side effects. These two levels define the therapeutic range of the drug. With conventional oral dosing and injections, typically a large quantity of drug is administered to the patient at one time, which results in high blood levels of drug immediately after dosing. Because of these high levels, the patient can be over-medicated during the period immediately following dosing, resulting in wasted drug and possible side effects. Due to distribution processes and drug clearance, the blood level of drug falls as time elapses from the last dose. For some duration, the patient is within the desired therapeutic range of blood levels. Eventually, the blood level of drug falls sufficiently such that the patient becomes under-medicated and experiences little or no drug effect until the next dose is administered.

The Biotechnology Industry. Over the past twenty-five years, the biotechnology revolution and the expanding field of genomics have led to the discovery of huge numbers of proteins and genes. Tremendous resources have been committed in the hope of developing drug therapies that would better mimic the body s own processes and allow for greater therapeutic specificity than is possible with small molecule drugs. Unfortunately, this huge effort has led to only a limited number of therapeutic products. The proteins and genes identified by the biotechnology industry are large, complex, intricate molecules, and many are unsuitable as drugs. If these molecules are given orally, they are often digested before they can have an effect; if given by injection, they may be destroyed by the body s natural processes before they can reach their intended sites of action. The body s natural elimination processes require frequent, high dose injections that may result in unwanted side effects. As a result, the development of biotechnology molecules for the treatment of human diseases has been limited.

The Drug Delivery Industry. In the last thirty-five years, a multibillion dollar drug delivery industry has developed on the basis that medicine can be improved by delivering drugs to patients in a precise, controlled fashion. Several commercially successful oral controlled release products, transdermal controlled release patches, and injectable controlled release formulations have been developed. These products demonstrate that the delivery system can be as important to the ultimate therapeutic value of a pharmaceutical product as the drug itself. However, drug delivery products on the market today can still be improved, for example, by providing reduced abuse potential, targeted delivery to minimize systemic effects and longer delivery durations where useful. Furthermore, traditional drug delivery products are generally not capable of administering biotechnology agents such as proteins, peptides and genes.

The DURECT Solution: Pharmaceutical Systems

We are developing and commercializing pharmaceutical systems that will deliver the right drug to the right place in the right amount at the right time to treat chronic and episodic diseases and conditions. By integrating chemistry and engineering advancements, we can achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration. In addition, if advantageous for the therapy, our pharmaceutical systems can target the delivery of the drug to its intended site of action.

The Right Drug: By precisely controlling the dosage or targeting delivery to a specific site, we can expand the therapeutic use of compounds that otherwise would be too potent to be administered systemically, do not remain in the body long enough to be effective, or have significant side effects when administered systemically. This flexibility allows us to work with a variety of drug candidates including small molecules, proteins, peptides or genes.

The Right Place: In addition to enabling systemic delivery, if advantageous for the therapy, with precise placement of our proprietary catheters or biodegradable drug delivery formulations, we can design our pharmaceutical systems to deliver drugs directly to the intended site of action. This can ensure that the drug reaches the target tissue in effective concentrations, eliminate many side effects caused by delivery of drug to unintended sites in the body, and reduce the total amount of drug administered to the body.

The Right Amount: Our pharmaceutical systems can automatically deliver drug dosages continuously within the desired therapeutic range for the duration of the treatment period, from days to up to one

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year, without the fluctuations in drug levels associated with conventional pills or injections. This can reduce side effects, eliminate gaps in drug therapy, conveniently ensure accurate dosing and patient compliance, and may reduce the total amount of drug administered to the body.

The Right Time: Our pharmaceutical systems technologies are designed to minimize the need for intervention by the patient or care-giver and enhance dosing compliance. In addition to reducing the cost of care, continuous drug therapy frees the patient from repeated treatment or hospitalization, improving convenience and quality of life. Our systems are well-suited to deliver drug for the right period of time for the intended indication, whether for hours or days for acute indications or months or years for treating chronic, debilitating diseases such as chronic pain, cancer, heart disease, and neurodegenerative diseases. We believe that it is more effective to treat chronic diseases with continuous, long-term therapy than with alternatives such as multiple conventional injections or oral dosage forms that create short-term effects.

DURECT Pharmaceutical Systems Technology

Our pharmaceutical systems combine technology innovations from the drug delivery and medical device industries with proprietary pharmaceutical and biologic drug formulations. These capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biologics such as proteins, peptides and genes. We currently have six major technology platforms:

The SABER Delivery System

The SABER system is a patented controlled-release technology that can be formulated for systemic or local administration of active agents via the parenteral or oral route. We are researching and developing a variety of controlled-release products based on the SABER technology. These include injectable controlled release products for systemic and local delivery and oral products. We believe that our SABER system can provide the basis for the development of a state-of-the-art biodegradable, controlled-release injectable. The SABER system uses a high-viscosity base component, such as sucrose acetate isobutyrate (SAIB), to provide controlled release of the drug. When the high viscosity SAIB is formulated with drug, biocompatible excipients and other additives, the resulting formulation is liquid enough to inject easily with standard syringes and needles. After injection of a SABER formulation, the excipients diffuse away, leaving a viscous depot. Depending on how it is formulated, the SABER system can successfully deliver therapeutic levels of a wide spectrum of drugs from one day to three months from a single injection. Based on research and development work to date, our SABER technology has shown the following advantages:

Peptide/Protein Delivery The chemical nature of the SABER system tends to repel water and body enzymes from its interior and thereby stabilizes proteins and peptides. For this reason, we believe that the SABER system is well suited as a platform for biotechnology therapeutics based on proteins and peptides.

Less Burst Typically, controlled release injections are associated with an initial higher release of drug immediately after injection (also called burst). Animal and human studies have shown that injectables based on the SABER technology can be associated with less post-injection burst than is typically associated with other commercially available injectable controlled release technologies.

High Drug Concentration Drug concentration in a SABER formulation can be as high as 30%, considerably greater than is typical with other commercially available injectable controlled release technologies. As a result, smaller injection volumes are possible with this technology.

Ease of Administration Prior to injection, SABER formulations are fairly liquid and therefore can be injected through small needles. Additionally, because of the higher drug concentration of SABER formulations, less volume is required to be injected. Small injection volumes and more liquid solutions are expected to result in easier, less painful administration.

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Strong Patent Protection The SABER system, SABER-like materials, and various applications of this technology to pharmaceuticals, medical devices and drug delivery are covered by United States and foreign patents. See Patents, Licenses and Proprietary Rights below.

Ease of Manufacture Compared to microspheres and other polymer-based controlled release injectable systems, SABER is readily manufacturable at low cost.

The SABER Technology is the basis of POSIDUR, which is in Phase II clinical trials. In our clinical studies thus far, SABER formulations have been observed to be safe and well-tolerated, and no significant side effects or adverse events were reported.

The TRANSDUR Transdermal Delivery System

Our TRANSDUR technology is a proprietary transdermal delivery system that enables delivery of drugs continuously for up to 7 days. The TRANSDUR technology is the basis for TRANSDUR-Sufentanil for which an end-of-Phase II meeting with the FDA was held in February 2009. The development and commercialization rights in the U.S. and Canada have been licensed to Endo until August 26, 2009, after which we will hold worldwide development and commercialization rights. The TRANSDUR technology is also the basis for ELADUR, which is currently in Phase II testing and which we have licensed worldwide development and commercialization rights to Alpharma Ireland, Ltd. (which was acquired by King in December 2008).

The ORADUR Sustained Release Gel Cap Technology

We are developing ORADUR sustained release oral technology based on our SABER technology. We believe that ORADUR can transform short-acting oral capsule dosage forms into sustained release oral products. Products based on our ORADUR technology can take the form of an easy to swallow gelatin capsule that uses a high-viscosity base component such as sucrose acetate isobutyrate (SAIB) to provide controlled release of active ingredients for a period of 12 to 24 hours of drug delivery. Oral dosage forms based on the ORADUR gel-cap may also have the added benefit of being less prone to abuse (e.g., by crushing or alcohol or water extraction) than other controlled release dosage forms on the market today. ORADUR-based products can be manufactured by a simple process using conventional methods making them readily scalable. These properties have the potential to make ORADUR-based products an attractive option for pharmaceutical companies that seek to develop abuse deterrent oral products. The ORADUR Technology is the basis of Remoxy, a novel long-acting oral formulation of the opioid oxycodone which is targeted to decrease the potential for oxycodone abuse. In December 2007, Remoxy successfully completed a pivotal Phase III study. Pain Therapeutics submitted an NDA for Remoxy to the FDA in June 2008, and in August 2008, the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics has indicated that they plan to meet with the FDA in the second quarter of 2009 regarding the NDA for Remoxy, and they believe this FDA meeting will provide them with a more reliable context in which to make projections about Remoxy.

We also have two other ORADUR-based opioid drug candidates for which Phase I clinical trials have been completed. According to Pain Therapeutics, the data from these Phase I trials indicate that these drug candidates are safe and well-tolerated with release profiles that appear well suited to use with a chronic pain population. The active ingredients in these two drug candidates are opioids whose identities have not been publicly disclosed.

The DURIN Biodegradable Implant Technology

Our DURIN technology is a proprietary biodegradable implant that enables parenteral delivery of drugs from several weeks to six months or more using our LACTEL® brand polymers and co-polymers of lactic and glycolic acid. The DURIN technology can deliver a wide variety of drugs including small and large molecule

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compounds. Our proprietary implant design allows for a variety of possible delivery profiles including constant rate delivery. Because DURIN implants are biodegradable, at the end of its delivery life, what remains of the DURIN implant is absorbed by the body. The DURIN technology is the basis of Memryte for the treatment of Alzheimer s disease, with any future development controlled by Voyager.

The DUROS Technology

The DUROS system is a miniature drug-dispensing pump which can be as small as a wooden matchstick. We have licensed the DUROS system for specified fields of use from ALZA, pursuant to a development and commercialization agreement entered into effective April 1998. The potential of the DUROS technology as a platform for providing drug therapy was demonstrated by the FDA s approval in March 2000 of ALZA s VIADUR® product (leuprolide acetate implant), a once-yearly implant for the palliative treatment of prostate cancer, the first approved product to incorporate the DUROS implant technology. The DUROS system can be used for therapies requiring systemic or site-specific administration of drug. To deliver drugs systemically , the DUROS system is placed just under the skin, for example in the inner side of the upper arm, in an outpatient procedure that is completed in just a few minutes using local anesthetic. Removal or replacement of the product is also a simple and quick procedure completed in the doctor s office.

The MICRODUR Biodegradable Microparticulate Technology

Our MICRODUR technology is a patented biodegradable microparticulate depot injectable. We have experience in microencapsulation of a broad spectrum of drugs using our LACTEL® brand polymers and co-polymers of lactic and glycolic acid. In our MICRODUR process, both standard and proprietary polymers are used to entrap an active agent in solid matrices or capsules comprising particles generally between 10 and 125 microns in diameter. Through suitable choice of polymers and processing, sustained release from a few days to many months can be achieved. As with the DURIN technology, MICRODUR particles degrade fully in the body after the active agent is released. Our range of experience extends from manufacture of the polymer raw material to process and product development, scale-up and cGMP manufacture.

DURECT Strategy

Our objective is to become a specialty pharmaceutical company by developing, and in the future, commercializing pharmaceutical systems that address significant medical needs and improve patients quality of life. To achieve this objective, our strategy includes the following key elements:

Focus on Chronic Debilitating Medical Conditions and Certain Local Pain Conditions. Many of the diseases that present the greatest challenges to medicine are chronic, debilitating diseases such as chronic pain, central nervous system disorders, cardiovascular disorders, cancer and degenerative neurological diseases. In addition, we have identified certain local and acute pain conditions that we believe can benefit from improved therapeutics. Our initial efforts will focus on using our versatile drug delivery platform technologies to develop products that address these medical conditions.

Minimize Product Development Risk and Speed Time-to-Market. Initially, we intend to minimize product development risk and speed time-to-market by using our drug delivery platform technologies to administer drugs for which medical data on efficacy and safety are available. This strategy reduces much of the development risk that is inherent in traditional pharmaceutical product discovery. We anticipate that we can expand the medical usefulness of existing well-characterized drugs in several ways:

- expand uses or create new uses for existing drugs by delivering drugs continuously for convenient long dosing intervals;

- create new uses for drugs which were previously considered to be too potent to be used safely by precisely controlling dosing or by delivering them directly to the site of action;

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enhance drug performance by minimizing side effects; and

expand uses of drugs by delivering them to the target site.

We anticipate that our pharmaceutical systems can be more rapidly developed at lower cost than comparable products that are developed purely based on chemical solutions to the problems of efficacy, side effects, stability and delivery of the active agent. We believe that our ability to innovate more rapidly will allow us to respond more quickly to market feedback to optimize our existing pharmaceutical systems or develop line extensions that address new market needs.

Enable the Development of Pharmaceutical Systems Based on Biotechnology and Other New Compounds. We believe there is a significant opportunity for pharmaceutical systems to add value to therapeutic medicine by administering biologics, such as proteins, peptides and genes. We believe our technologies will improve the specificity, potency, convenience and cost-effectiveness of proteins, peptides, genes and other newly discovered drugs. Our systems can enable these compounds to be effectively administered, thus allowing them to become viable medicines. We can address the stability and storage needs of these compounds through our advanced formulation technology and package them in a suitable pharmaceutical system for optimum delivery. Through continuous administration, the SABER, TRANSDUR, ORADUR, DURIN, DUROS and MICRODUR technology platforms may eliminate or reduce the need for multiple injections of these drugs. In addition, through precise placement of our proprietary biodegradable drug formulations, proteins and genes can be delivered to specific tissues for extended periods of time, thus ensuring that large molecule agents are present at the desired site of action and minimizing the potential for adverse side effects elsewhere in the body.

Diversify Risk by Pursuing Multiple Programs in Development. In order to reduce the risks inherent in pharmaceutical product development, we have diversified our product pipeline such that, between our own programs and those we have partnered, we presently have one program for which an NDA has been accepted but not approved by the FDA, and for which a Complete Response Letter has been received, and five different disclosed programs in clinical development, including two oral drug candidates, two transdermal patch candidates and one injectable drug candidate. We believe that having multiple programs in development helps mitigate the negative consequences to us of any setbacks or delays in any one of our programs.

Enable Product Development Through Strategic Collaborations. We believe that entering into selective collaborations with respect to our product development programs can enhance the success of our product development and commercialization, mitigate our risk and enable us to better manage our operating costs. Additionally, such collaborations enable us to leverage investment by our collaborators and reduce our net cash burn, while retaining significant economic rights.

Build Our Own Sales and Marketing Organization. Our goal is to become a specialty pharmaceutical company where we commercialize products with significant market potential. To that end, we intend, over the course of a few years, to build up commercial, sales and marketing capability and other required infrastructure in focused specialty areas. We will continue to pursue strategic alliances from time to time consistent with our strategy to leverage the established sales organizations of third-party collaborators to achieve greater market penetration for some of our products than we could on our own. If we choose to enter into third-party collaborations to commercialize our pharmaceutical systems, we believe we have the flexibility to enter into these alliances under circumstances that allow us to retain greater economic participation because our pharmaceutical systems combine drugs for which medical data on efficacy and safety are available with proven technology platforms.

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Third-Party Collaborations

We have entered into the following collaboration agreements:

Alpharma Ireland Limited (acquired by King Pharmaceuticals in December 2008). In September 2008, we and Alpharma Ireland Limited, an affiliate of Alpharma Inc. (Alpharma), entered into a development and license agreement granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR, our investigational transdermal bupivacaine patch currently under development for the treatment of pain associated with post-herpetic neuralgia (PHN). The agreement became effective in October 2008 after clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. Under the terms of the agreement, upon closing of the transaction, Alpharma paid us an upfront license fee of $20 million, with possible additional payments of up to $93 million upon the achievement of predefined development and regulatory milestones spread over multiple clinical indications and geographical territories as well as possible additional payments of up to $150 million in sales-based milestones. If ELADUR is commercialized, we would also receive royalties on product sales. Alpharma will control and fund further development of the program. We will perform development activities through completion of Phase II, and formulation and manufacturing scale-up activities for the program, the costs of which shall be reimbursed by Alpharma. The term of the agreement will continue on a jurisdiction-by-jurisdiction basis until the later of fifteen (15) years from the date of first commercial sale of ELADUR or the expiration of patent coverage or data exclusivity in such jurisdiction. During the term of the agreement, subject to specified conditions, neither party nor their affiliates may develop or commercialize a transdermal patch containing bupivacaine. Upon expiration of the term of the agreement, the rights and licenses granted to Alpharma shall convert to fully paid-up, non-royalty bearing, perpetual rights and licenses. The agreement provides each party with specified termination rights, including the right of Alpharma to terminate at any time without cause and each party to terminate the agreement upon material breach of the agreement by the other party. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities. As a result of the acquisition of Alpharma by King in December 2008, the rights and obligations of the agreement are now controlled by King. As of December 31, 2008, the cumulative aggregate payments received by us under this agreement were $21.6 million.

Nycomed Danmark, APS. In November 2006, we entered into a collaboration agreement with Nycomed. Under the terms of the agreement, we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. Nycomed paid us an upfront license fee of $14.0 million in 2006 and an $8.0 million milestone payment in 2007 triggered by achievement of a clinical development milestone, with future potential additional milestone payments of up to $180.0 million upon achievement of defined development, regulatory and sales milestones. We will jointly direct and equally fund with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. In addition, we will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay us blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. We retain full commercial rights to POSIDUR in the U.S., Canada, Asia and certain other countries. The agreement shall continue in effect until terminated. The agreement provides each party with specified termination rights, including the right of each party to terminate the agreement upon material breach of the agreement by the other party. In addition, Nycomed shall have the right to terminate the agreement after expiry of patents covering POSIDUR in all major market countries in the E.U. and for adverse product events. As of December 31, 2008, the cumulative aggregate payments received by us under this agreement were $30.0 million. In addition, the cumulative aggregate payments paid by us to Nycomed were $2.3 million as of December 31, 2008.

Pain Therapeutics, Inc. In December 2002, we entered into an exclusive agreement with Pain Therapeutics to develop and commercialize on a worldwide basis oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs using our ORADUR technology. The agreement also provides Pain Therapeutics with the exclusive right to commercialize products developed under the agreement on a worldwide basis. In connection with the execution of the agreement, Pain Therapeutics paid us an upfront fee. In November 2005, Pain Therapeutics sublicensed the commercialization rights to certain products developed under the agreement (including Remoxy) to King. In December 2005, we amended our agreement with Pain

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Therapeutics in order to specify our obligations with respect to the supply of key excipients for use in the licensed products. Under the agreement, as amended, we are responsible for formulation development, supply of selected key excipients used in the manufacture of licensed product and other specified tasks. We receive reimbursement for our research and development efforts on the licensed products and a manufacturing profit on our supply of key product excipients to Pain Therapeutics for use in the licensed products. Under the agreement with Pain Therapeutics, we are eligible to receive milestone payments of up to $9.3 million in the aggregate upon the achievement of predetermined development and regulatory milestones for the four drug candidates currently in development. As of December 31, 2008, we have received $1.7 million in milestone payments. In addition, if commercialized, we will receive royalties for Remoxy and other licensed products which do not contain an opioid antagonist of between 6.0% to 11.5% of net sales of the product depending on the sales volumes. This agreement can be terminated by either party for material breach by the other party and by Pain Therapeutics without cause. As of December 31, 2008, the cumulative aggregate payments received by us under this agreement were $31.3 million.

Endo Pharmaceuticals Inc. (TRANSDUR-Sufentanil). On March 10, 2005, we entered into a license agreement with Endo under which we granted to Endo the exclusive right to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. We have received an initial payment of $10.0 million in connection with the execution of the Agreement. In February 2009, Endo notified us that it was terminating the license agreement with us, and thereby returning Endo s right to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada to us effective August 26, 2009. Endo has committed to assist in an orderly and rapid transition of this program back to us. As of December 31, 2008, the cumulative aggregate payments received by us under this agreement were $21.4 million.

Voyager Pharmaceutical Corporation. In July 2002, we entered into a development and commercialization agreement with Voyager. Under the terms of the agreement, we will collaborate with Voyager to develop a product using our DURIN technology to provide sustained release of leuprolide based on Voyager s patented method of treatment of Alzheimer s disease. The agreement also provides Voyager with the right to commercialize the resulting product on a worldwide basis. We are responsible for preclinical development, product manufacture and other specified tasks. Under the agreement, as amended, we are eligible to receive milestone payments from Voyager of up to $3.0 million in the aggregate upon the achievement of predetermined development and regulatory milestones. As of December 31, 2008, we have received $500,000 in milestone payments. We are also eligible to receive reimbursement for any research and development work we perform. If Memryte is commercialized, we will receive royalties based on product sales. This agreement can be terminated by either party for material breach by the other party. Effective January 2007, we amended our agreement with Voyager. Under the amendment, among other changes to the Agreement, the royalty rate that we will receive on net sales of Memryte, if commercialized, is doubled (to 10-14% of net sales after the amendment), and in addition, we will receive 10% of any upfront, milestone and other fees received by Voyager in the event that the product is sublicensed to a third party. In return, we paid Voyager $1 million in cash and forgave approximately $725,000 which was owed to us for previously provided services. As of December 31, 2008, the cumulative aggregate payments received by us under this agreement were $11.6 million.

ALZA Corporation. In April 1998, we entered into a development and commercialization agreement with ALZA, which has been subsequently amended and restated, most recently in October 2002. The agreement provides us with exclusive rights to develop, commercialize and manufacture products using ALZA s patented DUROS technology in selected fields of use, and obligates us to pay ALZA a royalty on the net sales of our DUROS-based products and a percentage of upfront license fees, milestone payments, or any other payments or consideration received by us with respect to such DUROS-based products. In connection with the execution of the Agreement, we issued 5,600,000 shares of Series A-1 preferred stock, which were subsequently converted into 5,600,000 shares of common stock concurrent with our initial public offering in 2000. We issued an additional 1,000,000 shares of our common stock and a warrant to purchase 1,000,000 shares of common stock to ALZA in connection with an amendment of the Agreement in April 2000. The warrant expired in September 2004. This agreement can be terminated by either party for material breach by the other party and by us without cause.

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EpiCept Corporation. In December 2006, we entered into a license agreement with EpiCept Corporation (EpiCept) that provides us with the exclusive, worldwide rights to certain of EpiCept s intellectual property for a transdermal patch containing bupivacaine for the treatment of back pain. Pursuant to the agreement, we paid EpiCept $1.0 million upfront in December 2006 and, subject to our achievement of specified milestones, agreed to pay EpiCept an additional $9.0 million in milestone payments as well as a royalty on net sales of any product covered by the license. In September 2008, we and EpiCept entered into an amendment to the license agreement. Under the amendment, among other changes, the scope of the license was broadened from the treatment of back pain to all uses covered by the EpiCept intellectual property including myofascial pain and muscle tension pain, and the license was converted to an exclusive, worldwide, fully paid up, royalty-free, perpetual and irrevocable license. In consideration of this amendment, we made a one-time payment of $2.25 million to EpiCept in full satisfaction of all future payment obligations to EpiCept under the license agreement.

NeuroSystec Corporation. In May 2004, we entered into an exclusive license agreement with NeuroSystec Corporation (NeuroSystec), a privately-held corporation founded by Al Mann, under which we granted to NeuroSystec exclusive worldwide rights to develop and commercialize products designed for the treatment of tinnitus and to improve post-operative recovery and tolerance of surgical implantation of cochlear devices using specified DURECT proprietary drug treatment methods and drug delivery technologies to deliver precise doses of appropriate medications directly to the middle or inner ear. The first development product is currently in early clinical development. We are responsible for formulation development of products utilizing our drug delivery platforms and manufacture and supply of product components consisting of our drug delivery platforms. We will receive certain milestone payments if certain development and commercialization milestones are achieved, as well as royalties based on product sales if products are commercialized under the agreement. This agreement will remain in effect until the expiration of NeuroSystec s royalty obligations under the agreement, which will occur when the last of our related patent rights expire or are found to be invalid, unless the agreement is otherwise terminated earlier. This agreement can be terminated by either party for material breach by the other party and by NeuroSystec without cause. In connection with the agreement, we received equity constituting a minority ownership interest in NeuroSystec.

Commercial Businesses

ALZET®

We currently make and sell the ALZET product line on a worldwide basis. We market the ALZET product line through a direct sales force in the U.S. and through a network of distributors outside the U.S.

The ALZET product line consists of miniature, implantable osmotic pumps and accessories used for experimental research in mice, rats and other laboratory animals. These pumps are neither approved nor intended for human use. ALZET pumps continuously deliver drugs, hormones and other test agents at controlled rates from one day to four weeks without the need for external connections, frequent handling or repeated dosing. In laboratory research, these infusion pumps can be used for systemic administration when implanted under the skin or in the body. They can be attached to a catheter for intravenous, intracerebral, or intra-arterial infusion or for targeted delivery, where the effects of a drug or test agent are localized in a particular tissue or organ.

We acquired the ALZET product line and assets used primarily in the manufacture, sale and distribution of this product line from ALZA in April 2000. We believe that the ALZET business provides us with innovative design and application opportunities for potential new products.

LACTEL® Absorbable Polymers

We currently design, develop and manufacture a wide range of standard and custom biodegradable polymers based on lactide, glycolide and caprolactone under the LACTEL® brand for pharmaceutical and medical device clients for use as raw materials in their products. These materials are manufactured and sold by us directly from our facility in Pelham, Alabama and are used by us and our third-party customers for a variety of controlled-

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release and medical-device applications, including several FDA-approved commercial products. Until December 31, 2004, this business was conducted by our wholly owned subsidiary, Absorbable Polymers International Corporation (API), formerly known as Birmingham Polymers Inc., an Alabama corporation. API was merged with and into DURECT on December 31, 2004.

Marketing and Sales

Historically, we have established strategic distribution and marketing alliances for our pharmaceutical systems to leverage the established sales organizations that certain pharmaceutical companies have in markets we are targeting. However, our goal is to become a specialty pharmaceutical company that commercializes its own products with significant market potential. To that end, we intend, over the course of a few years, to build up commercial, sales and marketing capability and other required infrastructure in focused specialty areas, although there can be no assurance that we will be able to do so. We will continue to pursue strategic alliances from time to time consistent with our strategy to leverage the established sales organizations of third-party collaborators to achieve greater market penetration for some of our products than we could on our own. If we choose to enter into third-party collaborations to commercialize our pharmaceutical systems, we believe we have the flexibility to enter into these alliances under circumstances that allow us to retain greater economic participation because our pharmaceutical systems combine drugs for which medical data on efficacy and safety are available with proven technology platforms.

We market and sell our ALZET product line in the U.S. through a direct sales force, and we have a network of distributors for this product line outside of the U.S. We market and sell our LACTEL product line through a direct sales force.

Suppliers

We purchase sucrose acetate isobutyrate, a raw material for our ORADUR and SABER-based pharmaceutical systems, including POSIDUR, Remoxy and other ORADUR-based opioid drug candidates licensed to Pain Therapeutics, pursuant to a supply agreement with Eastman Chemical Company. We also purchase sufentanil for TRANSDUR-Sufentanil pursuant to a supply agreement with Mallinckrodt, Inc., and we have entered into a supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR and a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR.

Our supply agreement with Eastman Chemical Company requires us to purchase a certain portion of our requirements for sucrose acetate isobutyrate from Eastman Chemical and obligates us to pay a small fee per annum if our purchases do not meet specified sales targets. The Agreement may be terminated by either party under certain circumstances, including any material uncured breach by, or the insolvency, liquidation or bankruptcy of, or similar proceedings involving, the other party.

Our supply agreement with Mallinckrodt, Inc. requires us to purchase a certain portion of our requirements for sufentanil from Mallinckrodt, and has no other minimum purchase requirements or exclusivity provisions. The agreement expires on September 30, 2009 and is subject to automatic renewal for additional one-year terms unless either party provides one year notice of its intention not to renew the agreement. In addition, either party may terminate the Mallinckrodt agreement on 30 days notice for any material uncured breach by, or the bankruptcy of or similar proceedings involving, the other party. Finally, we may terminate the Mallinckrodt agreement on 60 days notice if we reasonably determine that the price being charged by Mallinckrodt is higher than the prevailing price for similar quantities of like grade or quality, or if we cease to develop or commercialize any products incorporating the products we purchase from Mallinckrodt.

We believe that these agreements will provide a sufficient supply of these raw materials and drug product to meet our needs for the foreseeable future. We do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical systems, however, and are subject to the risk that we may not be able to procure all required components in adequate quantities with acceptable quality, within acceptable time frames or at reasonable cost.

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Customers

Our product revenues are derived from sale of the ALZET and LACTEL product lines. Until such time that we are able to bring our pharmaceutical systems to market, if at all, we expect this trend to continue. We also receive revenue from collaborative research and development arrangements with our third-party collaborators. In 2008, revenues from our collaborative agreements with Pain Therapeutics, Endo, Alpharma, and Nycomed represented 24%, 15%, 13% and 11% of our total revenues, respectively. In 2007, revenues from our collaborative agreements with Nycomed, Pain Therapeutics, and Endo represented 36%, 16% and 16% of our total revenues, respectively. In 2006, revenues from our collaborative agreements with Pain Therapeutics and Endo represented 34% and 20% of our total revenues, respectively.

At December 31, 2008, Nycomed and Alpharma accounted for 31% and 29% of our net accounts receivable, respectively. At December 31, 2007, Pain Therapeutics, Nycomed and Endo accounted for 36%, 19% and 16% of our net accounts receivable, respectively. At December 31, 2006, Pain Therapeutics, Nycomed and Endo accounted for 22%, 20% and 16% of our net accounts receivable, respectively.

Manufacturing

The process for manufacturing our pharmaceutical systems is technically complex, requires special skills, and must be performed in a qualified facility. Our manufacturing facility in Cupertino, CA is a functional multi-discipline site that we have used to manufacture research and clinical supplies of several of our pharmaceutical systems under GMP, including POSIDUR, Remoxy, TRANSDUR-Sufentanil, ELADUR, and Memryte. In the future, we intend to develop additional manufacturing capabilities for our pharmaceutical systems and components to meet our demands and those of our third party collaborators by contracting with third party manufacturers and by construction of additional manufacturing space at our current facilities in Cupertino, CA, Vacaville, CA and Pelham, AL. We manufacture our ALZET product line and certain key components for Remoxy at our Vacaville, CA facility and our LACTEL product line at our Pelham, AL facility.

Patents, Licenses and Proprietary Rights

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. In the fourth quarter of 2007 and first quarter of 2008, in two separate tranches, we acquired from a third party a portfolio of worldwide patents relating to drug delivery technologies. This portfolio consists of approximately 22 issued and pending U.S. patents and patent applications as well as their international counterparts. We believe this portfolio will benefit our business by broadening our drug delivery technology base and strengthening our intellectual property position. As of February 27, 2009, we held 55 issued U.S. patents and 356 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 99 pending U.S. patent applications and have filed 107 patent applications under the Patent Cooperation Treaty, from which 549 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries. Our patents expire at various dates starting in 2012.

Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. Patents owned by or licensed to us may not afford protection against competitors, and our pending patent applications now or hereafter filed by or licensed to us may not result in patents being issued. In addition, the laws of certain foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S.

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The patent positions of biopharmaceutical companies involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with certainty. Our patents or patent applications, or those licensed to us, if issued, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide proprietary protection or competitive advantages to us against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

Because patent applications in the U.S. are maintained in secrecy for at least 18 months after filing and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications or that we were the first to file for protection of inventions set forth in such patent applications.

Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case we would need to obtain a license to continue developing or marketing these products. Any required licenses may not be available to us on acceptable terms, if at all. If we do not obtain any required licenses, we could encounter delays in product introductions while we attempt to design around these patents, or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. Litigation may be necessary to defend against or assert such claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Litigation or interference proceedings could result in substantial costs to and diversion of effort by us, and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees and certain contractors. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Government Regulation

The Food and Drug Administration. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products. We believe that our initial pharmaceutical systems will be regulated as drugs by the FDA rather than as biologics or devices.

The process required by the FDA under the new drug provisions of the Federal Food, Drug and Cosmetics Act (the Act) before our initial pharmaceutical systems may be marketed in the U.S. generally involves the following:

- preclinical laboratory and animal tests;
- submission of an IND application which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use; and
- FDA approval of a new drug application.

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Section 505 of the Act describes three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use, among other things, to a previously approved product (section 505(j)). A supplement to an application is a new drug application. We expect that most of our drug candidates will be approved by submission of a new drug application under section 505(b)(2).

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all. Even though several of our pharmaceutical systems utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and effectiveness of those active ingredients in the formulation and dosage forms that we are developing.

Preclinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the pharmaceutical system. We then submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. Each subsequent new clinical protocol must also be submitted to the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. Further, an independent Institutional Review Board at each medical center proposing to conduct the clinical trials must review and approve any clinical study as well as the related informed consent forms and authorization forms that permit us to use individually identifiable health information of study participants.

Human clinical trials are typically conducted in three sequential phases which may overlap:

PHASE I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

PHASE II: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

PHASE III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population, at multiple, geographically dispersed clinical study sites.

In the case of products for severe diseases, such as chronic pain, or life-threatening diseases such as cancer, the initial human testing is often conducted in patients with disease rather than in healthy volunteers. Since these patients already have the target disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials, and thus these trials are frequently referred to as Phase I/II trials. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our pharmaceutical systems within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Board or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. During the clinical development of products, sponsors frequently meet and consult with the FDA in order to ensure that the design of their studies will likely provide data both sufficient and relevant for later regulatory approval; however, no assurance of approvability can be given by the FDA.

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The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of a new drug application, or NDA, for approval of the marketing and commercial shipment of the product. Submission of an NDA requires the payment of a substantial user fee to the FDA, and although the agency has defined user fee goals for the time in which to respond to sponsor applications, we cannot assure you that the FDA will act in any particular timeframe. The FDA may deny a new drug application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market. Requirements for additional Phase IV studies (post approval marketing studies) to confirm safety and effectiveness in a broader commercial use population may be imposed as a condition of marketing approval. In addition, the FDA requires surveillance programs to monitor approved products which have been commercialized, and the agency has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs. Any comparative claims that we would like to make for our products vis-à-vis other dosage forms or products will need to be substantiated generally by two adequate and well-controlled head-to-head clinical trials.

In addition to the drug approval requirements applicable through the Center for Drug Evaluation and Research (CDER), the FDA, through its Office of Combination Products, may require an intercenter consultation review by the Center for Devices and Radiological Health (CDRH), in order to determine a product s Primary Method of Action (PMOA). This request for consultation may be based on the device-like nature of a number of aspects of the DUROS technology.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our pharmaceutical systems under development on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Evolving safety concerns can result in the imposition of new requirements for expensive and time consuming tests, such as for QT interval cardiotoxicity testing. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Any pharmaceutical systems that we may develop and obtain approval for would also be subject to adverse findings of the active drug ingredients being marketed in different dosage forms and formulations. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our pharmaceutical systems abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any pharmaceutical systems manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon us and our third party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP regulations and other FDA regulatory requirements.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses, and federal and state authorities are also actively litigating against sponsors who promote their drugs for unapproved uses under various fraud and abuse and false

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claims act statutes. We and our pharmaceutical systems are also subject to a variety of state laws and regulations in those states or localities where our pharmaceutical systems are or will be marketed. Any applicable state or local regulations may hinder our ability to market our pharmaceutical systems in those states or localities. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

The FDA s policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential pharmaceutical systems. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks.

According to the FDA, opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients. Opioid drugs have serious risks when used improperly. The FDA, drug manufacturers, and others have taken a number of steps in the past to prevent misuse, abuse and accidental overdose of these drugs, including providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients. Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade. The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access.

According to the FDA, it recognizes the need to achieve balance between appropriate access and risk mitigation, and believes an effective strategy would benefit from input from industry, patient advocacy groups, the pain and addiction treatment communities, the general public, and other stakeholders. In the first of a series of meetings with stakeholders, the FDA invited those companies that market the affected opioid drugs to a meeting with the agency on March 3, 2009 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. FDA is planning a public meeting in late spring or early summer to allow for broader public input and participation. Through this process, FDA hopes to gain valuable information that will lead to practical and effective solutions for development of a REMS and for appropriate use of these opioid drug products.

Many of our drug candidates including Remoxy, our other ORADUR-opioid drug candidates and TRANSDUR-Sufentanil are subject to the REMS requirement. Until the contours of required REMS programs are established by the FDA and understood by drug developers and marketers such as ourselves and our collaborators, there may be delays in marketing approvals for these drug candidates. In addition, there may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of drug candidates subject to the REMS requirement, which could negatively impact the commercial benefits to us and our collaborators from the sale of these drug candidates.

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The Drug Enforcement Administration. The Drug Enforcement Administration (DEA) regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients in TRANSDUR-Sufentanil, and Remoxy and our other ORADUR-based opioid drug candidates, are listed by the DEA as Schedule II under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the drugs used in our clinical trials, and, in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Competition

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and the other ORADUR- based opioid drug candidates licensed to Pain Therapeutics, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, and implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, King, Knoll, Janssen, Medtronic, Endo Pharmaceuticals, AstraZeneca, Arrow International, Tricumed, I-Flow and others. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira Pharmaceuticals, EpiCept, Innocoll, Inovio, Nektar, Anesiva, NeurogesX, Alexza, Focal, I-Flow, Javelin Pharmaceuticals, Cadence Pharmaceuticals and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us.

If approved, Memryte will compete against the five drugs currently approved for the treatment of Alzheimer s disease. Four of the drugs are ACIs, including: Aricept, marketed by Pfizer, Inc. and Eisai Company, Ltd.; Exelon, marketed by Novartis AG; Reminyl, marketed by Shire Pharmaceuticals Group plc and Janssen Pharmaceutical Products, LP; and Cognex, marketed by Sciele Pharma, Inc. The fifth drug, Namenda, marketed by Forest Pharmaceuticals, Inc., is an NMDA receptor antagonist. In addition, Memryte could face competition from other leuprolide acetate products that are already on the market or may later be approved for other indications, if they are used or prescribed off label for Alzheimer s disease.

Any products we develop using our pharmaceutical systems technologies will compete in highly competitive markets. Many of our potential competitors in these markets have greater development, financial, manufacturing, marketing, and sales resources than we do and we cannot be certain that they will not succeed in developing products or technologies which will render our technologies and products obsolete or noncompetitive. In addition, many of those potential competitors have significantly greater experience than we do in their respective fields.

Corporate History, Headquarters and Website Information

DURECT Corporation was incorporated in Delaware in February 1998. We completed our initial public offering on September 28, 2000. Our principal executive offices are located at 2 Results Way, Cupertino, California, 95014. Our telephone number is (408) 777-1417, and our web site address is www.durect.com. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports available free of charge on our web site as soon as reasonably practicable after we file these reports with the Securities and Exchange Commission. DURECT Corporation s Code of Ethics can be found on our website.

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Employees

As of February 27, 2009 we had 171 employees, including 103 in research and development, 30 in manufacturing and 38 in selling, general and administrative. From time to time, we also employ independent contractors to support our research, development and administrative organizations. None of our employees are represented by a collective bargaining unit, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

Executive Officers of the Registrant

The executive officers of DURECT Corporation and their ages as of February 27, 2009 are as follows:

Name	Age	Position
Felix Theeuwes, D.Sc.	71	Chairman, Chief Scientific Officer and Director
James E. Brown, D.V.M.	52	President, Chief Executive Officer and Director
Matthew J. Hogan, M.B.A.	49	Chief Financial Officer
Peter J. Langecker, M.D., Ph.D	58	Chief Medical Officer
Jean I Liu, J.D., M.S.	40	Senior Vice President, General Counsel and Secretary
Paula Mendenhall, Pharm.D.	65	Executive Vice President, Operations and Administration
Su Il Yum, Ph.D.	69	Executive Vice President, Pharmaceutical Systems Research and Development

Felix Theeuwes, D.Sc. co-founded DURECT in February 1998 and has served as our Chairman, Chief Scientific Officer and a Director since July 1998. Prior to that, Dr. Theeuwes held various positions at ALZA Corporation, including President of New Ventures from August 1997 to August 1998, President of ALZA Research and Development from 1995 to August 1997, President of ALZA Technology Institute from 1994 to April 1995 and Chief Scientist from 1982 to June 1997. Dr. Theeuwes holds a D.Sc. degree in Physics from the University of Leuven (Louvain), Belgium. He also served as a post-doctoral fellow and visiting research assistant professor in the Department of Chemistry at the University of Kansas and has completed the Stanford Executive Program.

James E. Brown, D.V.M. co-founded DURECT in February 1998 and has served as our President, Chief Executive Officer and a Director since June 1998. He previously worked at ALZA Corporation as Vice President of Biopharmaceutical and Implant Research and Development from June 1995 to June 1998. Prior to that, Dr. Brown held various positions at Syntex Corporation, a pharmaceutical company, including Director of Business Development from May 1994 to May 1995, Director of Joint Ventures for Discovery Research from April 1992 to May 1995, and held a number of positions including Program Director for Syntex Research and Development from October 1985 to March 1992. Dr. Brown holds a B.A. from San Jose State University and a D.V.M. (Doctor of Veterinary Medicine) from the University of California, Davis where he also conducted post-graduate work in pharmacology and toxicology.

Matthew J. Hogan, M.B.A. has served as our Chief Financial Officer since September 2006. He was the Chief Financial Officer at Ciphergen Biosystems, Inc. from 2000 to 2006, and a consultant from March 2006. Prior to joining Ciphergen, Mr. Hogan was the Chief Financial Officer at Avocet Medical, Inc. from 1999 to 2000. From 1996 to 1999, Mr. Hogan was the Chief Financial Officer at Microcide Pharmaceuticals, Inc. From 1986 to 1996, he held various positions in the investment banking group at Merrill Lynch & Co., most recently as a Director focusing on the biotechnology and pharmaceutical sectors. Mr. Hogan holds a B.A. in economics from Dartmouth College and an M.B.A. from the Amos Tuck School of Business Administration.

Peter J. Langecker, M.D., Ph.D. has served as our Chief Medical Officer since May 2006. Prior to joining DURECT, Dr. Langecker served as Chief Medical Officer and Vice President of Clinical Affairs at Intarcia Therapeutics, Inc. from October 1999 to April 2006. Prior to that, Dr. Langecker was Vice President of Clinical Affairs at Sugen, Inc. from 1997 to 1999, Vice President, Clinical Research at Coulter Pharmaceuticals from

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1995 to 1997 and Director of Clinical Research, Oncology, at Schering-Plough from 1992 to 1995. Previously, Dr. Langecker worked as a Project Physician Central Medical Advisor, Oncology at Ciba-Geigy (now Novartis) in Basel, Switzerland. He received his M.D. degree and his doctorate in medical sciences from the Ludwig-Maximilians University in Munich.

Jean I Liu, J.D., M.S. has served as our Senior Vice President and General Counsel since February 2003. She was appointed Secretary of the corporation in March 2004. She served as our Vice President of Legal and General Counsel from February 1999 to February 2003. Previously, from October 1998, Ms. Liu served as our Vice President of Legal. Prior to that, Ms. Liu worked as an attorney at Venture Law Group, a law firm, from May 1997 to October 1998. Ms. Liu worked as an attorney at Pillsbury Madison & Sutro LLP, a law firm, from September 1993 to May 1997. Ms. Liu holds a B.S. in Cellular & Molecular Biology from University of Michigan, an M.S. in Biology from Stanford University and a J.D. from Columbia University School of Law. Ms. Liu is a member of the State Bar of California and is admitted to practice before the United States Patent and Trademark Office.

Paula Mendenhall, Pharm.D. has served as our Executive Vice President of Operations and Administration since January 2007 and as Senior Vice President of Operations since January 2005. Prior to joining DURECT, Dr. Mendenhall was an independent consultant for various pharmaceutical companies for in-house and outsourcing of pharmaceutical manufacturing, including development of manufacturing strategies and plans and development and training of personnel. From 1997 to 2000, Dr. Mendenhall served as Vice President, Group Vice President and President of Oread Pharmaceutical Manufacturing at Oread Inc. From 1979 to 1997, Dr. Mendenhall served in a variety of roles for Hoffmann-La Roche Inc./Syntex, including in the areas of manufacturing, quality assurance, finance, planning and facilities, as well as provided technical assistance and support to Syntex Global Operations for marketed products and new product launches. Dr. Mendenhall received a Pharm D. degree from the University of California, San Francisco, and is a member of the American Association of Pharmaceutical Scientists (AAPS) and the Parenteral Drugs Association.

Su Il Yum, Ph.D. has served as our Executive Vice President of Pharmaceutical Systems Research and Development since January 2007 and as our Senior Vice President of Pharmaceutical Systems Research and Development since January 2006. Previously, Dr. Yum served as our Senior Vice President, Engineering since December 2003 and as our Vice President of Engineering from December 1999 to December 2003. Prior to joining DURECT, Dr. Yum served as Senior Technical Advisor at Amira Medical in Scotts Valley, California, where he participated in the development of a pain-free blood glucose detector called AtLast®. Prior to joining Amira, he held a number of senior positions in project management and engineering at Alza Corporation for 27 years. Dr. Yum earned his Ph.D. degree in Chemical Engineering from the University of Minnesota, and completed a Post-doctoral research in Biomedical Engineering at the University of Utah. Dr. Yum is a Fellow of the AAPS.

Item 1A. Risk Factors.

In addition to the other information in this Form 10-K, a number of factors may affect our business and prospects. These factors include but are not limited to the following, which you should consider carefully in evaluating our business and prospects.

Risks Related To Our Business

Development of our pharmaceutical systems is not complete, and we cannot be certain that our pharmaceutical systems will be able to be commercialized

To be profitable, we or our third-party collaborators must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our pharmaceutical systems under development. For each pharmaceutical system that we or our third-party collaborators intend to commercialize, we must successfully meet a number of critical developmental milestones for each disease or medical condition targeted, including:

selecting and developing drug delivery platform technology to deliver the proper dose of drug over the desired period of time;

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determining the appropriate drug dosage for use in the pharmaceutical system;

developing drug compound formulations that will be tolerated, safe and effective and that will be compatible with the system;

demonstrating the drug formulation will be stable for commercially reasonable time periods;

demonstrating through clinical trials that the drug and system combination is safe and effective in patients for the intended indication; and

completing the manufacturing development and scale-up to permit manufacture of the pharmaceutical system in commercial quantities and at acceptable prices.

The time frame necessary to achieve these developmental milestones for any individual product is long and uncertain, and we may not successfully complete these milestones for any of our products in development. We have not yet selected the drug dosages nor finalized the formulation or the system design of POSIDUR, TRANSDUR-Sufentanil, ELADUR, our ORADUR-based drug candidates other than Remoxy, and Memryte, and we have limited experience in developing such products. We may not be able to finalize the design or formulation of any of these pharmaceutical systems. In addition, we may select components, solvents, excipients or other ingredients to include in our pharmaceutical systems that have not been previously approved for use in pharmaceutical products, which may require us or our collaborators to perform additional studies and may delay clinical testing and regulatory approval of our pharmaceutical systems. Even after we complete the design of a pharmaceutical system, the pharmaceutical system must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our pharmaceutical systems and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency and performance. We and our collaborators may not be able to complete development of any pharmaceutical systems that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we or our third-party collaborators are unable to complete development of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and our ORADUR-based drug candidates other than Remoxy, Memryte or other pharmaceutical systems, we will not be able to earn revenue from them, which would materially harm our business.

We or our third-party collaborators must conduct and satisfactorily complete required laboratory performance and safety testing, animal studies and clinical trials for our pharmaceutical systems before they can be sold

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical systems, we or they, as applicable, must demonstrate through laboratory performance studies and safety testing, nonclinical (animal) studies and clinical (human) trials that each system is safe and effective for human use for each targeted indication. The clinical development status of our publicly announced development programs is as follows:

Remoxy In December 2007, Pain Therapeutics and King reported positive results from the pivotal Phase III trial submitted under an approved Special Protocol Assessment (SPA) with the FDA; the NDA was submitted to the FDA in June 2008, and in August 2008, the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy, but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics has indicated that they plan to meet with the FDA in the second quarter of 2009 regarding the NDA for Remoxy, and they believe this FDA meeting will provide them with a more reliable context in which to make projections about Remoxy.

POSIDUR A successful Phase IIb clinical trial in hernia surgery was completed and an end-of-Phase II meeting has been held with the FDA. We are currently in dialogue with the FDA regarding our Phase III program. In parallel with these discussions, we are conducting a 60-patient Phase IIb study in

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Australia in shoulder surgery in order to allow us to confirm aspects of our clinical study design and conduct. Additionally, Nycomed is commencing Phase IIb studies in surgical procedures in Europe.

TRANSDUR-Sufentanil Patch Endo recently successfully completed a Phase II program for TRANSDUR-Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. The most recent Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. On February 26, 2009, Endo notified us that it was terminating its license agreement for TRANSDUR-Sufentanil and thereby returning to us Endo s rights to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada effective August 26, 2009.

ELADUR A Phase IIa clinical trial was completed and positive results were reported in the fourth quarter of 2007. In 2008, we conducted manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies, and developed our clinical and regulatory strategy for further development of this program. In September 2008, we entered into a development and license agreement with Alpharma Ireland Ltd., an affiliate of Alpharma Inc., granting such party the exclusive worldwide rights to develop and commercialize ELADUR. The agreement became effective in October 2008 upon clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR). Alpharma was acquired by King Pharmaceuticals in December 2008 and, as a result, the rights and obligations of the agreement are now controlled by King.

Second and third ORADUR-Opioid Drug Candidates under Pain Therapeutics/King alliance We also have two other ORADUR-based drug candidates for which Phase I clinical trials have been completed. According to Pain Therapeutics, the data from these Phase I trials indicate that these drug candidates are safe and well-tolerated with a release profile that appears well suited to use with a chronic pain population. The active ingredients in these two drug candidates are opioids whose identities have not been publicly disclosed.

We are currently in the clinical, preclinical or research stages with respect to all our other pharmaceutical systems under development. We plan to continue extensive and costly tests, clinical trials and safety studies in animals to assess the safety and effectiveness of our pharmaceutical systems. These studies include laboratory performance studies and safety testing, clinical trials and animal toxicological studies necessary to support regulatory approval of development products in the United States and other countries of the world. These studies are costly, complex and last for long durations, and may not yield the data required for regulatory approval. We and our collaborators may not be permitted to begin or continue our planned clinical trials for our potential pharmaceutical systems. If our trials are permitted, our potential pharmaceutical systems may not prove to be safe or produce their intended effects. In addition, we or our collaborators may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our pharmaceutical systems which we have not planned or anticipated. For example, according to Pain Therapeutics, the FDA has indicated that additional non-clinical data will be required prior to regulatory approval for Remoxy. This additional data could delay commercialization of such pharmaceutical systems and harm our business and financial condition.

The length of clinical trials will depend upon, among other factors, the rate of trial site and patient enrollment and the number of patients required to be enrolled in such studies. We or our third-party collaborators may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on us. In addition, even if we or our third-party collaborators enroll the number of patients we expect in the time frame we expect, such clinical trials may not provide the data necessary to support regulatory approval for the pharmaceutical systems for which they were conducted. Additionally, we or our third-party collaborators may fail to effectively oversee and monitor these clinical trials, which would result in increased costs or delays of our

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clinical trials. Even if these clinical trials are completed, we or our third-party collaborators may fail to complete and submit a new drug application as scheduled. The Food and Drug Administration (FDA) may not clear any such application in a timely manner or may deny the application entirely. Data already obtained from preclinical studies and clinical trials of our pharmaceutical systems do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, preclinical and clinical data such as ours are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical system under development could delay or prevent regulatory clearance of the potential pharmaceutical system, resulting in delays to the commercialization of our pharmaceutical system, and could materially harm our business. Clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our pharmaceutical systems, and thus our pharmaceutical systems may not be approved for marketing.

Regulatory action or failure to obtain product approvals could delay or limit development and commercialization of our pharmaceutical systems and result in failure to achieve anticipated revenues

The manufacture and marketing of our pharmaceutical systems and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. We or our third-party collaborators must obtain clearance or approval from applicable regulatory authorities before we or they, as applicable, can perform clinical trials, market or sell our development products in the United States or abroad. Clinical trials, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. In particular, recent recalls of and reported adverse side effects of marketed drugs have made regulatory agencies, including the FDA, increasingly focus on the safety of drug products. Regulatory agencies are requiring more extensive and ever increasing showings of safety at every stage of drug development and commercialization from initial clinical trials to regulatory approval and beyond. These rigorous and evolving standards may delay and increase the expenses of our development efforts. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators development and commercialization activities due to safety concerns, in which case our business will be harmed. In addition, the FDA or other foreign regulatory agency may refuse or delay approval of our or our collaborators drug candidates for failure to collect sufficient clinical or animal safety data, and require us or our collaborators to conduct additional clinical or animal safety data which may cause lengthy delays and increased costs to our programs. For example, Pain Therapeutics has announced that the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. These laws and regulations are complex and subject to change. Furthermore, these laws and regulations may be subject to varying interpretations, and we may not be able to predict how an applicable regulatory body or agency may choose to interpret or apply any law or regulation to our pharmaceutical systems. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. We or our third-party collaborators, as applicable, may encounter delays or rejections based upon administrative action or interpretations of current rules and regulations. We or our third-party collaborators, as applicable, may not be able to timely reach agreement with the FDA on our clinical trials or on the required clinical or animal data we or they must collect to continue with our clinical trials or eventually commercialize our pharmaceutical systems.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical systems outside the United States are subject to foreign regulatory standards that vary from country to country.

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The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical systems, which will limit our ability to generate revenue.

Many of our drug candidates under development including Remoxy and TRANSDUR-Sufentanil are subject to mandatory Risk Evaluation and Mitigation Strategy (REMS) programs, a new requirement by the FDA, which could delay the approval of these drug candidates and increase the cost, burden and liability associated with the commercialization of these drug candidates

On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks.

According to the FDA, opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients. Opioid drugs have serious risks when used improperly. The FDA, drug manufacturers, and others have taken a number of steps in the past to prevent misuse, abuse and accidental overdose of these drugs, including providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients. Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade. The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access.

According to the FDA, it recognizes the need to achieve balance between appropriate access and risk mitigation, and believes an effective strategy would benefit from input from industry, patient advocacy groups, the pain and addiction treatment communities, the general public, and other stakeholders. In the first of a series of meetings with stakeholders, the FDA invited those companies that market the affected opioid drugs to a meeting with the agency on March 3, 2009 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. FDA is planning a public meeting in late spring or early summer to allow for broader public input and participation. Through this process, FDA hopes to gain valuable information that will lead to practical and effective solutions for development of a REMS and for appropriate use of these opioid drug products.

Many of our drug candidates including Remoxy, our other ORADUR-opioid drug candidates and TRANSDUR-Sufentanil are subject to the REMS requirement. Until the contours of required REMS programs are established by the FDA and understood by drug developers and marketers such as ourselves and our collaborators, there may be delays in marketing approvals for these drug candidates. In addition, there may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of drug candidates subject to the REMS requirement, which could negatively impact the commercial benefits to us and our collaborators from the sale of these drug candidates.

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We depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our pharmaceutical systems which are the subject of third-party collaborative or license agreements

Our performance depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain approvals for our pharmaceutical systems. We have entered into an agreement with Endo related to the development, promotion and distribution of TRANSDUR-Sufentanil in the United States and Canada, which agreement will terminate effective August 26, 2009. In addition, we have entered into agreements with Pain Therapeutics, Nycomed, Alpharma (acquired by King in December 2008) and Voyager under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute Remoxy and other ORADUR-based products incorporating specified opioids, POSIDUR, ELADUR and Memryte, respectively, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these pharmaceutical systems, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. They may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such pharmaceutical systems ourselves. Further, our collaborators may elect not to develop or commercialize pharmaceutical systems arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these pharmaceutical systems. If any of these events occur, we may not recognize revenue from the commercialization of our pharmaceutical systems based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our pharmaceutical systems. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Our near-term revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and also make our revenues dependent on the performance of such third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease

Our near-term revenues are based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in the agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new pharmaceutical systems, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Endo with respect to TRANSDUR-Sufentanil (which will terminate effective August 26, 2009), Pain Therapeutics with respect to Remoxy and other ORADUR-based products incorporating specified opioids, Nycomed with respect to POSIDUR, Alpharma (acquired by King) with respect to ELADUR, and Voyager with respect to Memryte, may be terminated by the other party at will or upon specified conditions including, for example, if we fail to satisfy specified performance milestones or if we breach the terms of the agreement.

If any of our collaborative agreements are terminated, our revenues may be reduced or not materialize, and our development products related to those agreements may not be commercialized.

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Our near-term revenues also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues.

In addition to payments based on our performance of research and development activities, our revenues also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to clinical trial developments, regulatory approvals or sales accomplishments. To the extent third-party collaborators do not achieve such milestones, we will not receive the associated revenues, which could harm our financial condition and may cause us to defer or cut-back development activities or forego the exploitation of opportunities in certain geographic territories, any of which could have a material adverse effect on our business.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our pharmaceutical systems. The negotiation and consummation of these type of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well the collaborators own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

We may have difficulty raising needed capital in the future

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our pharmaceutical systems. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities and to provide for the marketing and distribution of our pharmaceutical systems. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.

We believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs for at least the next 12 months. However, our actual capital requirements will depend on many factors, including:

- continued progress and cost of our research and development programs;
- the continuation of our collaborative agreements that provide financial funding for our activities;
- success in entering into collaboration agreements and meeting milestones under such agreements;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our pharmaceutical systems;

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costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our pharmaceutical systems;

competing technological and market developments;

market acceptance of our pharmaceutical systems;

costs for recruiting and retaining employees and consultants; and

unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies or pharmaceutical systems that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs, and reduced revenues.

We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical systems and components to support the clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience

We or our third-party collaborators to whom we have assigned such responsibility must manufacture our pharmaceutical systems and components in clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our pharmaceutical systems are complex. Except with respect to Remoxy, we and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any pharmaceutical systems or components including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Memryte, and other ORADUR-based drug candidates. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our pharmaceutical systems, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our pharmaceutical systems. We have also committed to manufacture and supply pharmaceutical systems or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a pharmaceutical system or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that pharmaceutical system or we may be in breach of our supply obligations to our third-party collaborators.

Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical systems under good manufacturing practices (GMP), including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and additional ORADUR-based drug candidates, and Memryte. We have not manufactured commercial quantities of any of our pharmaceutical systems. In the future, we intend to develop additional manufacturing capabilities for our pharmaceutical systems and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by construction of additional manufacturing space at our current facilities in Cupertino, CA, Vacaville, CA and Pelham, AL. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely manner.

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If we and our third-party collaborators, where relevant, are unable to manufacture pharmaceutical systems or components in a timely manner or at an acceptable cost, quality or performance level, and attain and maintain compliance with applicable regulations, the clinical trials and the commercial sale of our pharmaceutical systems and those of our third-party collaborators could be delayed. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the clinical trials and commercial launch of our pharmaceutical systems and those of our third-party collaborators.

We have entered into a supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR and a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR. These third parties are currently our sole source for drug product required for development and commercialization of these drug candidates. Furthermore, we and our third-party collaborators, where relevant, may also need or choose to subcontract with additional third-party contractors to perform manufacturing steps of our pharmaceutical systems or supply required components for our pharmaceutical systems. Where third party contractors perform manufacturing services for us, we will be subject to the schedule, expertise and performance of third parties as well as incur significant additional costs. Failure of third parties to perform their obligations could adversely our operations, development timeline and financial results. Under our development and commercialization agreement with ALZA, we cannot subcontract the manufacture of subassemblies of the DUROS system components of our DUROS-based pharmaceutical systems to third parties which have not been approved by ALZA.

If we or our third-party collaborators cannot manufacture pharmaceutical systems or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

Failure to comply with ongoing governmental regulations for our pharmaceutical systems could materially harm our business in the future

Marketing or promoting a drug is subject to very strict controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our pharmaceutical systems, which in turn would materially harm our business, financial condition and results of operations:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain approvals for clinically intended uses of our pharmaceutical systems under development; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our pharmaceutical systems.

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our development products. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements. We have not been subject to a good manufacturing regulation inspection

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by the FDA relating to our pharmaceutical systems. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our pharmaceutical systems we or they manufacture, the FDA may refuse or withdraw marketing clearance or require product recall, which may cause interruptions or delays in the manufacture and sale of our pharmaceutical systems.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability

We have incurred significant operating losses since our inception in 1998 and, as of December 31, 2008, had an accumulated deficit of approximately $283.6 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed pharmaceutical systems, obtain the required regulatory clearances, and manufacture and market our proposed pharmaceutical systems. Development of pharmaceutical systems is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our pharmaceutical systems. The license fees for these technologies or rights would increase the costs of our pharmaceutical systems.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical systems and do not expect to do so in the near future. Our current product revenues are from the sale of the ALZET product line and the sale of LACTEL biodegradable polymers, and from payments under collaborative research and development agreements with third parties. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our pharmaceutical systems in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may develop our own sales force to market POSIDUR but we have limited sales experience and may not be able to do so effectively

We may choose to develop our own sales force to market POSIDUR in the United States if POSIDUR is approved for marketing by the FDA. Developing a sales force will require substantial expenditures. DURECT has limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. We may not be able to effectively sell our pharmaceutical systems, if approved, and our failure to do so could limit or materially harm our business.

We and our third-party collaborators may not sell our pharmaceutical systems effectively

We and our third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborations may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our pharmaceutical systems;
- cease operations with little or no notice to us;
- offer, design, manufacture or promote competing product lines;
- fail to maintain adequate inventory and thereby restrict use of our pharmaceutical systems; or

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build up inventory in excess of demand thereby limiting future purchases of our pharmaceutical systems resulting in significant quarter-to-quarter variability in our sales.

The failure of us or our third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our pharmaceutical systems will hurt our business and financial results.

We rely heavily on third parties to support development, clinical testing and manufacturing of our pharmaceutical systems

We rely on third-party contract research organizations, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our pharmaceutical systems. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our pharmaceutical systems. These third parties may not execute their responsibilities and tasks competently or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our pharmaceutical systems or components. We anticipate that we will continue to rely on these and other third-party contractors to support development, clinical testing, and manufacturing of our pharmaceutical systems. Failure of these contractors to provide the required services in a competent or timely manner or on reasonable commercial terms could materially delay the development and approval of our development products, increase our expenses and materially harm our business, financial condition and results of operations.

Key components of our pharmaceutical systems are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs

Certain components and drug substances used in our pharmaceutical systems (including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and our additional ORADUR-based drug candidates, and Memryte) are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemicals is the sole supplier, pursuant to a supply agreement entered into in December 2005, of our requirements of sucrose acetate isobutyrate, a necessary component of POSIDUR, Remoxy, our additional ORADUR-opioids and certain other pharmaceuticals systems we have under development. The reliance on a sole or limited number of suppliers could result in:

delays associated with redesigning a pharmaceutical system due to a failure to obtain a single source component;

an inability to obtain an adequate supply of required components; and

reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain components of our pharmaceuticals systems, but do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical system candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components could cause us to seek alternative sources of supply or manufacture these components internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our pharmaceutical systems is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our pharmaceutical systems, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

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If we are unable to adequately protect or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us

Our success will depend in part on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. As of February 27, 2009, we held 55 issued U.S. patents and 356 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 99 pending U.S. patent applications and have filed 107 patent applications under the Patent Cooperation Treaty, from which 549 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries. Our patents expire at various dates starting in 2012.

Under our agreement with ALZA, we must assign to ALZA any intellectual property rights relating to the DUROS system and its manufacture and any combination of the DUROS system with other components, active agents, features or processes. In addition, ALZA retains the right to enforce and defend against infringement actions relating to the DUROS system, and if ALZA exercises these rights, it will be entitled to the proceeds of these infringement actions.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

The patent laws of the U.S. have recently undergone changes through court decisions which may have significant impact on us and our industry. The recent decisions of the U.S. Supreme Court (e.g., *KSR v. Telefex, EBay v. MercExchange*) and other courts (e.g., *In re Seagate*) with respect to the standards of patentability, enforceability, availability of injunctive relief and damages may make it more difficult for us to procure, maintain and enforce patents. In addition, bills are pending before the U.S. Congress including the Patent Reform Act of 2007 that may fundamentally change the patent laws of the U.S. on issues ranging from priority entitlement, filing and prosecution matters to enforcement and damages. These changes and proposed reforms have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

We are party to several collaborative agreements. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business. To the extent that our agreements call for future royalties to be paid conditional on our having patents covering the royalty-bearing subject matter, the decision by the Supreme Court in the case of *MedImmune, Inc. v. Genentech, Inc.* could encourage our licensees to challenge the validity of our patents and thereby seek to avoid future royalty obligations without losing the benefit of their license. Should they be successful in such a challenge, our ability to collect future royalties could be substantially diminished.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the

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course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual s relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We may be sued by third parties which claim that our pharmaceutical systems infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We and our collaborators may be exposed to future litigation by third parties based on claims that our pharmaceutical systems or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

- cease selling, incorporating or using any of our pharmaceutical systems that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our pharmaceutical systems, which would be costly and time-consuming.

We may be required to obtain rights to certain drugs

Some of the pharmaceutical systems that we may choose to develop may include proprietary drugs to which we do not have commercial rights. To complete the development and commercialization of pharmaceutical systems containing drugs to which we do not have commercial rights, we will be required to obtain rights to those drugs. We may not be able to do this at an acceptable cost, if at all. If we are not able to obtain required rights to commercialize certain drugs, we may not be able to complete the development of pharmaceutical systems which require use of those drugs. This could result in the cessation of certain development projects and the potential write-off of certain assets.

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Technologies and businesses which we have acquired may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention. We may also acquire additional businesses or technologies in the future, which could have these same effects

We may acquire technologies, products or businesses to broaden the scope of our existing and planned product lines and technologies. Future acquisitions expose us to:

- increased costs associated with the acquisition and operation of the new businesses or technologies and the management of geographically dispersed operations;
- the risks associated with the assimilation of new technologies, operations, sites and personnel;
- the diversion of resources from our existing business and technologies;
- the inability to generate revenues to offset associated acquisition costs;
- the requirement to maintain uniform standards, controls, and procedures; and
- the impairment of relationships with employees and customers or third party collaborators as a result of any integration of new management personnel.

Acquisitions may also result in the issuance of dilutive equity securities, the incurrence or assumption of debt or additional expenses associated with the amortization of acquired intangible assets or potential businesses. Past acquisitions, such as our acquisitions of IntraEAR, ALZET, SBS and APT, as well as future acquisitions, may not generate any additional revenue or provide any benefit to our business.

Some of our pharmaceutical systems contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies

Some of our pharmaceutical systems currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. The TRANSDUR-Sufentanil patch, Remoxy and our additional ORADUR-based drug candidates, and other pharmaceutical systems we have under development contain active ingredients which are classified as controlled substances under the regulations of the U.S. Drug Enforcement Agency. For our pharmaceutical systems containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our pharmaceutical systems containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems containing controlled substances.

Write-offs related to the impairment of long-lived assets and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets. We will continue to incur non-cash charges related to amortization of other intangible assets. For example, we had a $13.5 million non-cash write down of deferred royalties and commercial rights related to CHRONOGESIC in the fourth quarter of 2008, which impacted our financial statements. We are required to perform periodic impairment reviews of our goodwill at least annually.

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To the extent these reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the cost of our long-lived assets, we will be required to measure and record an impairment charge to write down these assets to their realizable values. We completed our last review during the fourth quarter of 2008 and determined that goodwill was not impaired as of December 31, 2008. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

In December 2004, the FASB issued Statement No. 123 (revised 2004, or SFAS 123(R), *Share-Based Payment,* which was originally effective for annual or interim periods beginning after June 15, 2005. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plans. We adopted SFAS 123(R) using the modified prospective basis on January 1, 2006. Our adoption of SFAS 123(R) has and will continue to have a material adverse impact on our results of operations and will adversely impact or delay our profitability.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days and less than one year at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since December 31, 2008, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments or our ability to meet our financing objectives.

We depend upon key personnel who may terminate their employment with us at any time, and we need to hire additional qualified personnel

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel, including Felix Theeuwes, our Chairman and Chief Scientific Officer and James E. Brown, our President and Chief Executive Officer. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources.

We may not successfully manage our company through varying business cycles

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

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Our business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials and pharmaceutical systems, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Our corporate headquarters, manufacturing facilities and personnel are located in a geographical area that is seismically active

Our corporate headquarters, primary manufacturing facilities and personnel are located in a geographical area that is known to be seismically active and prone to earthquakes. Should such a natural disaster occur, our ability to conduct our business could be severely restricted, and our business and assets, including the results of our research, development and manufacturing efforts, could be destroyed.

Risks Related To Our Industry

The market for our pharmaceutical systems is rapidly changing and competitive, and new products or technologies developed by others could impair our ability to grow our business and remain competitive

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our pharmaceutical systems under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based opioids, and Memryte, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, and implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, King, Knoll, Janssen, Medtronic, Endo Pharmaceuticals, AstraZeneca, Arrow International, Tricumed, I Flow and others. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira Pharmaceuticals, EpiCept, Innocoll, Inovio, Nektar, Focal, I-Flow, Anesiva, NeurogesX, Alexza, Cadence Pharmaceuticals, Javelin Pharmaceuticals and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development

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capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our pharmaceutical systems. Our competitors may develop products that are safer, more effective or less costly than our pharmaceutical systems and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our pharmaceutical systems even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, and implantable drug delivery devices which will be competitive with our pharmaceutical systems. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our pharmaceutical systems to receive widespread acceptance if commercialized.

We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, manufacture, marketing and sale of our pharmaceutical systems involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our pharmaceutical systems, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our pharmaceutical systems, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our pharmaceutical systems. A product liability claim could also significantly harm our reputation and delay market acceptance of our pharmaceutical systems.

Acceptance of our pharmaceutical systems in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues

Our future financial performance will depend upon the successful introduction and customer acceptance of our future products, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based drug candidates, and Memryte. Even if approved for marketing, our pharmaceutical systems may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, or external or implantable drug delivery products; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

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Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve anticipated revenues.

If users of our products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our pharmaceutical systems will depend in part on the extent to which appropriate reimbursement levels for the cost of our pharmaceutical systems and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly limiting payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

If we or our third-party collaborators are unable to train physicians to use our pharmaceutical systems to treat patients diseases or medical conditions, we may incur delays in market acceptance of our products

Broad use of our pharmaceutical systems will require extensive training of numerous physicians on the proper and safe use of our pharmaceutical systems. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our pharmaceutical systems may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our pharmaceutical systems. Any delay in training would materially delay the demand for our pharmaceutical systems and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

Potential new accounting pronouncements and legislative actions are likely to impact our future financial position or results of operations

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, PCAOB pronouncements and NASDAQ Global Market rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are increasing as a result of

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this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related To Our Common Stock

Our operating history makes evaluating our stock difficult

Our quarterly and annual results of operations have historically fluctuated and we expect will continue to fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and commercialize our pharmaceutical systems, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our pharmaceutical systems and to fund operating losses to be incurred in the next several years.

Investors may experience substantial dilution of their investment

Investors may experience dilution of their investment if we raise capital through the sale of additional equity securities or convertible debt securities or grant additional stock options to employees and consultants. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices for our common stock.

The price of our common stock may be volatile

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- failure of our third-party collaborators (such as Endo, Pain Therapeutics or its commercialization sublicensee King Pharmaceuticals, Nycomed, Alpharma (now owned by King) or Voyager) to develop and commercialize successfully the respective pharmaceutical systems they are developing;
- adverse results (including adverse events) or delays in our clinical and non-clinical trials of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy, our additional ORADUR-based drug candidates, Memryte or other pharmaceutical systems;
- announcements of FDA non-approval of our pharmaceutical systems, or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies with respect to our pharmaceutical systems, clinical trials, manufacturing processes or sales and marketing activities, or those of our third party collaborators;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;

any lawsuit involving us or our pharmaceutical systems including intellectual property infringement or product liability suits;

announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;

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developments concerning our strategic alliances or acquisitions;

actual or anticipated variations in our operating results;

changes in recommendations by securities analysts or lack of analyst coverage;

deviations in our operating results from the estimates of analysts;

sales of our common stock by our executive officers or directors or sales of substantial amounts of common stock by others;

changes in accounting principles; and

loss of any of our key scientific or management personnel.

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

In the past, following periods of volatility in the market price of a particular company s securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management s attention and our company s resources.

We have broad discretion over the use of our cash and investments, and their investment may not always yield a favorable return

Our management has broad discretion over how our cash and investments are used and may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

Executive officers, directors and principal stockholders have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders

Our directors, executive officers and principal stockholders, together with their affiliates, have substantial control over us. The interests of these stockholders may differ from the interests of other stockholders. As a result, these stockholders, if acting together, would have the ability to exercise control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

the election of directors;

the amendment of charter documents;

the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets; or

the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

Our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us.

Provisions of Delaware law, our certificate of incorporation, bylaws and stockholder rights plan may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

providing for a dividend on our common stock, commonly referred to as a poison pill , which can be triggered after a person or group acquires 17.5% or more of common stock;

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providing for a classified board of directors with staggered terms;

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

eliminating the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The following chart indicates the facilities that we lease, the location and size of each such facility and their designated use.

Location	Approximate Square Feet	Operation	Expiration
Cupertino, CA	30,000 sq. ft.	Office, Laboratory and Manufacturing	Lease expired February 2009 (an option to renew for an additional five years has been exercised by us and the terms of the renewal period are under negotiation between us and the landlord)
Cupertino, CA	20,000 sq. ft.	Office and Laboratory	Lease expires 2014 (with an option to renew for an additional five years)
Cupertino, CA	40,560 sq. ft.	Office	Lease expires 2012 (with an option to renew for an additional six years)
Vacaville, CA	24,634 sq. ft.	Manufacturing	Lease expires 2013 (with an option to renew for an additional five years)
Pelham, AL	9,400 sq. ft.	Office, Laboratory and Manufacturing	Lease expires 2010 (with an option to renew for an additional five years)

We believe that our existing facilities are adequate to meet our current and foreseeable requirements or that suitable additional or substitute space will be available as needed.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted during the fourth quarter of the year ended December 31, 2008.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matter and Issuer Purchases of Equity Securities.

Price Range of Common Stock

Our common stock has been traded on the NASDAQ Global Market under the symbol DRRX since our initial public offering on September 28, 2000. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the NASDAQ Global Market.

	Common Stock Price	
Year ended December 31, 2007	**Low**	**High**
First Quarter	$ 3.89	$ 4.59
Second Quarter	3.78	4.87
Third Quarter	3.68	5.66
Fourth Quarter	5.00	6.90

Year ended December 31, 2008	**Low**	**High**
First Quarter	$ 4.07	$ 6.43
Second Quarter	3.67	5.41
Third Quarter	3.66	5.96
Fourth Quarter	2.87	5.38

The closing sale price of our common stock as reported on the NASDAQ Global Market on February 27, 2009 was $1.99 per share. As of that date there were approximately 142 holders of record of the common stock. This does not include the number of persons whose stock is in nominee or street name accounts through brokers. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to a number of events and factors, such as progress in our development programs, quarterly variations in our operating results, announcements of technological innovations or new products by us or our competitors, changes in financial estimates and recommendations by securities analysts, the operating and stock performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets. These fluctuations, as well as general economic and market conditions, may adversely affect the market price for our common stock.

Dividend Policy

We have never paid cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying any cash dividends in the foreseeable future.

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STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data for our stock with the cumulative return of (i) The NASDAQ Stock Market (U.S.) Index and (ii) the NASDAQ Biotechnology Index since December 31, 2003. The graph assumes that $100 was invested on December 31, 2003. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

* $100 Invested on 12/31/03 in stock or index including reinvestment of dividends. Fiscal year ending December 31.

DURECT CORPORATION

	Cumulative Total Return					
	12/31/03	**12/31/04**	**12/31/05**	**12/31/06**	**12/31/07**	**12/31/08**
DURECT CORPORATION	100.00	131.20	202.80	177.60	257.20	135.60
NASDAQ STOCK MARKET (U.S.)	100.00	108.59	110.08	120.56	132.39	78.72
NASDAQ BIOTECHNOLOGY	100.00	106.13	109.14	110.25	115.30	100.75

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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Item 6. Selected Financial Data.

The following selected consolidated financial data should be read in conjunction with and are qualified by reference to Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes, which are included in this Form 10-K. The statement of operations data for the years ended December 31, 2008, 2007 and 2006 and the balance sheet data at December 31, 2008 and 2007 are derived from, and are qualified by reference to, the audited financial statements included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2005 and 2004, and the balance sheet data at December 31, 2006, 2005 and 2004 are derived from our audited statements not included in this Form 10-K. Historical operating results are not necessarily indicative of results in the future. See Note 1 of notes to financial statements for an explanation of the determination of the shares used in computing net loss per share.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Statement of Operations Data:					
Collaborative research and development and other revenue	$ 18,336	$ 22,417	$ 13,786	$ 20,032	$ 7,437
Product revenue, net	8,765	8,258	8,108	6,939	6,416
Revenue from sale of intellectual property rights				1,600	
Total revenue	27,101	30,675	21,894	28,571	13,853
Operating expenses:					
Cost of revenue	3,365	3,225	3,248	2,815	2,730
Research and development	39,411	38,342	37,241	29,141	24,390
Selling, general and administrative	15,462	13,618	12,417	11,034	9,793
Write down of deferred royalties and commercial rights	13,480				

The table below sets forth the 2012 annual incentive plan award target percentages, as well as the threshold, target, maximum and actual award payments approved for each of our named executive officers. The actual award payments are also reported in the Non-Equity Incentive Plan Compensation column of the Summary Compensation Table and the threshold, target and maximum bonus amounts are also reported in the Estimated Future Payouts Under Non-Equity Incentive Plan Awards column of the Grants of Plan-Based Awards Table.

Fiscal Year 2012 Annual Incentive Awards

Executive Officer	Target Percentage	Threshold[1]	Target	Maximum[2]	Actual
José E. Almeida	130%	$763,750	$1,527,500	$3,055,000	$1,682,517
Charles J. Dockendorff	85%	$328,185	$656,370	$1,312,740	$722,981
Bryan C. Hanson	80%	$216,320	$432,640	$865,280	$355,965
Peter L. Wehrly	80%	$216,320	$432,640	$865,280	$650,127
Mark C. Trudeau	80%	$260,000	$520,000	$1,040,000	$507,252[3]

(1) Threshold award payments are 50% of target award payments.

(2) Maximum award payments are 200% of target award payments.

(3) Mr. Trudeau s actual award is pro-rated for the number of days during fiscal 2012 that he served as President of our Pharmaceuticals business.

In setting individual target percentages for fiscal 2012, the Compensation Committee reviewed, for each named executive officer (other than Mr. Trudeau, who joined the Company in February 2012), the target percentages applicable in fiscal 2011, the total cash compensation

established for fiscal 2011 and the projected cash compensation for fiscal 2012, considering how the total cash compensation of each named executive officer compared to peer group and related market data. The Compensation Committee also took into account the day-to-day responsibilities of each named executive officer. Following this review, and in light of peer group data and the overall compensation of each named executive officer, the Compensation Committee determined that the fiscal 2011 award target percentage remained appropriate for Mr. Dockendorff and should be increased for Messrs. Hanson and Wehrly, in-line with the expanded roles these two named executive officers assumed in July 2011. Following the setting of individual target percentages for fiscal 2012, Mr. Almeida was just above the

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50th percentile of total cash compensation (i.e., base salary plus the annual incentive bonus payable if target performance is attained) paid to executives in comparable positions, based on market data, while, for their respective positions, Mr. Dockendorff was just above the 75th percentile, Mr. Hanson was just above the 50th percentile and Mr. Wehrly was just below the 50th percentile. With respect to Mr. Trudeau, the Compensation Committee utilized the same methodology as used to establish base salary when establishing his individual target percentage, selecting a percentage that would result in an annual incentive bonus that, if target performance is attained, is significantly below the 50th percentile and which, when combined with his base salary, provides Mr. Trudeau with total cash compensation (i.e., base salary and target bonus opportunity) that is just above the 25th percentile of market.

Mr. Almeida s target percentage was significantly higher than those of other named executive officers given his position as Chief Executive Officer and the significant responsibilities that accompany that position. His target percentage, as with the target percentages for each of the other named executive officers, was in-line with market data.

Long-Term Incentive Awards

The Compensation Committee uses long-term incentive compensation in the form of equity awards to deliver competitive compensation that recognizes employees for their contributions to the Company and aligns the interests of named executive officers with shareholders by focusing them on long-term growth and stock performance. Recognizing that long-term incentives are generally the most significant element of total remuneration at the senior level and also acknowledging that long-term incentives are a crucial part of the total rewards compensation package that the Company offers, during fiscal 2011 the Compensation Committee, with input from its consultant, conducted a review of the Company s long-term incentive structure.

The Compensation Committee examined a number of potential long-term incentive vehicles for equity grants, considering the pros and cons of each. The Compensation Committee also considered the proportion of long-term incentive value to be allocated to vehicles with time-based vesting versus vehicles with performance-based vesting. Based on this evaluation, the Compensation Committee determined that the long-term incentive vehicles of stock options, restricted units and performance units continued to serve the Company well. To emphasize the Company s pay-for-performance philosophy, the Compensation Committee did, however, deem it appropriate to increase the proportion of long-term incentive value allocated to performance units. The Compensation Committee also reviewed the performance share plan payout curve and determined that relative total shareholder return (total shareholder return for the Company as compared to total shareholder return of companies comprising a healthcare industry index), measured over the three-year performance period, continued to be the appropriate metric for performance units. Total shareholder return in the top quartile of peer group performance is a key long-term financial goal of the Company. The healthcare industry index selected by the Compensation Committee for the fiscal 2012 grant is comprised of the Company as well as 17 healthcare companies that generally replicate the Company s mix of businesses and includes all of the members of the peer group established by the Company for purposes of establishing fiscal 2012 compensation.

When setting long-term incentive compensation for named executive officers, the Compensation Committee employs the process described in the *How We Determine Compensation Peer Group Reviews and Market Data* section of this CD&A. In determining the dollar value of the fiscal 2012 annual long-term incentive award for each named executive officer (other than for Mr. Trudeau, who joined the Company in February 2012), the Compensation Committee also considered individual performance, including TLR performance ratings, the officer s total direct compensation (i.e., base salary, annual incentive compensation and long-term incentive compensation in the aggregate) and mix of compensation for the previous fiscal year, the resulting compensation mix projected for fiscal 2012, previous equity grants and the dollar value of the proposed equity grant relative to market data and to proposed equity grants for other executive officers. After the Compensation Committee established a dollar value for each named executive officer s fiscal 2012 annual long-term incentive compensation award, that dollar value was then allocated between stock option, restricted unit and performance unit awards, with the exact number of restricted units and performance units based on the closing price of a

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Company share on the grant date and the exact number of stock options based on such closing price and the applicable Black-Scholes ratio. The dollar value awarded to each named executive officer for fiscal 2012 grants was allocated between the long-term incentive vehicles as follows:

40% of the dollar value was allocated to performance units with performance-based vesting over a three-year vesting period based on relative total shareholder return;

40% of the dollar value was allocated to stock options with a four-year vesting period; and

20% of the dollar value was allocated to restricted units with time-based vesting over a four-year vesting period.

The Compensation Committee considers this allocation appropriate, as performance-orientation is reflected in performance units and stock options (which only have value to the extent the Company s stock price increases from the stock price on the grant date), while grants of restricted units allow the program to support retention, even in down stock markets. In addition, the Compensation Committee took into consideration the fact that consistency of program vehicles is likely to enhance employee understanding of the function and benefits of the long-term incentives offered.

Following the Compensation Committee s determination of the dollar value of long-term incentive compensation awarded to each named executive officer for the fiscal 2012 annual long-term incentive awards, Mr. Almeida was significantly below the 50th percentile of long-term incentive compensation paid to executives in comparable positions, based on market data, while, for their respective positions, Mr. Dockendorff was just below the 75th percentile, Mr. Hanson was between the 50th and 75th percentile and Mr. Wehrly was just below the 50th percentile. With respect to Mr. Trudeau, the Compensation Committee utilized the same methodology as used to establish base salary and individual target percentage, selecting a value for the long-term incentive award that was significantly below the 25th percentile.

The table below compares the dollar value awarded by the Compensation Committee to each named executive officer as long-term incentive compensation during 2012 versus the dollar value awarded to each named executive officer during fiscal 2011.

Long-Term Incentive Compensation

Executive Officer	Award Type	Fiscal 2011[(1)]	Fiscal 2012[(1)]	% Change
José E. Almeida	Annual	$3,100,000	$6,250,000	102%
	Promotion	$3,792,000[(2)]	N/A	N/A
	Total	$6,892,000	$6,250,000	-9%
Charles J. Dockendorff	Annual	$2,400,000	$2,400,000	0%
Bryan C. Hanson	Annual	$770,000	$1,680,000	118%
	Promotion	$264,167[(3)]	N/A	N/A
	Asia Growth	$423,700[(4)]	N/A	N/A
	Total	$1,457,867	$1,680,000	15%
Peter L. Wehrly	Annual	$600,000	$1,400,000	133%
	Promotion	$318,750[(3)]	N/A	N/A
	Asia Growth	$468,000[(4)]	N/A	N/A
	Total	$1,386,750	$1,400,000	1%
Mark C. Trudeau	Pro-Rated Annual	N/A	$1,192,000	N/A

New Hire	N/A	$350,000	N/A
Total	N/A	$1,542,000[5]	N/A

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(1) The amounts in the table above differ from the grant date fair value of the awards reported in the Grants of Plan-Based Awards Table. The amounts in the table above are the dollar amounts awarded by the Compensation Committee while the grant date fair value of each award reported in the Grants of Plan-Based Awards Table is the award value for accounting purposes. The award value for accounting purposes is calculated by application of a Monte Carlo simulation model for performance units and by application of the Black-Scholes ratio for stock options.

(2) Represents a grant made in connection with Mr. Almeida s election as President and Chief Executive Officer.

(3) Represents a grant made in connection with the promotion of these executive officers.

(4) Represents a grant under the Asia Growth Incentive Plan.

(5) The Compensation Committee granted to Mr. Trudeau an annual long-term incentive award with a value of $1.3 million which, when pro-rated to reflect the number of days during fiscal 2012 that he served as President of our Pharmaceuticals business, resulted in an award of $1.192 million. The amounts reported include the pro-rated annual equity award of $1.192 million and an additional equity award of $350,000 to compensate Mr. Trudeau for equity he forfeited when he left his former employer to join Covidien.

For fiscal 2012, the value of annual long-term incentive awards (which excludes the promotion and other special awards) for Messrs. Almeida, Hanson and Wehrly increased significantly while the value for Mr. Dockendorff stayed the same. Messrs. Almeida, Hanson and Wehrly received significant increases in annual long-term incentive award values from 2011 to 2012 because the 2011 value was based on market data for their previous positions while the 2012 value reflects the expanded roles in which each currently serves.

The value of Mr. Almeida s 2012 long-term incentive award was lower than the value of his 2011 long-term incentive awards due to the fact that his 2012 award was a single annual grant while his 2011 awards consisted of an initial annual award as well as an award made in connection with his election as President and Chief Executive Officer. A significant portion of this award consists of restricted units which do not vest until the third anniversary of the award, at which time the award vests in full. This cliff-vesting feature is intended to incent Mr. Almeida over a three year period above and beyond the incentive provided by the annual grant and other part of this grant, both of which vest in equal installments each year over a four-year period.

Total Direct Compensation

In establishing the three major components of compensation payable to our named executive officers base salary, annual incentive compensation and long-term incentive awards the Compensation Committee assessed each component against market data applicable to the respective component. The Compensation Committee also considered the total direct compensation payable to named executive officers, which aggregates all three major components of compensation, so that the Compensation Committee could assess each named executive officer s total compensation against market data. Following the establishment of all three major components of compensation payable to our executive officers, Mr. Almeida was just below the 50th percentile of total direct compensation paid to executives in comparable positions, based on market data, while, for their respective positions, Mr. Dockendorff was just below the 75th percentile, Mr. Hanson was between the 50th and 75th percentile, Mr. Wehrly was just above the 50th percentile and Mr. Trudeau was moderately below the 25th percentile of market.

The Compensation Committee believed that the level of overall compensation for each named executive officer was appropriate, particularly with respect to Mr. Dockendorff given his exceptional performance in leading the Company s sustainable productivity initiative in order to drive operational efficiency and fuel further growth and his receipt of the highest possible TLR performance rating and with respect to Messrs. Hanson and Wehrly, given their expanded roles.

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Other Benefits

Retirement Benefits

We maintain retirement plans to assist our named executive officers with retirement income planning and increase the attractiveness of employment with us. For our named executive officers, we currently provide:

- a tax-qualified defined contribution 401(k) plan, the Covidien Retirement Savings and Investment Plan, that is available to all eligible United States employees (the Retirement Savings Plan); and
- a non-qualified deferred compensation plan, the Covidien Supplemental Savings and Retirement Plan, in which executive officers and other senior employees may participate.

For more information regarding our non-qualified deferred compensation plan, see Non-Qualified Deferred Compensation below.

Health and Welfare and Other Benefits

Health and Welfare Benefits. As part of our overall compensation offering, our health and welfare benefits are intended to be competitive with peer companies. The health and welfare benefits we provide to our named executive officers are offered to all of our eligible United States-based employees and include medical, dental, prescription drug, vision, life insurance, accidental death and dismemberment, business travel accident, personal and family accident, flexible spending accounts, short- and long-term disability coverage and the employee assistance program. The Company also provides Mr. Almeida with supplemental long-term disability insurance, which commenced when he became our President and Chief Executive Officer on July 1, 2011. The Company does not provide tax assistance with respect to premiums paid by the Company for this insurance coverage (i.e., no gross-ups).

Perquisites. Although the Company does not have a perquisite program, the Compensation Committee determined that it was in the Company s and the executives best interests to establish an executive physical program which offers comprehensive and coordinated annual physical examinations at a nominal cost to the Company. Other than the executive physical program and the limited use of corporate aircraft described below, we do not provide our named executive officers with any perquisites. The Compensation Committee believes that the emphasis on performance-based compensation, rather than on entitlements such as perquisites, is consistent with its compensation philosophy.

Airplane Usage. The Compensation Committee believes that it is important to have a corporate aircraft policy due to the security and efficiency benefits that such a policy provides to us. Personal travel for our named executive officers is permitted only if such use is at no incremental cost to the Company and is approved in advance by the Chief Executive Officer or if there are unusual circumstances, such as a medical or family emergency, that the Chairman of the Compensation Committee or the Chief Executive Officer believe warrant such use. Additionally, our policy was amended during 2012 to permit our Chief Executive Officer to use our corporate aircraft for personal travel, up to forty (40) block hours per fiscal year. Pursuant to current income tax rules applicable to personal use of aircraft, the Company imputes income to named executive officers for any personal use based on the Standard Industry Fare Level rates set by the Civil Aeronautics Division of the Department of Transportation. This imputed income amount is included in a named executive officer s earnings at the end of the year and reported as W-2 income to the Internal Revenue Service. The Company does not provide tax assistance with respect to this imputed income (i.e., no gross-ups).

Employee Stock Purchase Plan. We maintain a broad-based employee stock purchase plan which provides eligible employees, including our named executive officers, with the opportunity to purchase Company shares. We believe that providing an employee stock purchase plan is consistent with our philosophy that compensation should align the interests of executive officers and shareholders and promote a long-term shareholder

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perspective. Eligible employees authorize payroll deductions to be made for the purchase of Company shares. The Company provides a fifteen percent (15%) matching contribution on up to $25,000 of an employee s payroll deductions in any calendar year. All shares are purchased on the open market by a designated broker. Mr. Wehrly participated in the employee stock purchase plan in 2012.

Severance and Change in Control Benefits

The Company maintains executive severance and change in control benefit plans. The Compensation Committee believes that providing severance and change in control benefits to our named executive officers is appropriate, given the fact that these are standard benefits provided by peer companies and also given the need to provide for continuity of management in the event of an actual or threatened change in control.

Severance Plan. Under the severance plan, benefits are payable to any named executive officer upon an involuntary termination of employment for any reason other than cause, permanent disability or death. Severance benefits, in the form of base salary, bonus and health benefits are generally payable for 18 months (24 months for our Chief Executive Officer) following termination of employment.

Change in Control Plan. Under the change in control plan, benefits are payable to any named executive officer upon an involuntary termination of employment or good reason resignation that occurs during a period shortly before and continuing after a change in control (a double trigger arrangement). Benefits are generally payable following termination in a lump sum cash payment equal to two times (2.99 times for our Chief Executive Officer) the sum of the executive s base salary and the average of the executive s bonus for the previous three fiscal years. Additional benefits provided upon a change in control termination include full vesting of outstanding equity awards, continued Company subsidy for health plan premiums for a 24 month period (36 months for our Chief Executive Officer) and outplacement services. Receipt of these benefits is conditioned upon the named executive officer signing a release of any claims against the Company. The Compensation Committee has carefully evaluated these arrangements and believes that it is important to provide named executive officers with protection in the event that their employment is terminated in connection with a change in control or their position is modified in such a way as to diminish their authority, responsibilities or compensation. Maintaining a double trigger for payment of change in control benefits helps to provide that protection while simultaneously precluding the named executive officer from receiving benefits solely due to a change in control (a single trigger arrangement). After carefully considering the issue, the Compensation Committee amended the change in control plan, effective October 1, 2011, to eliminate for all covered executive officers other than the Chief Executive Officer tax gross-up amounts which otherwise would have been payable as a result of the application of Internal Revenue Code Section 280G to certain payments made under the change in control plan.

In addition to the benefits described above, the Company has entered into a Letter Agreement with Mr. Trudeau providing Mr. Trudeau with certain enhanced benefits, including severance benefits, upon the consummation of a strategic transaction such as the spin-off or sale of the Company s Pharmaceuticals business. The Letter Agreement is described in more detail below under the heading Potential Payments upon Termination Letter Agreement with Mr. Trudeau.

How We Determine Compensation

Compensation Committee Role and Input from Management

The Compensation Committee is responsible for the Company s executive compensation strategies, structure, policies and programs and must specifically approve compensation actions relating to our executive officers. For each executive officer, other than our Chief Executive Officer, the Compensation Committee relies on input from our Chief Executive Officer and our Senior Vice President of Human Resources in setting the officer s performance objectives, evaluating the actual performance of the officer against those objectives and making appropriate salary and incentive awards. The Chief Executive Officer and Senior Vice President of Human Resources participate in Compensation Committee meetings, at the request of the Compensation

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Committee, to provide background information and explanations supporting compensation recommendations, including the results of the annual performance evaluations that our Chief Executive Officer conducts on each named executive officer, as well as a TLR performance rating. Additionally, in light of Mr. Almeida s relationship with Mr. Hanson, who is Mr. Almeida s brother-in-law, the Compensation Committee determined that it would be appropriate to provide for additional oversight of this process. Mr. Hanson s performance assessments are conducted by the Chief Financial Officer and the Senior Vice President of Human Resources. In addition, the Compensation Committee reviews and approves all compensation actions relating to Mr. Hanson.

The Compensation Committee conducts the annual performance evaluation of our Chief Executive Officer. Generally, the process begins with the Compensation Committee approving an evaluation form which is then completed by the Chief Executive Officer as a self-evaluation. This completed self-evaluation is submitted to the full Board of Directors for review along with a blank evaluation for completion by each Director. The Compensation Committee s independent consultant compiles the results of the evaluations and prepares a summary for the Compensation Committee. The Compensation Committee reviews and discusses the results, after which the Chairman of the Compensation Committee leads a further discussion with the full Board of Directors. Following this extensive discussion with the full Board of Directors, the Lead Director provides feedback to the Chief Executive Officer. The Compensation Committee uses these evaluations and discussions in setting the Chief Executive Officer s compensation.

In setting Mr. Almeida s compensation for fiscal 2012, which is done at the beginning of fiscal 2012, the Committee employed an alternative process from the one described above. Mr. Almeida s initial compensation as Chief Executive Officer was established by the Compensation Committee following consideration of, among other things, the compensation of Chief Executive Officers of peer companies, the compensation of the Company s then President and Chief Executive Officer and the business experience of Mr. Almeida. Based on Company performance, as well as an assessment of Mr. Almeida s value to the Company, a review of total direct compensation and a comparison to market data, the Compensation Committee set Mr. Almeida s compensation for fiscal 2012; they determined that it was premature to conduct a formal performance evaluation based on Mr. Almeida s service as Chief Executive Officer for one quarter of fiscal 2011. Following the completion of fiscal 2012, Mr. Almeida s first full year as Chief Executive Officer, the Compensation Committee expects to continue the annual performance evaluation process described above in setting Mr. Almeida s compensation.

Compensation Consultants

The Compensation Committee has the sole authority to retain, compensate and terminate any independent compensation consultants of its choosing. During fiscal 2012, Steven Hall & Partners served as the Compensation Committee s independent compensation consultant. The Compensation Committee has assessed the independence of Steven Hall & Partners and determined that the compensation consultant is independent and that no conflicts of interest exist currently or existed during fiscal 2012. Steven Hall & Partners reports directly to the Compensation Committee and does not provide services to, or on behalf of, any other part of our business. Steven Hall typically provides the Compensation Committee with advice on compensation program design and best practices and, as noted below, produces the comparative information derived from the peer group and published survey data that the Compensation Committee reviews. Major services provided during fiscal 2012 by Steven Hall & Partners under its engagement with the Compensation Committee included: (1) preparing the market study described below; (2) reviewing the Company s compensation peer group; (3) analyzing the Company s share allocation and utilization as compared with 10 peer companies; (4) providing regulatory updates; (5) assisting the human resources department in preparing the tally sheets reporting total compensation for each executive officer; and (6) assisting in the Chief Executive Officer evaluation process. Steven Hall & Partners is the only compensation consultant who played a role in determining or recommending the amount or form of executive compensation for fiscal 2012.

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Peer Group Review and Market Data

When reviewing compensation programs for the named executive officers, the Compensation Committee considers the compensation practices of specific peer companies and reviews compensation data from general industry published surveys.

In selecting the peer group from among companies with annual revenues generally within the range of one-half to two times our annual revenues, the Compensation Committee considered various other factors relating to similarly-situated medical device and pharmaceutical companies, including net income and market capitalization. The Compensation Committee reviews this peer group on an on-going basis and modifies it as circumstances warrant. Based on its review in 2012, the Compensation Committee determined that the peer group utilized in setting compensation for 2011 remained appropriate for 2012, as it continues to represent our primary competitors for capital, executive talent and, in some cases, business within our industry. The following table sets forth the peer group approved by the Compensation Committee for purposes of setting 2012 compensation (except for Mr. Trudeau), along with fiscal 2011 financial information for each. The table also includes information regarding Covidien s relative position in the peer group in each of the categories.

Company	Fiscal Year End	Revenue	Net Income	Market Capitalization at 3/30/2012
			(dollars in millions)	
Baxter International Inc.	12/11	$13,893	$2,224	$33,257
Becton, Dickinson & Company	9/11	7,829	1,271	16,315
Boston Scientific Corporation	12/11	7,622	441	8,679
Bristol-Myers Squibb Company	12/11	21,244	3,709	56,974
Eli Lilly & Company	12/11	24,287	4,348	46,724
Medtronic, Inc.	4/11	15,933	3,096	40,781
St. Jude Medical, Inc.	12/11	5,612	826	14,200
Stryker Corporation	12/11	8,307	1,345	21,153
Thermo Fisher Scientific, Inc.	12/11	11,726	1,330	20,627
Zimmer Holdings, Inc.	12/11	4,452	761	11,450
Covidien plc	9/11	11,574	1,868	26,429
Rank		6 of 11	5 of 11	5 of 11
Percentile		55	62	60

As noted above, the Compensation Committee also reviews a market study prepared by its independent compensation consultant (the results of which we refer to throughout this CD&A as the market data). The market data compiled by the Compensation Committee s independent compensation consultant included information regarding base salary, annual cash incentive awards and the value of equity awards. The study included data derived from a number of sources, including the proxy statements of the Company s peer group companies, a Towers Watson 2010/2011 Survey Report on Top Management Compensation, a 2011 Radford Global Technology Survey, the 2011 Towers Watson US General Industry Executive Database, the Hewitt 2011 General Industry/Retail Total Compensation Measurement, the 2011 US Mercer Benchmark Database Executive and, for companies with revenue of approximately $12 billion, general industry data as well as data for the medical instruments, pharmaceuticals and bio-technology industries where available and as appropriate. The Compensation Committee did not strictly tie target compensation for our named executive officers to any one

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type of peer group data, but instead considered all of these sources in determining the appropriate level of compensation for our executives. Data drawn from our peer group proxy statements was given greater consideration for the chief executive officer and chief financial officer positions than for group head positions.

Use of Tally Sheets

In setting compensation for each named executive officer, in addition to reviewing market data, the Compensation Committee reviews each named executive officer s total annual compensation from the previous four years. The Compensation Committee uses individual tally sheets prepared by our human resources department and the Compensation Committee s compensation consultant as a presentation format to facilitate this review. The tally sheets identify the value of each pay element, including base salary, annual incentive bonus, sign-on bonus or other cash payments, long-term incentives, grant date value of equity awards and retirement benefits. The tally sheets also reflect current share ownership and equity awards held as well the value of termination and change-in-control payments under various potential termination and change-in-control scenarios. Reviewing the tally sheets helps the Compensation Committee to balance the various elements of compensation so that no one element is weighted too heavily and so that there is an appropriate mix between fixed and variable compensation and between short- and long-term compensation, consistent with our belief that our executive compensation program should not encourage excessive or unnecessary risk-taking.

Talent and Leadership Review

The Company utilizes a Talent and Leadership Review, or TLR, process to manage its talent and organizational capability with the goal of maximizing organizational excellence and business success. TLR assists the Company in understanding its leadership strengths and gaps, helps identify key and emerging talent and provides insight into current organizational capability versus strategic goals and objectives. As part of the TLR process, the Chief Executive Officer in conjunction with the Senior Vice President of Human Resources assigns to each executive officer a rating on two discrete dimensions: leadership behaviors and results. Three possible ratings can be assigned in each of these two dimensions: exceptional, effective, and not yet effective. While the TLR process is intended to assist in evaluating the needs of the Company from a human resources perspective, these performance ratings are also considered by the Chief Executive Officer in formulating compensation recommendations to the Compensation Committee. These performance ratings impacted both base salary decisions as well as decisions regarding the value of long-term incentive compensation awards.

Other Compensation Policies and Arrangements

Executive Compensation Recoupment Policy

Accountability is one of our core values. To encourage our senior executives to take responsibility and affirm the Company s commitment to integrity and the highest standards of ethical conduct, to reinforce these values through our compensation program, and to support good governance practices, we maintain an Executive Compensation Recoupment Policy (the Recoupment Policy). The Recoupment Policy requires that the Company recoup, or claw-back , portions of incentive compensation paid to our executive officers if there is a restatement of the Company s financial statements due to the material noncompliance by the Company with financial reporting requirements under applicable securities laws or regulations and the amount of incentive compensation that was awarded to an executive officer during the three (3) fiscal years immediately preceding the date of the restatement (or such other period as may be required under applicable securities laws or regulations) is higher than the amount of incentive compensation that would have been awarded to the executive officer had the financial results subject to the restatement been properly reported. For this purpose, incentive compensation includes any compensation determined to be incentive compensation pursuant to regulations to be issued by the SEC.

In addition, our equity awards are subject to a claw-back provision, pursuant to which we may recover the amount of any profit the named executive officer realized upon the exercise of options or vesting of other equity awards during the 12-month period that occurs immediately prior to the officer s involuntary termination for cause.

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Executive Officer Share Retention and Ownership Guidelines

The Compensation Committee has determined that it is in the best interests of the Company for all named executive officers to have meaningful share ownership positions in Covidien in order to reinforce the alignment of management and shareholder interests. Accordingly, the Compensation Committee adopted share retention and ownership guidelines for named executive officers. Under these guidelines, named executive officers are expected to hold company equity with a value expressed as a multiple of base salary as follows:

Chief Executive Officer	5 times base salary
Other Named Executive Officers	3 times base salary

In determining an executive s ownership, shares held directly as well as shares underlying restricted units subject to time-based vesting and their accompanying dividend equivalent units are included. Shares underlying unexercised stock options and unvested performance units and their accompanying dividend equivalent units are not included in the calculation. Executives are required to achieve the requisite ownership position within five years of first becoming subject to the share ownership guidelines. Messrs. Almeida and Dockendorff have each achieved shareholdings in excess of the applicable multiple set forth above. Messrs. Trudeau, Hanson and Wehrly, each of whom has become a named executive officer within the past year (Trudeau and Wehrly) or two (Hanson) are well on their way to satisfying the target holdings within the five year phase-in period. The Company s Insider Trading Policy prohibits employees, including named executive officers, from engaging in transactions in puts, calls, cashless collars, options or similar rights and obligations involving Covidien securities, other than the exercise of a Company-issued stock option.

Deductibility of Executive Compensation

Internal Revenue Code Section 162(m) limits to $1 million the tax deduction available to public companies for annual compensation that is paid to covered employees (generally, the named executive officers other than the Chief Financial Officer), unless the compensation qualifies as performance-based or is otherwise exempt from Code Section 162(m). In evaluating compensation programs applicable to our named executive officers (including the 2007 Stock and Incentive Plan, under which our named executive officers receive annual incentive bonuses and equity awards), the Compensation Committee considers the potential impact on the Company of Code Section 162(m). The Compensation Committee generally intends to structure the Company s executive compensation in a manner designed to qualify for deductibility under Code Section 162(m) when consistent with our overall compensation program objectives, while also maintaining maximum flexibility in the design of our compensation programs and in making appropriate payments to named executive officers.

Compensation Committee Report on Executive Compensation

The Compensation Committee is responsible for the oversight of the Company s compensation programs on behalf of the Board of Directors. In fulfilling these responsibilities, the Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis set forth in this Proxy Statement.

Based on the review and discussions referred to above, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in the Company s Annual Report on Form 10-K for the fiscal year ended September 28, 2012, and Proxy Statement for the 2013 Annual Meeting of Shareholders, each of which will be filed with the Securities and Exchange Commission.

Compensation and Human Resources Committee

Timothy M. Donahue, Chairman

John M. Connors, Jr.

Dennis H. Reilley

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Executive Compensation Tables

Summary Compensation

The information included in the Summary Compensation Table below reflects compensation of our named executive officers for the fiscal year ended September 28, 2012 (fiscal 2012) and, where applicable, the fiscal years ended September 30, 2011 and September 24, 2010. The named executive officers are our Chief Executive Officer, Chief Financial Officer and the three other most highly compensated executive officers in fiscal 2012. For a more complete understanding of the table, please read the narrative following the table.

SUMMARY COMPENSATION TABLE

Name and Principal Position (A)	Fiscal Year (B)	Salary ($) (C)	Bonus ($) (D)	Stock Awards ($) (E)	Option Awards ($) (F)	Non-Equity Incentive Plan Compensation ($) (G)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($) (H)	All Other Compensation ($) (I)	Total ($) (J)
José E. Almeida Chairman, President and Chief Executive Officer	2012	$1,154,808		$4,549,997	$2,699,141	$1,682,517	(3)	$193,265	$10,279,728
	2011	$846,795		$5,224,971	$2,081,345	$1,125,587		$128,666	$9,407,766
	2010	$732,885		$1,652,014	$1,507,744	$910,440	$402	$72,579	$4,875,665
							$3		
Charles J. Dockendorff Executive Vice President and Chief Financial Officer	2012	$764,204		$1,747,191	$1,036,456	$722,981	$38,716	$115,745	$4,425,293
	2011	$734,800		$1,416,002	$1,255,281	$906,004	$68,419	$109,441	$4,489,947
	2010	$704,746		$1,357,019	$1,238,493	$849,541	$55,348	$94,639	$4,299,786
Bryan C. Hanson(1) Group President, Surgical Solutions	2012	$535,200		$1,223,049	$725,547	$355,965	(3)	$423,770	$3,263,531
	2011	$467,330		$1,010,069	$541,137	$626,578	$2,949	$61,617	$2,709,680
Peter L. Wehrly(2) Group President, Vascular Therapies, Respiratory & Monitoring Solutions and Developed Markets	2012	$536,546		$1,019,202	$604,623	$650,127		$138,137	$2,948,635
Mark C. Trudeau(2) President, Pharmaceuticals	2012	$420,000	$225,000	$945,965	$623,096	$507,252		$109,730	$2,831,043

(1) Mr. Hanson was not a named executive officer for fiscal 2010.

(2) Neither Mr. Wehrly nor Mr. Trudeau was a named executive officer for fiscal 2010 or fiscal 2011.

(3)

The present value of the accumulated benefit decreased for Messrs. Almeida and Hanson. See *Change in Pension Value and Non-Qualified Deferred Compensation Earnings (Column H)* note below for more information.

Bonus (Column D) This column reflects a one-time sign-on bonus paid to Mr. Trudeau in connection with his commencement of employment with the Company on February 1, 2012.

Stock Awards (Column E) and Option Awards (Column F) These columns represent the aggregate grant date fair value, computed in accordance with Accounting Standards Codification 718 (ASC 718), of restricted unit, performance unit and stock option awards issued to each of our named executive officers during the 2010, 2011 and 2012 fiscal years, as applicable. Further information regarding the 2012 awards is included in the Fiscal 2012 Grants of Plan-Based Awards Table, the Outstanding Equity Awards at 2012 Fiscal Year-End Table and the *Compensation Discussion and Analysis* (CD&A), beginning on page 18.

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In the case of performance unit awards issued to all named executive officers as part of our 2012 annual equity award, the grant date fair value is based on the probable outcome of the market-based performance conditions, calculated based on the application of a Monte Carlo simulation model. The actual amounts which vest are determined at the end of the three-year performance cycle and are based on total shareholder return for the Company as compared to total shareholder return of companies comprising a healthcare industry index. Depending upon whether or to what extent the performance conditions are met, twice as many performance units may vest, or none may vest at all. Amounts in these columns do not correspond to the actual value that may be recognized by the named executive officers, which may be higher or lower based on a number of factors, including the Company s performance, stock price fluctuations and applicable vesting. For additional information relating to assumptions made in the valuation for current year awards reflected in these columns, see Note 18 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended September 28, 2012.

Non-Equity Incentive Plan Compensation (Column G) The amounts reported in Column G represent annual incentive cash awards paid to the named executive officers under our 2012 Annual Incentive Plan. For information regarding the calculation of these awards, see the CD&A, beginning on page 18.

Change in Pension Value and Non-Qualified Deferred Compensation Earnings (Column H)

The amount reported in Column H for Mr. Dockendorff is attributable to the increase in the actuarial present value of his accumulated benefit under the frozen Kendall Pension Plan at September 28, 2012, as compared to September 30, 2011. The present value of the accumulated benefit decreased $5 for Mr. Almeida and decreased $149 for Mr. Hanson because of changes in assumptions regarding the interest crediting rate and discount rate. These changes in assumptions did not result in a decrease in Mr. Dockendorff s benefit because he is within two years of the unreduced retirement age (60). Messrs. Wehrly and Trudeau are not eligible to participate in the Kendall Pension Plan because it was frozen before each commenced employment with the Company. For more information, see the 2012 Pension Benefits Table and related narrative.

Amounts in Column H also include above-market earnings on amounts credited to the Supplemental Savings Plan for Mr. Dockendorff. All investments offered under the Supplemental Savings Plan mirror investments offered under the Retirement Savings Plan (our 401(k) plan), except that the Supplemental Savings Plan includes an additional investment alternative, the Enhanced Moody s Rate, which is available to eligible employees, including Mr. Dockendorff. During fiscal 2012, the Enhanced Moody s Rate produced above-market earnings of $34,521 for Mr. Dockendorff. For more information, see the Fiscal 2012 Non-Qualified Deferred Compensation Table and related narrative.

All Other Compensation (Column I) The amounts reported in Column I represent the aggregate dollar amount for each named executive officer for Company contributions to the Retirement Savings Plan, Company credits to the Supplemental Savings Plan, personal benefits, insurance premiums, relocation benefits and tax reimbursements attributable to relocation benefits. The following table shows the specific amounts included in Column I of the Summary Compensation Table for fiscal 2012. For a more complete understanding of the table, please read the related narrative.

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ALL OTHER COMPENSATION

Name and Principal Position (A)	Company Contributions to Retirement Savings Plan (B)	Company Credits to Supplemental Savings Plan (C)	Perquisites and Other Personal Benefits (D)	Relocation Benefits (E)	Tax Reimbursements on Relocation Benefits (F)	Total (G)
José E. Almeida Chairman, President and Chief Executive Officer	$14,821	$118,217	$60,227			$193,265
Charles J. Dockendorff Executive Vice President and Chief Financial Officer	$17,500	$98,245				$115,745
Bryan C. Hanson Group President, Surgical Solutions	$14,835	$54,291		$211,246	$143,397	$423,770
Peter L. Wehrly Group President, Vascular Therapies, Respiratory & Monitoring Solutions and Developed Markets	$14,856	$28,796		$57,034	$37,451	$138,137
Mark C. Trudeau President, Pharmaceuticals	$7,500	$2,975		$65,599	$33,656	$109,730

Perquisites & Other Personal Benefits (Column D)

Mr. Almeida. The amount in Column D includes the following: $2,350 for an annual physical under the Company s executive physical program; $17,123 for insurance premiums paid by the Company for supplemental long-term disability insurance; and $40,754 attributable to personal use of Company aircraft. The value of flights on corporate aircraft is based on the total variable incremental cost incurred by the Company in providing such flights, calculated on an annualized per hour basis. The variable costs associated with such flights include fuel, trip-related maintenance, crew travel expenses, on-board catering, landing and parking fees and other variable costs. As Company-owned aircraft are used predominantly for business purposes, we have not included fixed costs, such as pilots salaries, insurance and standard maintenance, which do not change based on usage. Mr. Almeida was taxed on the imputed income attributable to his personal use of Company aircraft and the value of insurance premiums paid by the Company during fiscal 2012 and the Company did not provide him with any tax assistance, *i.e.*, no gross-ups, with respect to that income.

Grants of Plan-Based Awards

The following table provides information concerning the annual incentive cash awards and equity incentive awards granted to each of our named executive officers in fiscal 2012.

AIP is the annual incentive cash award payable pursuant to our 2012 Annual Incentive Plan.

PSUs are restricted unit awards subject to performance-based vesting, which we refer to as performance units.

RSUs are restricted unit awards subject to time-based vesting.

Options are nonqualified stock options subject to time-based vesting.

For a more complete understanding of the table, please read the related narrative.

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FISCAL 2012 GRANTS OF PLAN-BASED AWARDS

			Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All other Stock Awards: Number of Shares of Stock or Units	All other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards	Grant Date Fair Value of Stock and Option Awards
Name	Grant Date	Date of Committee Action	Threshold ($)	Target ($)	Maximum ($)	Threshold (#)	Target (#)	Maximum (#)	(#)	(#)	($/Sh)	($)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)
José E. Almeida												
AIP			$763,750	$1,527,500	$3,055,000							
PSUs	12/1/2011	11/16/2011				26,911	53,821	107,642				$3,299,981
RSUs	12/1/2011	11/16/2011							26,911			$1,250,016
Options	12/1/2011	11/16/2011								244,860	$46.45	$2,699,141
Charles J. Dockendorff												
AIP			$328,185	$656,370	$1,312,740							
PSUs	12/1/2011	11/16/2011				10,334	20,667	41,334				$1,267,176
RSUs	12/1/2011	11/16/2011							10,334			$480,014
Options	12/1/2011	11/16/2011								94,025	$46.45	$1,036,456
Bryan C. Hanson												
AIP			$216,320	$432,640	$865,280							
PSUs	12/1/2011	11/16/2011				7,234	14,467	28,934				$887,030
RSUs	12/1/2011	11/16/2011							7,234			$336,019
Options	12/1/2011	11/16/2011								65,820	$46.45	$725,547
Peter L. Wehrly												
AIP			$216,320	$432,640	$865,280							
PSUs	12/1/2011	11/16/2011				6,028	12,056	24,112				$739,202
RSUs	12/1/2011	11/16/2011							6,028			$280,001
Options	12/1/2011	11/16/2011								54,850	$46.45	$604,623
Mark C.Trudeau												
AIP			$260,000	$520,000	$1,040,000							
PSUs												
RSUs	2/1/2012	11/28/2011							18,115			$945,965
Options	2/1/2012	11/28/2011								51,900	$52.22	$623,096

Non-Equity Incentive Plan Awards (Columns C through E) The amounts reported in Columns C through E reflect threshold, target and maximum award amounts for fiscal 2012 pursuant to the 2012 Annual Incentive Plan, which is an element of our 2007 Stock and Incentive Plan. The actual amounts earned by each named executive officer pursuant to such awards are set forth in Column G of the Summary Compensation Table.

Equity Incentive Plan Awards (Columns F through H) The amounts reported in Columns F through H reflect threshold, target and maximum award amounts for the FY12-FY14 performance cycle pursuant to performance unit awards issued as part of our fiscal 2012 annual equity awards. The actual amounts, if any, earned by each named executive officer pursuant to such awards are determined by the Compensation Committee at the end of the three-year performance cycle and are based upon total shareholder return for the Company as compared to the total shareholder return of companies comprising a healthcare industry index (*i.e.,* relative total shareholder return). Threshold, target and maximum award amounts are payable upon achievement of relative total shareholder return in the 25th, 50th and 75th percentile, respectively. Dividend equivalent units will be credited on performance unit awards only if, and to the extent that, dividends are payable on ordinary shares, and will vest only if the applicable performance criteria are satisfied. For more information regarding performance unit awards, see the CD&A beginning on page 18.

Stock Awards and Option Awards (Columns I and J) The amounts reported in Column I and Column J reflect the number of shares underlying restricted unit awards and stock option awards, respectively, that were granted as part of our fiscal 2012 annual equity awards and which vest one-quarter annually beginning on the first anniversary of the grant date. Dividend equivalent units will be credited on restricted unit awards only if, and to the extent that, dividends are payable on ordinary shares, and will vest according to the same schedule as the underlying restricted

units.

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Grant Date Fair Value (Column L) In the case of performance unit awards issued as part of our 2012 annual equity awards, the grant date fair value is based on the probable outcome of the market-based performance conditions, calculated based on the application of a Monte Carlo simulation model. Depending upon whether or to what extent the respective performance conditions are met, the number of shares for which the performance units are settled may range from zero to 200%.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding outstanding stock option awards and unvested restricted unit and performance unit awards held by each named executive officer as of September 28, 2012. Restricted unit and performance unit awards listed in the table include dividend equivalent units credited on such awards. Dividend equivalent units vest according to the same schedule as the underlying restricted unit award and, in the case of performance unit awards, if the applicable performance criteria are satisfied. For a more complete understanding of the table, please read the footnotes that follow the table. Unless otherwise specified, the market value of outstanding stock awards in the table is calculated by multiplying the number of unvested restricted or performance units by $59.42, the closing price of our stock on September 28, 2012.

OUTSTANDING EQUITY AWARDS AT 2012 FISCAL YEAR-END

	Option Awards				Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
(A)	(B)	(C)	(E)	(F)	(G)	(H)	(I)	(J)
José E. Almeida	33,554	0	$38.6485	11/20/2016	5,854[8]	$347,845	30,800[16]	$1,852,928
	161,500	0	$43.0878	07/01/2017	7,699[9]	$457,475	37,158[17]	$2,207,928
	113,595	37,865[1]	$34.1500	11/30/2018	13,934[10]	$827,958	108,976[18]	$6,475,354
	59,777	59,778[2]	$47.6000	11/30/2019	56,527[11]	$3,358,834		
	39,062	117,188[3]	$42.9400	11/30/2020	5,596[12]	$332,514		
	7,903	23,712[4]	$54.2200	06/30/2021	27,244[13]	$1,618,838		
	0	244,860[5]	$46.4500	11/30/2021				
Charles J. Dockendorff	32,457	0	$35.4533	03/25/2014	4,488[8]	$266,677	25,300[16]	$1,522,048
	32,457	0	$45.6575	03/09/2015	6,325[9]	$375,832	28,768[17]	$1,709,395
	25,009	0	$36.9903	11/21/2015	10,788[10]	$641,023	41,846[18]	$2,486,489
	47,039	0	$38.6485	11/20/2016	10,462[13]	$621,652		
	164,900	0	$43.0878	07/01/2017				
	87,090	29,030[1]	$34.1500	11/30/2018				
	49,102	49,103[2]	$47.6000	11/30/2019				
	30,242	90,728[3]	$42.9400	11/30/2020				
	0	94,025[5]	$46.4500	11/30/2021				
Bryan C. Hanson	0	8,835[1]	$34.1500	11/30/2018	1,365[8]	$81,108	7,698[16]	$463,112

	0	14,945[2]	$47.6000	11/30/2019	1,924[9]	$114,324	9,228[17]	$548,328
	0	29,108[3]	$42.9400	11/30/2020	3,461[10]	$205,653	29,292[18]	$1,740,531
	2,636	7,909[4]	$54.2200	06/30/2021	1,866[12]	$110,878	20,314[19]	$1,207,058
	0	65,820[5]	$46.4500	11/30/2021	7,323[13]	$435,133		
Peter L. Wehrly	12,067	4,023[6]	$32.3600	04/30/2019	1,240[14]	$73,681	5,720[16]	$344,115
	11,102	11,103[2]	$47.6000	11/30/2019	1,429[9]	$84,911	7,190[17]	$427,230
	7,560	22,680[3]	$42.9400	11/30/2020	2,696[10]	$160,196	24,410[18]	$1,450,442
	3,181	9,544[4]	$54.2200	06/30/2021	2,252[12]	$133,814	22,438[19]	$1,333,266
	0	54,850[5]	$46.4500	11/30/2021	6,102[13]	$362,581		
Mark C. Trudeau	0	51,900[7]	$52.2200	01/31/2022	18,261[15]	$1,085,069		

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Footnotes

Unless otherwise specified, stock option and restricted unit awards vest one-quarter annually, beginning on the first anniversary of the grant date.

(1) Represents stock options granted on December 1, 2008.

(2) Represents stock options granted on December 1, 2009.

(3) Represents stock options granted on December 1, 2010.

(4) Represents stock options granted on July 1, 2011 to Messrs. Almeida, Hanson and Wehrly in connection with their respective promotions.

(5) Represents stock options granted on December 1, 2011.

(6) Represents stock options granted on May 1, 2009 to Mr. Wehrly in connection with his commencement of employment with the Company.

(7) Represents stock options granted on February 1, 2012 to Mr. Trudeau in connection with his commencement of employment with the Company.

(8) Represents restricted units granted on December 1, 2008.

(9) Represents restricted units granted on December 1, 2009.

(10) Represents restricted units granted on December 1, 2010.

(11) Represents restricted units granted on July 1, 2011 to Mr. Almeida in connection with his promotion which vest in full on the third anniversary of the grant date.

(12) Represents restricted units granted on July 1, 2011 to Messrs. Almeida, Hanson and Wehrly in connection with their respective promotions.

(13) Represents restricted units granted on December 1, 2011.

(14) Represents restricted units granted on May 1, 2009 to Mr. Wehrly in connection with his commencement of employment with the Company.

(15) Represents restricted units granted on February 1, 2012 to Mr. Trudeau in connection with his commencement of employment with the Company; 6,756 of which vest one-third annually, beginning on the first anniversary of the grant date and 11,505 of which vest one-quarter annually, beginning on the first anniversary of the grant date.

(16) Represents performance units granted on December 1, 2009 that vested on October 4, 2012, shortly after the end of the FY10-FY12 performance cycle. The amounts reported in Column I and J are based on actual achievement, which was two hundred percent (200%) of target, and are valued by using the closing price of our stock on the vesting date, which was $60.16.

(17) Represents performance units granted on December 1, 2010 that vest at the end of the FY11-FY13 performance cycle if the applicable performance criteria have been satisfied. The amounts reported in this column are based on achievement of maximum performance through the end of fiscal 2012.

(18) Represents performance share units granted on December 1, 2011 that vest at the end of the FY12-FY14 performance cycle if the applicable performance criteria have been satisfied. The amounts reported in this column are based on achievement of maximum performance through the end of fiscal 2012.

(19) Represents performance share units granted on December 1, 2010 as part of the Asia Growth Initiative that vest at the end of the FY11-FY13 performance cycle if the applicable performance criteria have been satisfied. The amounts reported in this column are based on achievement of maximum performance, based upon above-target performance through the end of fiscal 2012.

Option Exercises and Stock Vested

The following table provides information regarding the number of Company stock options that were exercised by named executive officers during fiscal 2012 and the value realized from the exercise of such awards. The table also provides information regarding the vesting of restricted unit and performance unit awards during fiscal 2012.

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FISCAL 2012 OPTION EXERCISES AND STOCK VESTED

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
(A)	(B)	(C)	(D)	(E)
José E. Almeida	40,794	$575,758	37,667	$1,712,322
Charles J. Dockendorff	0	$0	27,696	$1,247,831
Bryan C. Hanson	34,010	$479,773	9,106	$415,585
Peter L. Wehrly	0	$0	3,567	$182,358
Mark C. Trudeau	0	$0	0	$0

Pension Benefits

Messrs. Almeida, Dockendorff and Hanson participate in the Kendall Pension Plan, which was frozen with respect to all future benefit accruals (except interest crediting on the cash balance benefit) as of July 1, 1995. The Pension Plan has two components:

- a final average pay benefit, which was frozen as of May 31, 1990; and
- a cash balance benefit.

Mr. Dockendorff is entitled to benefits payable pursuant to both components, while Messrs. Almeida and Hanson are entitled only to the cash balance benefit.

Participants retiring on their normal retirement date (age 65) are entitled to a monthly pension calculated as the sum of:

- the benefit accrued under the provisions of the plan as in effect on June 1, 1990, including the value of the benefit derived from employee contributions; and
- with respect to accruals on or after June 1, 1990, the actuarial equivalent of the participant s current account.

The current account is credited with interest at the one-year Treasury bill rate in effect on January 1st for each calendar year and service credits as follows:

Tier	Years of Benefit Service	Percent of Compensation
I	0-2	4.75%
II	3-9	5.25%
III	10-14	6.00%
IV	15-19	7.00%
V	20+	7.50%

Participants desiring to retire before normal retirement age may do so after attaining age 55 and completing five years of continuous service. If a participant chooses to retire before normal retirement age, the applicable accrued benefit as of June 1, 1990 will be reduced by 0.33% per month for each month commencement precedes age 60. Mr. Dockendorff is currently eligible for retirement.

The following table provides information with respect to these pension benefits. For a more complete understanding of the table, please read the footnotes that follow the table.

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2012 PENSION BENEFITS

Name (A)	Plan Name (B)	Number of Years Credited Service[1] (#) (C)	Present Value of Accumulated Benefit[2] ($) (D)	Payments During Last Fiscal Year ($) (E)
José E. Almeida	Kendall Pension Plan[4]	0.2	$1,729	
Charles J. Dockendorff		0.7	$14,010	
	Kendall Pension Plan[3] Kendall Pension Plan[4]	5.1	$59,124	
Bryan C. Hanson	Kendall Pension Plan[4]	2.7	$8,717	
Peter L. Wehrly				
Mark C. Trudeau				

Footnotes

(1) The number of years of service credited under the Kendall Pension Plan for the named executive officers is less than the number of actual years of service because the years of credited service were frozen as of July 1, 1995.

(2) All assumptions are as detailed in accordance with the Accounting Standards Codification 715 (formerly referred to as SFAS 87) actuarial reports for the fiscal year ending September 28, 2012, with the exception of the following: (a) retirement age is the earliest age at which unreduced payment of all benefits can be received; and (b) no pre-retirement mortality, disability or termination is assumed. The amounts are calculated as being payable at age 60, the earliest retirement age at which an unreduced benefit is payable.

(3) Represents benefit payable under the final average pay component.

(4) Represents benefit payable under the cash balance component.

Non-Qualified Deferred Compensation

The following table provides information with respect to fiscal 2012 non-qualified deferred compensation for each named executive officer. For more information regarding information contained in the table and the material terms of our non-qualified deferred compensation plan, please read the related narrative and footnotes that follow the table.

FISCAL 2012 NON-QUALIFIED DEFERRED COMPENSATION

Name	Executive Contributions in Last FY	Registrant Contributions in Last FY	Aggregate Earnings in Last FY	Aggregate Withdrawals/ Distributions	Aggregate Balance at Last FYE

(A)	($) (B)	($) (C)	($) (D)	($) (E)	($) (F)
José E. Almeida	$653,757	$118,217	$65,267		$2,584,254
Charles J. Dockendorff	$0	$98,245	$969,257		$13,921,298
Bryan C. Hanson	$257,789	$54,291	$213,853		$1,376,764
Peter L. Wehrly	$0	$28,796	$11,877		$90,074
Mark C. Trudeau	$59,500	$2,975	$2,275		$64,750

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Executive Contributions in Last Fiscal Year (Column B) Of the amounts reported in this column, the following amounts reflect deferrals from fiscal 2012 base salary that also are reported in Column C (Salary) of the Summary Compensation Table for fiscal 2012: Mr. Almeida, $203,522; Mr. Hanson, $163,803; and Mr. Trudeau, $59,500. The remaining amounts in this column for Messrs. Almeida and Hanson relate to the deferral of 2011 Annual Incentive Plan bonus payments paid in fiscal 2012, which payments are also included in Column G (Non-Equity Incentive Plan Compensation) of the Summary Compensation Table for fiscal 2011, the year in which they were earned.

Registrant Contributions in Last Fiscal Year (Column C) The amounts reported in Column C are included in Column I of the Summary Compensation Table for fiscal 2012.

Aggregate Earnings in Last Fiscal Year (Column D) The amounts reported in Column D include earnings credited to the named executive officer s account in the Supplemental Savings Plan. Earnings on amounts credited to the Supplemental Savings Plan are determined by investment selections made by each named executive officer in investment alternatives that generally mirror investment choices offered under the Retirement Savings Plan (our 401(k) plan). With respect to amounts credited to a predecessor plan, eligible employees, including Mr. Dockendorff, are entitled to select the Enhanced Moody s Rate as an investment alternative for amounts that were credited to such plan on their behalf prior to our assumption of the plan. The Enhanced Moody s Rate is published in Moody s Bond Record (or www.moodys.com) under the heading Moody s Long-Term Corporate Bond Yield Average and is equal to the average corporate bond yield (based on seasoned bonds with remaining maturities of at least 20 years) published as of the fiscal year-end of the Company preceding the plan year for which the rate is to be used. During the 2012 fiscal year, the Enhanced Moody s Rate was 4.635%, which exceeded 120% of the applicable federal long-term rate with compounding by 0.3075 percentage points. The excess attributable to this higher rate of return is also reported in Column H (Change in Pension Value and Non-Qualified Deferred Compensation Earnings) of the Summary Compensation Table for Mr. Dockendorff as above-market earnings for fiscal 2012 and is quantified in the related narrative.

Aggregate Balance at Last Fiscal Year End (Column F) The amounts reported in Column F include the following amounts reported in the Company s Summary Compensation Tables for previous fiscal years: Mr. Almeida, $1,226,568; Mr. Dockendorff, $452,265; and Mr. Hanson $275,870.

Supplemental Savings Plan. Under the Supplemental Savings Plan, participants, including named executive officers, may defer up to 50% of their base salary and 100% of their annual bonus. We provide matching credits based on the participant s deferred base salary and bonus at the same rate such participant is eligible to receive matching contributions under the Retirement Savings Plan and Company credits on any cash compensation (i.e., base and bonus) that the participant earns during a calendar year in excess of applicable IRS limits ($245,000 for 2011 and $250,000 for 2012). Participants are fully vested in matching and Company credits (including earnings on such credits) upon completion of two years of service. The Supplemental Savings Plan is a non-qualified deferred compensation plan that is maintained as an unfunded top-hat plan and is designed to comply with Internal Revenue Code Section 409A. Amounts credited to the Supplemental Savings Plan as participant deferrals or Company credits may also be credited with earnings (or losses) based upon investment selections made by each participant from investments that generally mirror investments offered under the Retirement Savings Plan. Participants may elect whether they will receive a distribution of their Supplemental Savings Plan account balances upon termination of employment or at a specified date. Distributions can be made in a lump sum or in up to 15 annual installments.

Under the Retirement Savings Plan, the Company makes an automatic contribution of three percent (3%) of an employee s eligible pay, irrespective of whether the employee contributes to such plan. Additionally, we match fifty cents ($0.50) for every one dollar ($1.00) employees contribute, up to the first six percent (6%) of eligible pay. Employees who were credited with more than 20 years of service as of December 31, 2009 are grandfathered for a five (5) year period (i.e., until December 31, 2014) and continue to receive matching contributions in accordance with the formula in place on December 31, 2009. Mr. Dockendorff had more than 20

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years of service as of December 31, 2009 and is a grandfathered participant. Accordingly, we will continue to match, through December 31, 2014, seven dollars ($7.00) for every one dollar ($1.00) that Mr. Dockendorff contributes, up to the first five percent (5%) of eligible pay.

Potential Payments upon Termination

Severance Plan. For all of the named executive officers, severance benefits are payable pursuant to the Covidien Severance Plan for U.S. Officers and Executives. Under the Severance Plan, benefits are payable to eligible executives, including named executive officers, upon an involuntary termination of employment for any reason other than cause, permanent disability or death. Post-termination benefits consist of:

- continuation of base salary for a period of 18 months (24 months for the Chief Executive Officer);
- payment of 1.5 times the average of the executive s bonus for the previous three fiscal years, paid over a period of 18 months (two times the average of the previous three fiscal year bonuses, paid over a period of 24 months for the Chief Executive Officer);
- continuation of health and dental benefits at active employee rates for a period of up to 18 months (24 months for the Chief Executive Officer);
- 12 months accelerated vesting of unvested stock options;
- 12 months to exercise vested stock options (unless a longer period is provided in the applicable award agreement);
- outplacement services, in our discretion, for up to 12 months; and
- payment of a pro-rata portion of the executive s annual incentive cash award for the fiscal year during which such executive s employment terminates.

Upon a termination of employment other than for cause, including an involuntary termination of employment where the executive becomes eligible for severance benefits, executives, including named executive officers, forfeit all unvested restricted unit and performance unit awards and any stock options which do not vest within 12 months after the executive s employment termination date.

Change in Control Plan. For all named executive officers, change in control severance benefits are payable pursuant to the Covidien Change in Control Severance Plan for Certain U.S. Officers and Executives. Under the Change in Control Plan, benefits are payable to eligible executives, including named executive officers, only if the plan s double trigger requirements are satisfied, meaning that, in order to receive any of the following benefits, the executive must experience an involuntary termination of employment or good reason resignation during a period that begins 60 days before and ends 2 years after a change in control. Post-termination benefits consist of:

- a single lump sum payment equal to 24 months of the executive s base salary (36 months for the Chief Executive Officer, provided that the total base salary paid does not exceed 2.99 times his base salary);
- a single lump sum payment equal to two times the average of the executive s bonus for the previous three fiscal years (2.99 times the average of the previous three fiscal year bonuses for the Chief Executive Officer);

continuation of health and dental benefits at active employee rates for a period of up to 24 months (36 months for the Chief Executive Officer);

full vesting of unvested stock options;

12 months to exercise vested stock options (unless a longer period is provided in the applicable option agreement);

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full vesting of unvested restricted unit awards which are subject solely to time-based vesting;

full vesting of unvested performance unit awards if, and to the extent that, the Compensation Committee determines that the applicable performance criteria have been or will be attained or would have been attained during the 24-month period after the executive s employment terminates (36-month period for the Chief Executive Officer);

outplacement services, in our discretion, for up to 12 months;

payment of a pro-rata portion of the executive s annual incentive cash award for the fiscal year during which such executive s employment terminates; and

for the Chief Executive Officer only, payment of a tax gross-up amount in the event that change in control payments to him exceed the applicable base amount (determined under Code Section 280G) by more than fifty thousand dollars ($50,000). For purposes of the Potential Payments Upon Termination Table, after applying the assumptions set forth below with respect to payments upon an assumed change in control termination, the Chief Executive Officer would not have been entitled to a tax gross-up payment. As discussed in the CD&A, effective October 1, 2011, the Company amended the change in control plan to eliminate tax gross-ups for all executive officers other than the Chief Executive Officer.

The payment of benefits under our Severance Plan and our Change in Control Plan is conditioned upon the executive executing a general release in favor of the Company and is subject to the terms of the Non-Competition, Non-Solicitation, and Confidentiality Agreement by and between the executive and the Company, under which the executive agreed not to disclose confidential Company information at any time and not to compete with the Company nor solicit our employees or customers, for a period of one year following termination of employment. We may cancel benefits that are payable or seek to recover benefits previously paid if the executive does not comply with these provisions or violates the release of claims. Payments may be delayed until six months after termination of employment if necessary to comply with Internal Revenue Code Section 409A.

Upon a termination of employment for cause, executives, including named executive officers, are not eligible for severance benefits under our Severance Plan or our Change in Control Plan and forfeit all unvested stock options, restricted unit and performance unit awards. In addition, the stock option, restricted unit and performance unit awards include a claw-back feature pursuant to which we may recover the amount of any profit the named executive officer realized upon the exercise of options, or the vesting of any restricted unit or performance unit award, during the 12-month period that occurs immediately prior to the executive officer s involuntary termination of employment for cause. For purposes of our Severance Plan and our Change in Control Plan, as well as the claw-back feature discussed in the preceding sentence, cause means substantial failure or refusal of the named executive officer to perform the duties and responsibilities of his job as required by the Company, violation of any fiduciary duty owed to the Company, conviction of a felony or misdemeanor, dishonesty, theft, violation of Company rules or policy, including a violation of our Guide to Business Conduct, or other egregious conduct that has or could have a serious and detrimental impact on the Company and its employees.

Other Termination Benefits. The terms of our annual incentive plan and equity plan provide for certain benefits upon a named executive officer s termination of employment due to death, disability or retirement. For this purpose, normal retirement occurs where an executive officer terminates employment after attaining age 60 and the sum of the executive s age and years of service equals at least 70 and early retirement occurs where an executive officer terminates employment after attaining age 55 and the sum of the executive s age plus years of service equals at least 60. Under the annual incentive plan, named executive officers are eligible to receive a pro-rated annual incentive cash award based on the number of days that the executive officer was employed by the Company during the fiscal year upon death, disability or normal or early retirement. Under the equity plan, named executive officers are eligible to receive full vesting of stock options, restricted units and performance

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units upon death, disability or normal retirement and pro-rated vesting of such awards upon early retirement, based on the number of whole months that the executive officer was employed by the Company during the applicable vesting period. As of the end of fiscal 2012, Mr. Dockendorff had satisfied the requirements for early retirement.

Letter Agreement with Mr. Trudeau. In connection with his joining the Company on February 1, 2012 as President of the Company s Pharmaceuticals business, the Company entered into a Letter Agreement with Mr. Trudeau. The letter agreement provides for certain retention benefits in the event of a sale of the Company s Pharmaceuticals business, including a sale bonus, a sale price bonus and an enhanced severance benefit. The sale bonus, which is payable upon a sale of the Pharmaceuticals business, equals the sum of Mr. Trudeau s then-current base salary and the average of his annual incentive bonuses for the previous three fiscal years or, if Mr. Trudeau has not been employed long enough to receive annual incentive bonuses for three fiscal years, the average of the bonuses actually paid to him. The sale price bonus is payable only if the sale proceeds received by the Company upon a sale of the Pharmaceuticals business exceed a threshold amount and is capped at $1 million. The enhanced severance benefit, which is payable if, in connection with a sale of the Pharmaceuticals business, the Company involuntarily terminates Mr. Trudeau s employment, the purchaser does not offer Mr. Trudeau a position after the consummation of the sale, or Mr. Trudeau resigns from employment for good reason within 12 months after the consummation of a sale, equals the severance Mr. Trudeau would be entitled to under the Severance Plan plus 1.5 times the sum of Mr. Trudeau s then-current base salary and the average of Mr. Trudeau s annual incentive bonus for the previous three fiscal years. The letter agreement requires the forfeiture of retention benefits in the event that Mr. Trudeau s employment is terminated for cause. The letter agreement also subjects the payment of the retention benefits to Mr. Trudeau s complying with the Covidien Guide to Business Conduct (or successor guide to business conduct), preserving confidentiality of the terms and conditions of any transaction or the status of any negotiations relating to any transaction, and cooperating with efforts surrounding a sale or spin-off transaction. The letter agreement applies the same definitions of cause and good reason that are used in our Change in Control Plan.

The table below reflects the amount of compensation that would become payable to each of our named executive officers under existing plans if the named executive officer s employment had terminated on September 28, 2012, the last day of our 2012 fiscal year, given the named executive s service levels as of such date and, if applicable, based on our closing stock price as of that date, which was $59.42. These benefits are in addition to benefits available prior to the occurrence of any termination of employment, including under then-exercisable stock options, and benefits available generally to salaried employees, such as distributions under the Retirement Savings Plan.

The actual amounts that would be paid upon a named executive officer s termination of employment or in connection with a change in control can be determined only at the time of any such event. Due to a number of factors that may affect the amount of any benefits provided upon the events discussed below, actual amounts paid or distributed may be higher or lower than indicated in the table. Factors that could affect these amounts include the timing during the year of any such event, our stock price, the executive s age and years of service, the attained level of performance for performance units, and any additional agreements or arrangements we may enter into in connection with any change in control or termination of employment. For a more complete understanding of the table, please read the narrative disclosures that follow the table.

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POTENTIAL PAYMENTS UPON TERMINATION

Name and Termination Scenario	Cash Severance	Bonus	Option Awards	Stock Awards	Welfare Benefits and Outplacement	Total
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
José E. Almeida						
Involuntary termination (other than for cause)	$4,081,225	$1,682,517	$2,788,954	$1,852,928	$49,296	$10,454,920
Death or Disability		$1,682,517	$6,893,819	$17,479,675		$26,056,011
Change in Control Termination	$6,101,432	$1,682,517	$6,893,819	$17,479,675	$59,431	$32,216,874
Charles J. Dockendorff						
Involuntary termination (other than for cause)	$2,393,444	$722,981	$1,827,058	$3,025,671	$43,659	$8,012,813
Voluntary Termination (early retirement)		$722,981	$1,141,657	$3,025,671		$4,890,309
Death or Disability		$722,981	$4,028,687	$7,623,115		$12,374,783
Change in Control Termination	$3,191,258	$722,981	$4,028,687	$7,623,115	$49,296	$15,615,337
Bryan C. Hanson						
Involuntary termination (other than for cause)	$1,503,483	$355,965	$698,613	$463,112	$43,659	$3,064,832
Death or Disability		$355,965	$1,774,422	$4,906,123		$7,036,510
Change in Control Termination	$2,004,643	$355,965	$1,774,422	$4,906,123	$49,296	$9,090,449
Peter L. Wehrly						
Involuntary termination (other than for cause)	$1,385,088	$650,127	$493,450	$344,115	$43,659	$2,916,439
Death or Disability		$650,127	$1,374,900	$4,370,236		$6,395,263
Change in Control Termination	$1,846,784	$650,127	$1,374,900	$4,370,236	$49,296	$8,291,343
Mark C. Trudeau						
Involuntary termination (other than for cause)	$1,735,878	$507,252	$93,420		$43,659	$2,390,684[(1)]
Death or Disability		$507,252	$373,680	$1,085,009		$1,976,416[(1)]
Change in Control Termination	$2,314,504	$507,252	$373,680	$1,085,009	$49,296	$4,340,216[(1)]

Footnote

(1) Also includes $7,500 in employer contributions to the Retirement Savings Plan and $2,975 in Company credits to the Supplemental Savings Plan that will become fully vested upon an involuntary termination of employment (other than for cause), death or disability or a change in control termination. All other named executive officers are fully vested in employer contributions and Company credits.

Cash Severance (Column B)

Involuntary Termination (other than for cause). For all named executive officers other than Mr. Almeida, the cash severance amount in this scenario represents continuation of the named executive officer s base salary, as of September 28, 2012, for an 18-month severance period, plus an amount equal to 1.5 times the average of the named executive officer s annual incentive cash awards for the previous three fiscal years (i.e., fiscal 2011, 2010 and 2009), payable during the 18-month severance period and on our normal payroll schedule. With respect to Mr. Wehrly, who commenced employment with the Company during fiscal 2009 and who received a pro-rated annual incentive bonus for such year, the average of his annual incentive cash awards has been adjusted to reflect the period of time that he has been employed by the Company. With respect to Mr. Trudeau, who commenced employment with the Company during fiscal 2012 and who received a pro-rated annual incentive bonus for such year, the average of his annual incentive cash awards equals the annual incentive bonus he received for fiscal 2012. For Mr. Almeida, the amount represents continuation of his base salary, as of September 28, 2012, for a 24-month severance period, plus an amount equal to two times the average of his annual incentive cash awards for the previous three fiscal years, payable during the 24-month severance period and on our normal payroll schedule.

Pursuant to the letter agreement that the Company entered into with Mr. Trudeau, if Mr. Trudeau s involuntary termination of employment (other than for cause) is in connection with a sale of the Pharmaceuticals business, the Company will provide him with an enhanced severance benefit. This enhanced severance benefit equals twice

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the cash severance amount payable to him under the Severance Plan and, in this scenario, if a sale of the Pharmaceuticals business had occurred on September 28, 2012, such an event would have increased the cash severance payable to Mr. Trudeau to $3,471,756, and resulted in a total potential payment of $4,126,562. While all of the other amounts payable under this scenario and listed in columns C, D and F would have remained the same, upon a sale of the Pharmaceuticals business, Mr. Trudeau would be eligible for a sale bonus and a sale price bonus. For more information about the enhanced severance benefit and the sale bonus and sale price bonus, please read the section above entitled *Letter Agreement with Mr. Trudeau*.

Change in Control Termination. The cash severance amount upon a change in control termination represents a lump sum payment equal to two times (2.99 times for Mr. Almeida) (1) the named executive officer s base salary as of September 28, 2012 plus (2) the average of the named executive officer s annual incentive cash awards for the previous three years. The average of the annual incentive cash awards for Messrs. Wehrly and Trudeau have been calculated as described under the *Involuntary Termination (other than for cause)* scenario.

Bonus (Column C)

Involuntary Termination (other than for cause). In the case of an involuntary termination (other than for cause), executive officers are entitled to a pro-rata payment of the annual incentive cash award based on the number of days they were employed by the Company during the fiscal year. Because we have assumed that the applicable terminations of employment occurred on the last day of our 2012 fiscal year, the amounts reported in Column C for this scenario represent the full annual incentive cash award payable to each named executive officer for fiscal 2012.

Voluntary Termination (early retirement). Because Mr. Dockendorff satisfied the requirements for early retirement under the 2012 Annual Incentive Plan, in the event of a voluntary termination, he is entitled to a pro-rata payment of the annual incentive cash award based on the number of days that he was employed by the Company during the fiscal year. Because we have assumed that the applicable termination of employment occurred on the last day of our 2012 fiscal year, the amounts reported in Column C for this scenario represent the full annual incentive cash award payable to Mr. Dockendorff for fiscal 2012.

Death or Disability and Change in Control Termination. The bonus amount represents the pro-rata payment of the annual incentive cash award based on the number of days that the named executive officer was employed by the Company during the fiscal year. Because we have assumed that the applicable termination of employment occurred on the last day of our 2012 fiscal year, the amounts reported in Column C for this scenario represent the full annual incentive cash award payable to each named executive officer for fiscal 2012.

Option Awards (Column D)

Involuntary Termination (other than for cause). For all named executive officers, the option award amount represents the value as of September 28, 2012 of outstanding options held by the named executive officer that would have vested during the 12-month period that immediately follows September 28, 2012 (*i.e.*, from September 28, 2012 to September 28, 2013).

Voluntary Termination (early retirement). As of September 28, 2012, Mr. Dockendorff satisfied the requirements for early retirement under our equity plan. The amount reported in Column D for this scenario represents the value attributable to the portion of the following stock option awards which would have vested on September 28, 2012, had Mr. Dockendorff voluntarily terminated employment on such date: the December 2008, December 2009 and December 2010 option awards. Mr. Dockendorff did not satisfy the requirements for early retirement with respect to the December 2011 option award because such award requires that the employee retire at least 12 months after the grant date to receive early retirement treatment. Because the assumed employment termination date (September 28, 2012) is less than 12 months after the December 2011 grant date, Mr. Dockendorff was not entitled to pro-rata vesting of the December 2011 option award as of the last day of fiscal 2012.

Death or Disability and Change in Control Termination. The option award amount represents the full vesting of unvested stock options held by the named executive officer as of September 28, 2012.

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Stock Awards (Column E)

Involuntary Termination (other than for cause). For all named executive officers other than Mr. Trudeau, the amounts reported in Column E for this scenario represent the value of the performance unit award issued in December 2009 which vested on October 4, 2012 and which the executive officer would have been entitled to receive upon an involuntary termination of employment on the last day of the fiscal year. For purposes of this scenario, the amount reported for the December 2009 performance unit award is based on the actual number of shares that vested after the conclusion of the FY10-FY12 performance cycle. With respect to Mr. Dockendorff who, as of September 28, 2012, satisfied the requirements for early retirement under our equity plan, the amount reported in Column E for this scenario also includes the value attributable to the portion of the following restricted unit and performance unit awards which would have vested on September 28, 2012, had Mr. Dockendorff involuntarily terminated employment on such date: the restricted unit awards issued in December 2009 and December 2010 and the performance unit award issued in December 2010. Mr. Dockendorff did not satisfy the requirements for early retirement with respect to the December 2011 restricted unit and performance unit awards because such awards require that the employee retire at least 12 months after the grant date to receive early retirement treatment. Because the assumed employment termination date (September 28, 2012) is less than 12 months after the December 2011 grant date, Mr. Dockendorff was not entitled to pro-rata vesting of the December 2011 restricted unit and performance unit awards. For purposes of this scenario, the amount attributable to the December 2010 performance unit award is reported as the value of the number of shares that would have become vested based on achievement of maximum performance.

Voluntary Termination (early retirement). For Mr. Dockendorff, the stock award amount represents the pro-rata vesting of restricted unit and performance unit awards, as described above under *Involuntary Termination (other than for cause).*

Death or Disability and Change in Control Termination. The amounts reported in Column E for this scenario represent the value that would have been attained upon the full vesting of all unvested restricted unit and performance unit awards held by the named executive officer as of September 28, 2012. For purposes of this scenario, amounts attributable to performance unit awards are based on the following assumptions: (1) for the December 2009 award, the actual number of shares that vested after the conclusion of the FY10-FY12 performance cycle; and (2) for the December 2010 and December 2011 awards, and the Asia Growth Initiative awards issued to Messrs. Hanson and Wehrly, the number of shares that would have vested based on achievement of maximum performance.

Welfare Benefits and Outplacement Services (Column F) The welfare benefits amount represents the employer portion of the premium paid on behalf of the named executive officer for continued coverage under the Company s medical, dental and vision plans during the applicable severance period. Amounts for calendar year 2012 and 2013 are based on actual rates determined by the Company for the respective plan in such years, while the rates for subsequent years, where applicable, are assumed based on the historic percentage increase in rates for such coverage. Although payable in our discretion, for purposes of this column we assume that we would pay $25,000 on behalf of each named executive officer for outplacement services upon an involuntary termination (other than for cause) and a change in control termination.

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SECURITY OWNERSHIP AND REPORTING

Security Ownership of Management and Certain Beneficial Owners

The following table shows the number of ordinary shares beneficially owned by each current director and nominee for director, each executive officer named in the Summary Compensation Table and our directors and executive officers as a group, as of January 1, 2013; to our knowledge, no shareholder beneficially owned 5% or more of our outstanding ordinary shares as of January 1, 2013.

A person is deemed to be a beneficial owner of ordinary shares if he or she, either alone or with others, has the power to vote or to dispose of those ordinary shares or the right to acquire such power within 60 days of the date of the table. Ordinary shares subject to stock options presently exercisable or exercisable within 60 days of January 1, 2013, restricted units and dividend equivalent units are deemed to be outstanding and beneficially owned by the person holding the securities for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person. There were Covidien ordinary shares outstanding as of January 1, 2013. The table below is based on information furnished by the persons named, public filings and our records.

Directors and Executive Officers

Name of Beneficial Owner	Number of Covidien Ordinary Shares Beneficially Owned	Percentage Ownership
Named Executive Officers		
José E. Almeida[1]		*
Charles J. Dockendorff[2]		*
Bryan C. Hanson[3]		*
Mark Trudeau[4]		*
Peter L. Wehrly[5]		*
Non-Employee Directors		
Joy A. Amundson[6]		*
Craig Arnold[7]		*
Robert H. Brust[7]		*
John M. Connors, Jr.[7]		*
Christopher J. Coughlin[8]		*
Timothy M. Donahue[7]		*
Randall J. Hogan, III[9]		*
Martin D. Madaus[10]		*
Dennis H. Reilley[7]		*
Joseph A. Zaccagnino[7]		*
All directors and executive officers as a group (24 persons)[11]		*

* Represents less than 1% of outstanding ordinary shares.

(1) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

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(2) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

(3) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

(4) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

(5) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

(6) Includes restricted units. Ms. Amundson joined our Board of Directors in June 2012.

(7) Includes restricted units and ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013.

(8) Includes restricted units, ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013 and shares held in a Grantor Retained Annuity Trust.

(9) Includes restricted units, ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013 and 64 shares held in a trust over which Mr. Hogan has shared dispositive and voting power.

(10) Includes restricted units. Dr. Madaus joined our Board of Directors in December 2011.

(11) Includes, for executive officers not specifically named in the table, an aggregate of ordinary shares issuable upon the exercise of stock options presently exercisable or exercisable within 60 days of January 1, 2013. Also includes an aggregate of ordinary shares pledged as security by two of our executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors and persons who beneficially own more than 10 percent of our ordinary shares to file reports of ownership and changes in ownership of such ordinary shares with the SEC and NYSE. These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. As a matter of practice, our administrative staff assists our officers and directors in preparing initial reports of ownership and reports of changes in ownership and files those reports on their behalf. Based on our review of the copies of such forms we have received, as well as information provided and representations made by the reporting persons, other than one Form 4 reporting one transaction for Peter L. Wehrly which was inadvertently filed late, we believe that all required Section 16(a) reports were timely filed during our fiscal year ended September 28, 2012.

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AUDIT AND AUDIT COMMITTEE MATTERS

Audit and Non-Audit Fees

Set forth below are the aggregate fees for professional services rendered to Covidien by Deloitte & Touche LLP for the period October 1, 2011 through September 28, 2012 (Fiscal 2012) and the period September 25, 2010 through September 30, 2011 (Fiscal 2011).

	Fiscal 2012	Fiscal 2011
	(in thousands)	
Audit Fees	$ 13,050	$ 14,995
Audit-Related Fees	4,145	906
Tax Fees	3,260	4,240
All Other Fees	280	0
Total	$ 20,735	$ 20,141

Audit Fees include fees for professional services rendered for the year-end audits of our consolidated financial statements and internal control over financial reporting, reviews of the financial statements included in our Quarterly Reports on Form 10-Q, consents, statutory filings, statutory audits, Irish statutory audits and discontinued operations reclassification.

Audit-Related Fees were primarily related to carve-out audits and services related to mergers and acquisitions.

Tax Fees include fees for tax compliance services such as assistance with the preparation of federal and state returns ($3.10 million for Fiscal 2012 and $3.12 million for Fiscal 2011) as well as fees for tax planning services ($0.16 million for Fiscal 2012 and $1.12 million for Fiscal 2011).

All Other Fees include services relating to project methodology and support for a non-financial system data integration initiative.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services

The Audit Committee has adopted a pre-approval policy that provides guidelines for audit, audit-related, tax and other permissible non-audit services that may be provided by our independent auditors. Pursuant to the policy, our Corporate Controller supports the Audit Committee by providing a list of proposed services to the Committee, monitoring the services and fees pre-approved by the Committee, providing periodic reports to the Committee with respect to pre-approved services and coordinating with management and the independent auditors to support compliance with the policy.

Under the policy, the Audit Committee annually pre-approves the audit fee and terms of the engagement, as set forth in the engagement letter. The Committee also annually approves a specified list of audit, audit-related and tax services. Any service not included in the specified list of services must be submitted to the Committee for pre-approval. The independent auditors may not begin work on any engagement without confirmation of Committee pre-approval from our Corporate Controller or his delegate.

Pursuant to the policy, the Audit Committee has delegated to its Chair the authority to pre-approve the engagement of the independent auditors in his discretion. The Chair reports all such pre-approvals to the Committee at the next Committee meeting.

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Audit Committee Report

As more fully described in its charter, the Audit Committee oversees Covidien s financial reporting process on behalf of the Board of Directors. Management has day-to-day responsibility for the Company s financial reporting process, including assuring that the Company develops and maintains adequate financial controls and procedures and monitoring and assessing compliance with those controls and procedures, including internal control over financial reporting. Covidien s independent auditors are responsible for auditing the annual financial statements prepared by management, expressing an opinion as to whether those financial statements fairly present the financial position, results of operations and cash flows of the Company in conformity with generally accepted accounting principles and discussing with the Audit Committee any issues they believe should be raised. The independent auditors are also responsible to the Audit Committee and the Board for testing the integrity of the financial accounting and reporting control systems, for issuing a report on the Company s internal control over financial reporting and for such other matters as the Audit Committee and Board determine.

In the performance of its oversight function, the Audit Committee has reviewed and discussed with management, the internal auditors and the independent auditors the consolidated financial statements for the fiscal year ended September 28, 2012 to be filed with the U. S. Securities and Exchange Commission (the SEC). Management represented to the Committee that these consolidated financial statements were prepared in accordance with generally accepted accounting principles in the United States (US GAAP). In addition, the Committee has:

- discussed with the independent auditors the matters required to be discussed pursuant to the applicable Auditing Standards relating to communication with audit committees;
- received from the independent auditors the written disclosures and letter required by the applicable requirements of the Public Company Accounting Oversight Board regarding the independent auditors communications with the Audit Committee concerning independence;
- discussed with the independent auditors their independence from the Company and its management; and
- considered whether the independent auditors provision of non-audit services to the Company is compatible with maintaining the auditors independence.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that Covidien s audited consolidated financial statements prepared in accordance with US GAAP be included in its Annual Report on Form 10-K for the fiscal year ended September 28, 2012 to be filed with the SEC.

Audit Committee

Robert H. Brust, Chairman

Joy A. Amundson

Craig Arnold

Randall J. Hogan, III

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Equity Compensation Plan Information

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)[1][2]	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)[3]	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)[4]
Equity compensation plans approved by security holders	18,827,334	$ 43.97	18,391,919
Equity compensation plans not approved by security holders			
TOTAL	18,827,334	$ 43.97	18,391,919

(1) As of September 28, 2012, there were 14,049,125 ordinary shares to be issued upon exercise of outstanding options with a weighted-average exercise price of $44.00, 4,730,050 ordinary shares to be issued upon settlement of restricted units, performance units and accompanying dividend equivalent units granted pursuant to our 2007 Stock and Incentive Plan and 48,159 ordinary shares to be issued upon exercise of outstanding options with a weighted-average exercise price of $35.60 pursuant to the Covidien Savings Related Share Plan.

(2) This table does not include information regarding options and restricted units converted from Tyco International Ltd. awards in connection with our separation from Tyco International in June 2007. We did not assume any equity compensation plans from Tyco International, and no grants of Covidien equity may be made pursuant to any Tyco International plans. As of September 28, 2012, there were 2,785,337 ordinary shares to be issued upon exercise of these converted options with a weighted-average exercise price of $39.23 and 64 ordinary shares to be issued upon settlement of converted restricted stock units.

(3) Does not take into account restricted units and performance units, which do not have an exercise price.

(4) As of September 28, 2012, there were 14,033,560 ordinary shares available for issuance pursuant to 2007 Stock and Incentive Plan, 3,435,678 ordinary shares available for issuance pursuant to the Covidien Employee Stock Purchase Plan and 922,681 ordinary shares available for issuance pursuant to the Covidien Savings Related Share Plan. If Proposal Number Four regarding our amended and restated Stock and Incentive Plan is approved by shareholders, the number of ordinary shares available for issuance under that plan will increase. See Proposal Number Four for more information.

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PROPOSALS REQUIRING YOUR VOTE

PROPOSALS 1 (A) THROUGH 1 (J):

ELECTION OF DIRECTORS

Upon the recommendation of the Nominating and Governance Committee, the Board has nominated for election at the 2013 Annual General Meeting a slate of 10 nominees, all of whom are currently serving on the Board. The nominees are José E. Almeida, Joy A. Amundson, Craig Arnold, Robert H. Brust, John M. Connors, Jr., Christopher J. Coughlin, Randall J. Hogan, III, Martin D. Madaus, Dennis H. Reilley and Joseph A. Zaccagnino. Biographical information, including qualifications, regarding each of the 10 nominees is set forth below. The election of directors will take place at the Annual General Meeting. In order to be elected as a director, each nominee must receive the affirmative vote of a majority of the votes cast by the holders of ordinary shares represented at the Annual General Meeting in person or by proxy. Shareholders are entitled to one vote per share for each of the 10 nominees. Covidien is not aware of any reason why any of the nominees will not be able to serve if elected. Each of the directors elected will serve until the conclusion of the 2014 Annual General Meeting or until his or her earlier death, resignation or removal. Timothy M. Donahue has decided not to stand for re-election to the Board. The Company and the Board expressed their appreciation for Mr. Donahue s years of service to the Board and the Company.

Current Directors Nominated for Re-Election Proposals 1 (a) through 1 (j)

Proposal 1 (a) José E. Almeida

Mr. Almeida, age 50, has served as the Chairman of our Board of Directors since March of 2012. He has served on our Board of Directors since becoming Covidien s President and Chief Executive Officer in July 2011. Prior to assuming the role of President and Chief Executive Officer of Covidien, Mr. Almeida served, from October 2006 to June 2011, as the President of our Medical Devices business segment. Prior to that, from April 2004 to September 2006, Mr. Almeida was President of Covidien s International business. From January 2003 to April 2004, Mr. Almeida was Chief Operating Officer of Greatbatch, Inc., a developer and manufacturer of power sources and components for implantable medical devices. Mr. Almeida joined the Company in 1995 as Director of Corporate Engineering and then held several positions of increasing responsibility, including Vice President of European Manufacturing and Vice President of Global Manufacturing, through December 2002.

As our Chairman, President and Chief Executive Officer, Mr. Almeida is focused on positioning the Company for the future. After over 15 years with the Company during which he, among other things, ran our largest business segment, headed up our international business and oversaw manufacturing operations, Mr. Almeida is familiar with all aspects of the business. Serving on the Executive Committee, the Board of Directors and as Chairman of the Board Committee on Ethics and Health Care Compliance of the Advanced Medical Technology Association (AdvaMed), a medical device trade association, Mr. Almeida also understands the responsibilities of a board member. With his keen global perspective, results-driven nature, commitment to operational intensity and depth of Company knowledge,

Mr. Almeida is an invaluable member of our Board of Directors.

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Proposal 1 (b) Joy A. Amundson

Ms. Amundson, age 58, joined our Board of Directors in June 2012. Ms. Amundson is a principal of Amundson Partners, Inc., a healthcare consulting firm. From August 2004 to October 2010, Ms. Amundson was the President of Baxter BioScience Corporation and Vice President of Baxter International, Inc. Prior to Baxter, she was with Amundson Partners for three years. Prior to joining Amundson Partners, she was with Abbott Laboratories for over 20 years, where she held several key positions, including Senior Vice President. Ms. Amundson began her business career in sales and brand management with Procter & Gamble, a packaged goods company, from 1977 to 1982. Ms. Amundson previously served as a director of ApaTech, Dial Corporation, Ilex Oncology, Inc., Inamed Corporation and Oridion Medical Ltd.

As the most recent addition to our Board of Directors, Ms. Amundson brings with her a fresh perspective on the healthcare industry. From her years as President of Baxter BioScience Corporation as well as her position as a principal of a healthcare consulting firm and over 20 years as an executive of Abbott Laboratories, Ms. Amundson has deep insight into the healthcare industry. These positions, coupled with her Master s Degree in management from Northwestern University s Kellogg Graduate School of Management, also afford Ms. Amundson an understanding of what it takes to be a leader and guide a business successfully. In addition, her experience on numerous Boards of Directors gives her perspective on the critical role the Board of Directors plays in guiding a company at the very highest level. Ms. Amundson s depth and breadth of experience make her a well-rounded and valuable member of our Board of Directors.

Proposal 1 (c) Craig Arnold

Mr. Arnold, age 52, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company. Mr. Arnold is the Vice Chairman and Chief Operating Officer, Industrial Sector of Eaton Corporation, a diversified industrial manufacturer. From 2000 to 2008 he served as Senior Vice President of Eaton Corporation and President of the Fluid Power Group of Eaton. Prior to joining Eaton, Mr. Arnold was employed in a series of progressively more responsible positions at General Electric Company from 1983 to 2000. Mr. Arnold previously served as a director of Unocal Corporation, where he also was a member of the Audit Committee.

With his years of managerial experience, both at Eaton and at General Electric, Mr. Arnold brings to the Board of Directors demonstrated management ability at senior levels. His position as Chief Operating Officer of the Eaton Industrial Sector gives Mr. Arnold critical insights into the operational requirements of a large company. In addition, in previously serving on the Audit Committee of another public company, Mr. Arnold gained valuable experience dealing with accounting principles and financial reporting rules and regulations, evaluating financial results and generally overseeing the financial reporting process of a large corporation.

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Proposal 1 (d) Robert H. Brust

Mr. Brust, age 69, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company. Mr. Brust served as the Chief Financial Officer of Sprint Nextel Corporation, a wireless and wireline communications company, from May 2008 until his retirement in April 2011. From February 2007 to May 2008, Mr. Brust was retired. From January 2000 to February 2007, Mr. Brust served as Executive Vice President of Eastman Kodak Company, a provider of photographic products and services, and, from January 2000 to November 2006, he also served as Chief Financial Officer of Kodak. Prior to joining Kodak, Mr. Brust was Senior Vice President and Chief Financial Officer of Unisys Corporation from 1997 to 1999. He also worked in a variety of financial and financial management positions at General Electric Company from 1965 to 1997. Mr. Brust is currently a director of Smith & Wesson Holding Corporation and previously served as a director of Delphi Corporation and Applied Materials, Inc.

Mr. Brust is an experienced financial leader with the skills necessary to lead our Audit Committee. His service as Chief Financial Officer of Sprint Nextel Corporation, the Eastman Kodak Company and Unisys Corporation as well as his 31 years at General Electric Company make him a valuable asset, both on our Board of Directors and as the Chairman of our Audit Committee. Mr. Brust s positions have provided him with a wealth of knowledge in dealing with financial and accounting matters. The depth and breadth of his exposure to complex financial issues at such large corporations makes him a skilled advisor.

Proposal 1 (e) John M. Connors, Jr.

Mr. Connors, age 70, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company. Since 2006, Mr. Connors has served as Chairman Emeritus of Hill, Holliday (formerly Hill, Holliday, Connors, Cosmopulos, Inc), a full-service advertising agency that is part of The Interpublic Group of Companies, Inc. From 2003 to 2006, Mr. Connors served as Chairman of Hill, Holliday, and from 1968 to 2003 he was Chairman, President and Chief Executive Officer of Hill, Holliday. Mr. Connors is currently a director of Hasbro, Inc and serves on Hasbro s Compensation Committee, Executive Committee and Nominating, Governance and Social Responsibility Committee.

Having been a founding member, former Chairman, President and Chief Executive Officer of Hill, Holliday, Mr. Connors has extensive business experience. In addition, having served as the Chairman of the Board of Directors of Partners Healthcare System, Inc., which includes Massachusetts General Hospital and Brigham and Women s Hospital, and also as a member of the Harvard Medical School Board of Fellows, Mr. Connors has a unique perspective to offer Covidien on a variety of healthcare-related issues.

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Proposal 1 (f) Christopher J. Coughlin

Mr. Coughlin, age 60, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone company. Mr. Coughlin served as an advisor to Tyco International, a global provider of security products and services, fire protection and detection products and services, valves and controls, and other industrial products from December 2010 to September 2012. From March 2005 to December 2010, Mr. Coughlin served as Executive Vice President and Chief Financial Officer of Tyco International. Prior to joining Tyco International, Mr. Coughlin served as Chief Operating Officer of The Interpublic Group of Companies, Inc. from June 2003 to December 2004. He joined Interpublic from Pharmacia Corporation, where he was Chief Financial Officer from 1998 to 2003. Previously, he held the position of Executive Vice President and Chief Financial Officer of Nabisco Holdings, where he also served as President of Nabisco International. Mr. Coughlin is currently the Lead Director of The Dun & Bradstreet Corporation board and a director of Forest Laboratories, Inc. He previously served as a director of Perrigo Company, Monsanto Company and Interpublic.

As Chief Financial Officer of Tyco International, Pharmacia Corporation and Nabisco Holdings and as Chief Operating Officer of The Interpublic Group of Companies, Mr. Coughlin has demonstrated leadership capability and extensive knowledge of complex financial and operational issues facing large organizations. He brings an understanding of operations and financial strategy in challenging environments. In addition, Mr. Coughlin is able to draw upon, among other things, his knowledge of the pharmaceutical industry garnered while at Pharmacia and his knowledge of the medical device industry developed while Covidien constituted the healthcare business of Tyco International.

Proposal 1 (g) Randall J. Hogan, III

Mr. Hogan, age 57, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company. Mr. Hogan has served as Chief Executive Officer of Pentair, Inc., an industrial manufacturing company, since 2001 and was appointed Chairman in 2002. From 1999 to 2000, he was President and Chief Operating Officer and from 1998 to 1999, he was Executive Vice President and President of Pentair s Electrical and Electronic Enclosures Group. Prior to joining Pentair, he was President of United Technologies Carrier Transicold Division. Before that, he was with the Pratt & Whitney division of United Technologies, General Electric Company and McKinsey & Company. Mr. Hogan previously served as a director of Unisys Corporation.

Having served in the roles of Chairman, Chief Executive Officer, President and Chief Operating Officer of Pentair, Mr. Hogan offers a wealth of management experience and business acumen. Running a public company gives Mr. Hogan front-line exposure to many of the issues facing public companies, particularly on the operational, financial and corporate governance fronts. Mr. Hogan s service on the Board of Directors and Governance Committee of Unisys further augments his range of knowledge, providing experience on which he can draw while serving as a member of our Board.

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Proposal 1 (h) Martin D. Madaus

Dr. Madaus, age 53, joined our Board of Directors in December 2011. Dr. Madaus is the Executive Chairman of Quanterix Corporation, a privately-held development stage diagnostics company seeking to develop and commercialize blood tests that measure clinically important proteins in blood. Prior to joining Quanterix, Dr. Madaus was the President and Chief Executive Officer of Millipore Corporation, a life sciences company serving the bioscience research and biopharmaceutical manufacturing industry, from January 2005 to July 2010, and Chairman from March 2005 to July 2010, when Millipore was acquired by Merck KGaA. Prior to joining Millipore, he was at Roche Diagnostics Corporation where, as President and Chief Executive Officer, he was responsible for the North American operations. Dr. Madaus is currently a director of Mettler-Toledo International, where he serves on the Audit Committee. Dr. Madaus is also a director of PPD Inc, a privately-held clinical research organization.

Dr. Madaus brings to the Board key life sciences industry knowledge and experience. Having served as Chief Executive Officer of Millipore and Roche Diagnostics and currently serving as Executive Chairman of Quanterix, Dr. Madaus has insight into many of the business challenges and opportunities facing the Company. Having led a public company, Dr. Madaus also understands the need to create shareholder value while continuing to focus on the long-term success of the Company. His leadership experience, his depth of industry knowledge and his financial expertise, position him well to serve as a member of our Board.

Proposal 1 (i) Dennis H. Reilley

Mr. Reilley, age 59, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company and served as the Chairman of our Board of Directors until October 2008. From 2000 to April 2007, Mr. Reilley served as Chairman of Praxair, Inc., a supplier of industrial gases and high-performance surface coatings, and also served as Chief Executive Officer of Praxair from 2000 to December 2006. Prior to joining Praxair, Mr. Reilley held many key positions at E. I. du Pont de Nemours and Company from 1989 to 1999 when he was named Chief Operating Officer. Earlier in his career he held various managerial positions at Conoco. Mr. Reilley is currently a director of H.J. Heinz Company, Marathon Oil Corporation and The Dow Chemical Company.

As Chairman and Chief Executive Officer of Praxair and Chief Operating Officer of DuPont, Mr. Reilley took on significant management, strategic and operational responsibilities. With his knowledge of the complex issues facing global companies today and his understanding of what makes businesses work effectively and efficiently, Mr. Reilley provides valuable insight to our Board. Mr. Reilley s experience as Chairman of the Praxair Board of Directors as well as his service on the Governance and Compensation Committees of H.J. Heinz and Marathon Oil, the Audit Committee of H.J. Heinz and on the Audit and Compensation Committees of Dow Chemical, position him well to serve as a member of our Board.

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Proposal 1 (j) Joseph A. Zaccagnino

Mr. Zaccagnino, age 66, joined our Board of Directors in June 2007 in connection with our establishment as a stand-alone public company. Mr. Zaccagnino, who has held leadership positions in the healthcare sector for over 40 years, served as President, Chief Executive Officer and Director of Yale New Haven Health System and its flagship Yale-New Haven Hospital, one of the country s largest and most prominent academic medical center hospitals and the primary teaching and research affiliate of the Yale University School of Medicine, from 1991 until his retirement in 2005. Yale New Haven Health System facilities include free-standing: acute care adult and children s hospitals; psychiatric and cancer hospitals; rehabilitation services; ambulatory surgery, outpatient diagnostic imaging, primary care and emergency centers; and health insurance products. Mr. Zaccagnino previously served as a director of NewAlliance Bancshares, Inc.

Nationally, Mr. Zaccagnino has served as Chairman of the Board of the National Committee for Quality Healthcare and as Chairman of the Board of VHA Inc., a 2,500 member hospital cooperative which provides supply chain and group purchasing services through its subsidiary, Novation. His broad healthcare management and governance experience and his knowledge of healthcare policy and regulation, patient care delivery and financing and of clinical research and medical technology assessment provides our Board with unique insights and a keen perspective on the complexities of the healthcare industry and on the priorities of and challenges facing both our Company and our major customers.

Unless otherwise instructed, the proxies will vote FOR each of these directors.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR EACH OF THE DIRECTORS NOMINATED FOR RE-ELECTION

IN PROPOSALS 1 (A) THROUGH 1 (J)

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PROPOSAL 2:

APPOINT THE INDEPENDENT AUDITORS AND

AUTHORIZE THE AUDIT COMMITTEE TO SET THEIR REMUNERATION

Shareholders are being asked to appoint our independent auditors and to authorize the Audit Committee of our Board of Directors to set the auditors remuneration. Appointment of the independent auditors and authorization of the Audit Committee to set their remuneration require the affirmative vote of a majority of the votes cast by the holders of ordinary shares represented at the Annual General Meeting in person or by proxy. The Audit Committee and the Board recommend that shareholders reappoint Deloitte & Touche LLP as our independent auditors to audit our accounts for the fiscal year ending September 27, 2013 and authorize the Audit Committee of the Board to set the auditors remuneration.

Representatives of Deloitte & Touche LLP will be at the Annual General Meeting, and they will be available to respond to appropriate questions.

Unless otherwise instructed, the proxies will vote FOR this proposal.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR PROPOSAL 2

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PROPOSAL 3:

ADVISORY VOTE TO APPROVE EXECUTIVE COMPENSATION

As described in the Compensation Discussion and Analysis section of this Proxy Statement (CD&A), the Compensation and Human Resources Committee s goal in setting executive compensation is to provide a compensation package that attracts, motivates and retains executive talent and rewards executive officers for superior Company and individual performance while encouraging behavior that is in the long-term best interests of the Company and its shareholders. Consistent with this philosophy, a significant portion of the total compensation opportunity for each of our executives is performance-based and dependent upon the Company s achievement of specified financial goals and the performance of the Company s shares on a long-term basis. In fiscal 2012, the Company delivered a strong operating performance, in line with its long-term goals of mid-single digit sales growth, improved margins and strong cash flow generation.

Shareholders are urged to read the CD&A, which discusses how our compensation policies and procedures implement our compensation philosophy, as well as the Summary Compensation Table and other related compensation tables and narrative disclosure which describe the compensation of our named executive officers in fiscal 2012. The Compensation and Human Resources Committee and the Board of Directors believe that the policies and procedures articulated in the CD&A are effective in implementing our compensation philosophy and in achieving its goals and that the compensation of our named executive officers in fiscal 2012 reflects and supports these compensation policies and procedures.

Shareholders will be asked at the 2013 Annual General Meeting to approve the following advisory resolution:

RESOLVED, that the compensation of the Company s named executive officers described in the Compensation Discussion and Analysis section of the Proxy Statement and disclosed in the 2012 Summary Compensation Table and related compensation tables and narrative disclosure included in this Proxy Statement is approved.

This advisory vote, commonly referred to as a say-on-pay advisory vote, is non-binding on the Board. Although non-binding, the Board and the Compensation and Human Resources Committee will review the voting results and take them into consideration when making future decisions regarding our executive compensation programs.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 3

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PROPOSAL 4:

APPROVAL OF THE AMENDED AND RESTATED

COVIDIEN STOCK AND INCENTIVE PLAN

General

You are being asked to approve the amended and restated Covidien Stock and Incentive Plan (the Covidien SIP). The Covidien SIP was last amended and restated by our Board of Directors on November 21, 2008, which amendment and restatement was approved by our shareholders on March 18, 2009. On November 15, 2012, our Board of Directors approved the further amendment and restatement of the Covidien SIP, subject to shareholder approval. The amendment increases the number of shares available for issuance under the Covidien SIP by 45 million shares and includes miscellaneous clarifications to plan language. The amended and restated plan maintains existing share counting rules and maintains the fungible share ratio for full value awards, which, as described further below, decreases the number of ordinary shares available for grant by a margin of 2.2 per ordinary share issued and increases the number of ordinary shares available for grant by a margin of 2.2 per ordinary share subject to an award that expires or is forfeited, cancelled or terminated.

Rationale for and Reasons Why the Board Recommends Voting for the Proposed Amendment and Restatement

The Company is seeking shareholder approval of the amended and restated Covidien SIP because of the increase in the number of shares available for issuance, in order to comply with the listing rules of the New York Stock Exchange and to preserve the exemption for certain awards from the application of the deduction limitations of Code Section 162(m), as described further below. Based on current projections, without increasing the number of shares available for issuance under the Covidien SIP, the Company will be unable to grant equity awards to employees, as part of our next ordinary course annual equity award cycle, in amounts consistent with past practice.

For the last five fiscal years, the Company has issued annual equity awards every December and off-cycle equity awards on the first trading day of each month from January through August. These awards have reduced the number of shares available for issuance under the Covidien SIP by an average of approximately 9.4 million shares each fiscal year. As of December 28, 2012, the Covidien SIP had [ ] shares available for issuance. Because the Company intends to continue issuing annual equity and off-cycle equity awards to key employees consistent with past practice, the number of shares available for issuance under the plan as of December 28, 2012, is not sufficient to issue the Company s fiscal 2013 off-cycle equity awards and the fiscal 2014 annual equity awards scheduled for issuance in December, 2013. In evaluating the Company s request to increase the number of shares available for issuance under the Covidien SIP, the Compensation and Human Resources Committee of the Board (the Committee) considered the number of shares required to continue making annual equity awards at levels consistent with prior practice and market conditions and the impact that the additional shares requested will have on the Company s dilution and overhang ratios. After concluding its evaluation, the Committee recommended to the full Board the amended and restated Covidien SIP, including the increase in the number of shares available for issuance, which the Board adopted and approved for inclusion in this proxy statement.

To assess the number of shares required to continue making equity awards consistent with past practice, the Committee reviewed the number of shares underlying equity awards previously issued from the Covidien SIP through the annual and off-cycle equity award processes as well as a forward-looking projection of the number of shares underlying equity awards that currently are anticipated to be granted from the Covidien SIP during the next five fiscal years. The forward-looking projection assumes that the Company continues to issue annual equity awards that are commensurate with historical grants and includes the following additional assumptions, which were based either on historical averages from the Covidien SIP and share usage or a reasonable estimate or anticipation for a future event or value: (i) a five percent (5%) increase each year in the number of shares issued

from the Covidien SIP to reflect anticipated market-based adjustments (*i.e.*, compensation increases and changes in long-term incentive grant practices) as well as organic and acquisitive growth in key employees; (ii) a ten percent (10%) rate of return of shares to be available again for issuance under the plan for shares that are forfeited, cancelled or terminated; (iii) continued usage of a fungible share ratio of 2.2 for full value shares being issued from or returned to the pool of shares that are available for issuance; (iv) an average share price of $50 per ordinary share; and (v) that performance units would payout at the maximum performance level. This forward-looking projection indicated that anticipated future equity awards would reduce the number of shares available for issuance under the plan by an average of approximately 8.4 million shares each year for fiscal year 2014 through fiscal year 2018. Accordingly, the Company has estimated that its request for an additional 45 million shares will be sufficient to continue to grant annual and off-cycle equity awards that are commensurate with historical grants for five annual equity award cycles.

To assess the impact that the request for 45 million additional shares will have on the Company s dilution and overhang ratios, if approved by shareholders, the Committee considered a report prepared by its independent compensation consultant. This report analyzed the Company s share allocation and utilization rates under the Covidien SIP as compared to the Company s peer group for purposes of setting compensation. For this purpose, share allocation is defined as the amount of outstanding shares that have been awarded to key employees and directors under the Covidien SIP, plus shares available for future grant, and share utilization is the number of shares underlying equity awards granted to key employees and directors in a fiscal year. Based on the analysis conducted by the Committee s independent compensation consultant and assuming that the Company s shareholders approve the 45 million additional shares, the Company s share allocation (overhang), when expressed as a percentage of ordinary shares outstanding, is projected to be 16.46% for fiscal 2013 as compared to 13.30%, which is the median allocation level for the comparator group. Additionally, the Company s share utilization rate is projected to be 1.29% for fiscal 2013 as compared to 1.21%, which is the median rate for the comparator group and, on a three-year average basis is projected to be 1.37% for fiscal 2011, 2012 and 2013 as compared to 1.40%, which is the median rate for the comparator group for the same three-year period. The Committee considered that, if shareholders approve the 45 million additional shares, the Company s share allocation would exceed the median allocation of the comparator group, but observed that this increase is typical for companies to experience upon receipt of shareholder approval for additional shares and that this allocation level will decrease each year as shares underlying restricted unit and performance unit awards vest and options are exercised.

For the reasons noted above, the Board of Directors recommends that you vote for the approval of the amended and restated Covidien SIP.

Material Terms of the Amended and Restated Covidien SIP

Purpose. The Covidien SIP is designed to assist in the recruitment and retention of directors and key employees, provide incentives to such individuals in consideration of their services to Covidien, promote the growth and success of our business by aligning the interests of such individuals with those of our shareholders, and provide such individuals with an opportunity to participate in the Company s growth and financial success. Replenishing the number of shares available for issuance under the Covidien SIP will enable the Company to continue to attract, retain and motivate qualified employees and directors.

The following description of the material terms of the Covidien SIP, as proposed to be amended and restated, is qualified in its entirety by the terms of the amended and restated document, which is attached hereto as Appendix A.

Governance Features. The following features of the Covidien SIP reinforce the Company s commitment to integrity and the highest standards of ethical conduct and illustrate our commitment to good corporate governance:

No in-the-money Options. The Covidien SIP prohibits the grant of stock options or stock appreciation rights with an exercise price that is less than 100% of the fair market value of the Company s ordinary shares.

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No Repricing or Replacement of Options. The Covidien SIP prohibits, without shareholder approval, (1) the amendment of an option or stock appreciation right to reduce the exercise price; and (2) the replacement of an option or stock appreciation right with another award that has a lower exercise price than the replaced option or stock appreciation right.

Share Counting Rules. The total number of shares available under the Covidien SIP shall be reduced by 2.2 shares for each ordinary share subject to an award of restricted stock, restricted units, performance units or annual bonus paid out in shares.

Forfeiture on Termination for Cause. Directors and employees who are terminated for cause forfeit all existing awards and employees who are terminated for cause also are required to deliver to the Company any profits realized on equity awards that vested or were exercised during the 12-month period prior to their employment termination date.

Non-Competition, Non-Solicitation and Confidentiality Agreements. The Compensation and Human Resources Committee has conditioned eligibility for U.S. employees to participate in the Covidien SIP on the employee s execution of, and compliance with, a non-competition, non-solicitation and confidentiality agreement.

No Material Amendments without Shareholder Approval. Any material amendment to the Covidien SIP requires shareholder approval before it can be effective.

Plan Administration. The Covidien SIP is administered by the Compensation and Human Resources Committee except with respect to director awards, which are administered by the Nominating and Governance Committee. The Compensation and Human Resources Committee or, to the extent required by applicable law, the Board of Directors, has broad discretion and authority under the Covidien SIP including the authority to:

interpret and administer the Covidien SIP;

select employees to receive awards and determine the form of awards, the number of ordinary shares subject to an award, and the terms and conditions of each award;

waive or amend any terms, conditions, restrictions or limitations on an award and/or vest awards upon a participant s termination of employment, except that the Covidien SIP s prohibition on the repricing of stock options and stock appreciation rights cannot be waived; and

delegate its duties and appoint agents to help administer the Covidien SIP.

Eligibility. Each of our approximately 43,000 employees providing services to us or any of our affiliates who is selected by the Compensation and Human Resources Committee or its delegate, is eligible to receive an award under the Covidien SIP. Each of our ten non-employee Directors selected by the Nominating and Governance Committee is eligible to receive an award under the Covidien SIP. As of December 28, 2012, approximately [3,700] employees, officers and Directors had been granted awards under the Covidien SIP.

Shares Available for Issuance. As of December 28, 2012, there were [ ] shares available for issuance under the Covidien SIP. With this amendment and restatement, we are proposing to increase the number of shares available for future awards by 45 million.

Set forth below is information regarding options, restricted units, dividend equivalent units and performance units granted under the Covidien SIP and outstanding as of December 28, 2012:

Shares of common stock to be issued upon exercise of outstanding options		
Weighted average exercise price of outstanding options	$	
Weighted average contractual term of outstanding options		years
Shares of common stock to be issued upon settlement of outstanding restricted units, dividend equivalent units and performance units		
Total shares subject to outstanding Covidien SIP awards		

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When ordinary shares are issued pursuant to a grant of full value awards, *i.e.*, restricted stock, restricted units, deferred stock units, performance units or as payment of an annual performance bonus or other stock-based awards (which are awards other than stock options, stock appreciation rights, annual performance bonuses or long-term performance awards), the total number of ordinary shares remaining available for grant is decreased by a margin of 2.2 per ordinary share issued; under the amended and restated Covidien SIP, we will continue to decrease the number of ordinary shares available for grant by a margin of 2.2 per ordinary share issued pursuant to a full value award. In determining the number of shares that remain available under the Covidien SIP, shares related to awards paid in cash do not count against the Covidien SIP s share limit. In addition, shares of restricted stock that are returned to us upon a participant s termination of employment or, if applicable, a director s termination of directorship and shares related to awards that expire or are forfeited or cancelled, or terminate for any other reason without issuance of shares, are added back to the share limit at a rate of 2.2 shares per each share subject to the expired, forfeited, cancelled or terminated award. Any shares issued in connection with awards that are assumed, converted or substituted as a result of the acquisition of an acquired company by us or a combination of our company with another company will not be deducted from the share limit. If the amended and restated Covidien SIP is approved by our shareholders, the maximum number of shares authorized for issuance pursuant to future awards under the Covidien SIP will be the number of shares currently authorized for issuance pursuant to future awards plus 45 million.

Stock Options and Stock Appreciation Rights. Stock options awarded under the Covidien SIP may be in the form of nonqualified stock options or incentive stock options or a combination of the two. Stock appreciation rights may be awarded either alone or in tandem with stock options. Stock appreciation rights will be paid in cash or ordinary shares or a combination of cash and ordinary shares, as determined by the Compensation and Human Resources Committee. Unless otherwise determined by the Compensation and Human Resources Committee or as required by law, stock options and stock appreciation rights granted under the Covidien SIP are subject to the following terms and conditions:

Exercise Price. The Compensation and Human Resources Committee will set the exercise price at the time of grant, which will be no less than the fair market value of an ordinary share as of the date of grant. Under the Covidien SIP, fair market value is closing sales price of an ordinary share of Covidien as reported on the New York Stock Exchange on the date for which fair market value is being determined which, in the case of establishing the exercise price of an option, is the grant date.

No Repricing. The exercise price may not be decreased after the grant date, other than in connection with required Covidien SIP adjustments such as recapitalizations, unless our shareholders specifically approve the repricing.

Vesting. Stock options and stock appreciation rights will vest at such time and in the manner as determined at the time of grant by the Compensation and Human Resources Committee. Unless otherwise provided in the award certificate, stock options and stock appreciation rights will immediately vest upon the normal retirement, death or disability of a participant, or upon a termination of employment without cause or resignation for good reason after a change in control.

Post-Termination Exercise. Unless the Compensation and Human Resources Committee provides otherwise in the award certificate, stock options and stock appreciation rights that have not vested as of the date of a participant s termination of employment will be forfeited, unless the participant is eligible for normal retirement or terminates as a result of death or disability, in which cases the awards may become exercisable in full or, in the case of an early retirement, on a pro rata basis. Subject to the term of the award, any vested stock option or stock appreciation right that has not already been exercised will remain exercisable for a period of three years after termination of employment because of early or normal retirement, death or disability, and any vested stock option or stock appreciation right that has not already been exercised will remain exercisable for a period of 90 days after termination of employment for any other reason except for a termination for cause.

Performance-Based Awards. The Covidien SIP provides for performance-based awards in the form of: (1) annual performance bonuses that may be granted in the form of cash or ordinary shares; and (2) long-term

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performance awards in the form of performance units that may be paid in cash or shares or performance-based restricted units or restricted stock awards that are paid in shares. The Compensation and Human Resources Committee, in its discretion, will fix the amount, terms and conditions of annual performance bonuses and long term performance awards, subject to the following:

Performance Cycles. Annual performance bonuses will be awarded in connection with a 12-month performance cycle, which will coincide with our fiscal year. Long-term performance awards will be awarded in connection with a performance cycle that will not be shorter than 12 months or longer than five years. The annual performance bonus amount and the number of shares or units that are earned will be determined by the level of performance attained in relation to the applicable performance measures, as certified by the Compensation and Human Resources Committee following completion of the performance period.

Target Awards and Award Criteria. The Compensation and Human Resources Committee will set a target amount or target number of shares or units for each participant receiving an annual performance bonus or long-term performance award within 90 days after the start of a performance cycle. At that time, the Compensation and Human Resources Committee will also establish criteria for these awards, including the minimum level of performance that must be attained before any annual performance bonuses and long-term performance award will be paid or vest and the annual performance bonus amounts and the number of shares or units that will become payable upon attainment of various levels of performance. The Compensation and Human Resources Committee may select as the performance measure(s) any operating and maintenance expense targets or financial goals as interpreted by the Compensation and Human Resources Committee, either individually, alternatively or in any combination, applied to either the Company as a whole or to a business unit or subsidiary, either individually, alternatively or in any combination, and that are absolute or relative to the performance of one or more comparable companies or an index of comparable companies and are measured during the performance cycle, provided that, as to an annual performance bonus or long-term performance award granted to a key employee (which is defined in the Covidien SIP as being a covered employee for purposes of Code Section 162(m)), performance measures are limited to the following criteria and with respect to such awards granted to an employee other than a key employee, performance measures may include, but not be limited to the following: (a) cash flow, (b) earnings per share, (c) earnings before interest, taxes and amortization, (d) return on equity, (e) total stockholder return, (f) share price performance, (g) return on capital, (h) return on assets or net assets, (i) revenue, (j) income or net income, (k) operating income or net operating income, (l) operating profit or net operating profit, (m) operating margin or profit margin, (n) return on operating revenue, (o) return on invested capital, (p) market segment share, (q) product release schedules, (r) new product innovation, (s) product cost reduction through advanced technology, (t) brand recognition/acceptance, (u) product ship targets, or (v) customer satisfaction. Financial performance measures may take into account such adjustments as the Compensation and Human Resources Committee may specify, including the exclusion of unusual or infrequently occurring items; provided, however, that such adjustments shall not impact a key employee unless the Compensation and Human Resources Committee determines to make such adjustments no later than ninety (90) days after the commencement of the applicable performance cycle.

Dividends and Dividend Equivalents. At the discretion of the Compensation and Human Resources Committee, dividends paid on shares may be paid immediately or withheld and deferred in the participant s account. In the event of a payment of dividends on ordinary shares, the Compensation and Human Resources Committee may credit long-term performance awards with dividend equivalent units, which may be distributed immediately, withheld and deferred in the participant s account or credited in the form of additional share units. The Compensation and Human Resources Committee has issued long-term performance awards which are credited with dividend equivalent units, the payment of which is deferred until the underlying performance units vest. The Compensation and Human Resources Committee expects to continue this practice going forward.

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Restricted Stock, Restricted Units, and Deferred Stock Units. Restricted stock, restricted units, and deferred stock units may be awarded under the Covidien SIP to any employee selected by the Compensation and Human Resources Committee. Restricted units and deferred stock units may be settled in shares or cash. The Compensation and Human Resources Committee has the discretion to fix the terms and conditions applicable to awards of restricted stock, restricted units and deferred stock units, subject to the following:

Vesting. Unless the award certificate provides otherwise, any restrictions on restricted stock, restricted units, or deferred stock units will vest in equal annual installments over a four year period after the grant date. Unless the award certificate provides otherwise, any restrictions on restricted stock, restricted units, or deferred stock units that have not vested or been satisfied on the date of a participant s termination of employment will immediately vest in full or in part upon early or normal retirement, death or disability of the participant or certain terminations of employment following a change in control. Upon a termination of employment for any other reason, any unvested restricted units, deferred stock units or shares of restricted stock will be forfeited.

Dividends and Dividend Equivalents. At the discretion of the Compensation and Human Resources Committee, dividends paid on shares may be paid immediately or withheld and deferred in the participant s account. In the event of a payment of dividends on ordinary shares, the Compensation and Human Resources Committee may credit restricted units and deferred stock units with dividend equivalent units, which may be distributed immediately, withheld and deferred in the participant s account or credited in the form of additional share units. The Compensation and Human Resources Committee has issued restricted unit awards which are credited with dividend equivalent units, the payment of which is deferred until the underlying restricted units vest. The Compensation and Human Resources Committee expects to continue this practice going forward.

Director Awards. The Nominating and Governance Committee has the exclusive authority to issue awards to Directors, which may consist of, but not be limited to, restricted stock, restricted units, deferred stock units, stock options, stock appreciation rights, or other stock-based awards. Each director award is governed by an award certificate that is approved by the Nominating and Governance Committee.

Other Stock-Based Awards. The Compensation and Human Resources Committee may grant other share-based awards under the Covidien SIP that consist of, or are denominated in, ordinary shares. These awards may include phantom or hypothetical shares. The Compensation and Human Resources Committee has broad discretion to determine the terms and conditions that will apply to other stock-based awards. Unless the Compensation and Human Resources Committee provides otherwise in an award certificate, restrictions on other stock-based awards based solely on continued service will vest in equal annual installments over a four year period after the grant date.

Substitute Awards. The Compensation and Human Resources Committee may make awards to grantees of an acquired company through the assumption of, or in substitution for, outstanding stock-based awards previously granted to the grantees. The assumed or substituted awards will be subject to the terms and conditions of the original awards made by the acquired company, with any adjustments that the Compensation and Human Resources Committee considers necessary to comply with applicable law or appropriate to give effect to the relevant provisions of any agreement for the acquisition of the acquired company.

Adjustments. The kind or maximum number of ordinary shares available for issuance under the Covidien SIP, the individual and aggregate maximums that may be issued under each form of award, the number of ordinary shares underlying outstanding awards and the exercise price applicable to outstanding stock options and stock appreciation rights shall be appropriately adjusted by the Compensation and Human Resources Committee upon any stock split, reverse stock split, dividend or other distribution, extraordinary cash dividend, recapitalization, merger, consolidation, split-up, spin-off, reorganization, combination, repurchase or exchange of ordinary shares or other securities, or similar corporate transaction or event, to prevent dilution or enlargement of the benefits intended to be made available under the Covidien SIP.

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Change in Control. All outstanding stock options, stock appreciation rights and long-term performance awards will become exercisable and all outstanding restricted stock, restricted units and deferred stock units will vest if there is a change in control *and* the change of control results in a termination without cause, resignation for good reason or substitution of the awards for awards not payable in publicly-traded stock. Each participant who has been granted an annual performance bonus or long term performance award that is outstanding as of the date of a change in control will be deemed to have achieved a level of performance, as of the change in control, that would cause all of the participant s target amount to become payable, unless the successor entity maintains the annual performance plan and the actual level of performance achieved would result in an annual performance bonus that exceeds the participant s target amount, in which case bonuses based on actual performance shall be paid.

Restrictions on Transfer of Awards. No award issued under the Covidien SIP may be alienated, anticipated, sold, sold, assigned, pledged, encumbered or transferred, except that (a) awards may be transferred by will or by the laws of descent or distribution; (b) unless the award certificate provides otherwise, stock options may be transferred to a family member without consideration; and (c) restricted stock may be freely transferable after the restrictions lapse or are satisfied and the shares are delivered. For this purpose, a family member includes any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the Participant, including adoptive relationships, any person sharing the Participant s household (other than a tenant or employee), a trust in which these persons have more than 50% of the beneficial interest, a foundation in which these persons (or the Participant) control the management of assets, and any other entity in which these persons (or the Participant) own more than 50% of the voting interests.

Amendment and Termination. The Covidien SIP may be amended or terminated by our Board of Directors at any time without shareholder approval, except that any material revision to the terms of the Covidien SIP requires shareholder approval before it can be effective. A revision is material for this purpose if it materially increases the number of ordinary shares that may be issued under the plan, other than an increase pursuant to an adjustment as described above, materially expands the class of persons eligible to receive awards, materially extends the term of the plan, materially decreases the exercise price at which stock options or stock appreciation rights may be granted, reduces the exercise price of outstanding stock options or stock appreciation rights, results in the replacement of outstanding stock options or stock appreciation rights with awards that have a lower exercise price, or is otherwise an amendment requiring shareholder approval pursuant to any law or the rules of any exchange on which the Company s Ordinary Shares are listed for trading. If not earlier terminated and if the Covidien SIP receives shareholder approval at the Company s 2013 Annual General Meeting to be held on March 20, 2013, the Covidien SIP will terminate on November 14, 2022 (the day before the tenth anniversary of the adoption by the Board of Directors of the amendment and restatement of the Plan). No awards may be granted under the Covidien SIP after it is terminated, but any previously granted awards will remain in effect until they expire.

Code Section 162(m). Code Section 162(m) generally limits a company s annual deduction for compensation in excess of $1 million paid to certain executive officers (these executive officers are referred to in the Covidien SIP as key employees). Compensation paid to key employees is not subject to the deduction limitation, however, if it is considered qualified performance-based compensation within the meaning of Code Section 162(m). Awards of stock options, stock appreciation rights, annual performance bonuses, performance units, performance-based restricted units and performance-based restricted stock under the Covidien SIP can, but are not required to, satisfy this standard under Code Section 162(m).

Summary of Federal Income Tax Consequences of Awards

The following is a brief summary of the principal United States federal income tax consequences of the grant, exercise and disposition of stock options, stock appreciation rights, restricted stock, restricted units and deferred stock units under the Covidien SIP, based on advice received from our counsel regarding current U.S.

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federal income tax laws. This summary is not intended to be exhaustive and, among other things, does not describe state, local or foreign tax consequences. Because the federal income tax rules governing awards and related payments are complex, subject to frequent change, and depend on individual circumstances, participants should consult their tax advisors before exercising options or other awards or disposing of stock acquired pursuant to awards.

Nonqualified Stock Options and Stock Appreciation Rights. A participant will not recognize any income at the time a nonqualified stock option or stock appreciation right is granted, nor will we be entitled to a deduction at that time. When a nonqualified stock option is exercised, the participant will recognize ordinary income in an amount equal to the excess of the fair market value of the ordinary shares received as of the date of exercise over the exercise price. When a stock appreciation right is exercised, the participant will recognize ordinary income in an amount equal to the cash received or, if the stock appreciation right is paid in ordinary shares, the fair market value of the ordinary shares received as of the date of exercise. Payroll taxes are required to be withheld from the participant on the amount of ordinary income recognized by the participant. We generally will be entitled to a tax deduction with respect to a nonqualified stock option or stock appreciation right at the same time and in the same amount as the participant recognizes income. The participant s subsequent sale of the ordinary shares generally will give rise to capital gain or loss equal to the difference between the sale price and the sum of the exercise price the participant paid for the shares plus the ordinary income the participant recognized with respect to the shares, and these capital gains will be taxable as long-term capital gains if the participant held the shares for more than one year following exercise.

Incentive Stock Options. A participant will not recognize any income at the time an incentive stock option (ISO) is granted. Nor will a participant recognize any income at the time an ISO is exercised. However, the excess of the fair market value of the ordinary shares on the date of exercise over the exercise price paid will be a preference item that could create liability under the alternative minimum tax. If a participant disposes of ordinary shares acquired on exercise of an ISO after the later of two years after the date of grant of the ISO or one year after the date of exercise of the ISO (the holding period), the gain, if any, will be long-term capital gain eligible for favorable tax rates. If the participant disposes of such ordinary shares before the end of the holding period, the participant generally will recognize ordinary income in the year of the disposition equal to the excess of the lesser of (i) the fair market value of the ordinary shares on the date of exercise or (ii) the amount received for the ordinary shares, over the exercise price paid. The balance of the gain or loss, if any, will be short- or long-term capital gain or loss, depending on how long the ordinary shares were held by the participant prior to disposition. We are not entitled to a deduction as a result of the grant or exercise of an ISO unless a participant recognizes ordinary income as a result of a disposition, in which case we will be entitled to a deduction at the same time and in the same amount as the participant recognizes ordinary income.

Restricted Stock. Unless a participant makes an election to accelerate recognition of the income to the date of grant (as described below), the participant will not recognize income, and the Company will not be allowed a tax deduction, at the time a restricted stock award is granted. When the restrictions lapse, the participant will recognize ordinary income equal to the fair market value of the common stock as of that date (less any amount paid for the stock) and the Company will be allowed a corresponding federal income tax deduction. The participant s subsequent sale of the ordinary shares will give rise to capital gain or loss equal to the difference between the sale price and the ordinary income the participant recognized with respect to the shares, and any capital gains will be taxable as long-term gains if the participant held the shares for more than one year following the date on which restrictions lapsed. If the participant files an election under Section 83(b) of the Internal Revenue Code within 30 days of the date of grant of the restricted stock, the participant will recognize ordinary income as of the date of grant equal to the fair market value of the stock as of that date (less any amount paid for the stock) and the Company will be allowed a corresponding federal income tax deduction. The participant s subsequent sale of the ordinary shares will give rise to capital gain or loss equal to the difference between the sale price and the ordinary income the participant recognized with respect to the shares, and any capital gains will be taxable as long-term gains if the participant held the shares for more than one year following the date of grant. However, if the stock is later forfeited, the participant will not be able to recover the tax previously paid pursuant to a Section 83(b) election.

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Restricted Units/Deferred Stock Units. A participant will not recognize any income at the time a restricted unit or deferred stock unit is granted, nor will we be entitled to a deduction at that time. Instead, the value of shares delivered on or after the vesting of restricted units or deferred stock units generally will be taxable to the recipient as ordinary income when shares are delivered to the participant. The amount of the income recognized will be the fair market value of the shares on the date shares are delivered. We will generally receive a deduction for federal income tax purposes in an amount equal to the amount of compensation included in the participant s income. The participant s subsequent sale of the ordinary shares will give rise to capital gain or loss equal to the difference between the sale price and the ordinary income the participant recognized with respect to the shares, and any capital gains will be taxable as long-term gains if the participant held the shares for more than one year following the date on which they were delivered.

Non-Competition and Non-Solicitation Agreements

The Compensation and Human Resources Committee may condition eligibility to participate in the Covidien SIP and receipt of benefits specified in an award agreement, such as vesting and exercisability of awards, on the participant s execution of, compliance with and/or certification of compliance with a non-competition and/or non-solicitation agreement.

New Plan Benefits

Awards issued after the Company s 2013 Annual General Meeting to be held on March 20, 2013 are subject to the amended and restated Covidien SIP if shareholder approval is obtained. Subject to annual individual limits set forth in the Covidien SIP, the number and types of awards that will be granted to any one individual or category of individuals under the amended and restated Covidien SIP in the future are not determinable, as the Compensation and Human Resources Committee, in conjunction with the Board of Directors and, in the case of director awards, the Nominating and Governance Committee, will make these determinations in their sole discretion.

Resolution

The text of the resolution in respect of Proposal 4 is as follows:

RESOLVED, that approval be and hereby is given to the adoption by the Company of the Covidien Stock and Incentive Plan, as amended and restated on November 15, 2012, and in accordance with the provisions of a document entitled Covidien Stock and Incentive Plan (the Plan), which has been made available to shareholders prior to the meeting and that the directors be and hereby are authorized to take all such actions with reference to the Plan as may be necessary to ensure the adoption and operation of the Plan.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 4

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PROPOSAL 5:

AUTHORIZE THE COMPANY AND/OR ANY SUBSIDIARY OF THE COMPANY

TO MAKE MARKET PURCHASES OF COMPANY SHARES

We have historically used open-market share purchases as a means of returning cash to shareholders and managing the size of our base of outstanding shares. These are longstanding objectives that management believes are important to continue. During fiscal 2012, we repurchased approximately 17 million of our ordinary shares in open-market purchases (effected as redemptions) as part of our share repurchase program.

Under Irish law, neither the Company nor any subsidiary of the Company may make market purchases of the Company s shares without shareholder approval. Accordingly, shareholders are being asked to authorize the Company, or any of its subsidiaries, to make market purchases of up to 10% of the Company s issued shares. If adopted, this authority will expire at the close of business on September 20, 2014 unless renewed at the Annual General Meeting in 2014; we expect to propose renewal of this authorization at subsequent annual general meetings. Such purchases would be made only at price levels which the Directors considered to be in the best interests of the shareholders generally, after taking into account the Company s overall financial position. The Company currently effects repurchases under our existing share repurchase program as redemptions pursuant to Article 3(d) of our Articles of Association. Whether or not this proposed resolution is passed, the Company will retain its ability to effect repurchases as redemptions pursuant to its Articles of Association, although subsidiaries of the Company will not be able to make market purchases of the Company s shares.

In order for the Company or any of its subsidiaries to make market purchases of the Company s ordinary shares, such shares must be purchased on a recognized stock exchange . The New York Stock Exchange, on which the Company s ordinary shares are listed, is specified as a recognized stock exchange for this purpose by Irish law. The general authority, if approved by our shareholders, will become effective from the date of passing of the authorizing resolution.

Resolution

The text of the resolution in respect of Proposal 5 is as follows:

RESOLVED, that the Company and any subsidiary of the Company is hereby generally authorized to make market purchases of ordinary shares in the Company (shares) on such terms and conditions and in such manner as the board of directors of the Company may determine from time to time but subject to the provisions of the Companies Act 1990 and to the following provisions:

(a) The maximum number of shares authorized to be acquired by the Company and/or any subsidiary of the Company pursuant to this resolution shall not exceed, in the aggregate, 52,094,325 ordinary shares of US$0.20 each (which represents 10% of the Company s issued ordinary shares as of our 2012 fiscal year end).

(b) The maximum price to be paid for any ordinary share shall be an amount equal to 110% of the closing price on the New York Stock Exchange for the ordinary shares on the trading day preceding the day on which the relevant share is purchased by the Company or the relevant subsidiary of the Company, and the minimum price to be paid for any ordinary share shall be the nominal value of such share.

(c) This general authority will be effective from the date of passing of this resolution and will expire eighteen months from the date of the passing of this resolution, unless previously varied, revoked or renewed by special resolution in accordance with the provisions of section 215 of the Companies Act 1990. The Company or any such subsidiary may, before such expiry, enter into a contract for the purchase of shares which would or might be executed wholly or partly after such expiry and may complete any such contract as if the authority conferred hereby had not expired.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 5

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PROPOSAL 6:

AUTHORIZE THE PRICE RANGE AT WHICH

THE COMPANY CAN REISSUE SHARES THAT IT HOLDS AS TREASURY SHARES

Our historical open-market share repurchases (redemptions) and other share buyback activities result in ordinary shares being acquired and held by the Company as treasury shares. We may reissue treasury shares that we acquire through our various share buyback activities in connection with our executive compensation program, our Employee Stock Purchase Program and our other compensation programs.

Under Irish company law, our shareholders must authorize the price range at which we may reissue any shares held in treasury. In this proposal, that price range is expressed as a minimum and maximum percentage of the prevailing market price (as defined below). Under Irish law, this authorization expires after eighteen months unless renewed; accordingly, we expect to propose renewal of this authorization at subsequent annual general meetings.

The authority being sought from shareholders provides that the minimum and maximum prices at which an ordinary share held in treasury may be reissued are 95% and 120%, respectively, of the average closing price per ordinary share of the Company, as reported by the New York Stock Exchange, for the thirty (30) trading days immediately preceding the proposed date of re-issuance. Any reissuance of treasury shares will be at price levels that the Board considers in the best interests of our shareholders.

Special Resolution

The text of the resolution in respect of Proposal 6 (which is proposed as a special resolution) is as follows:

RESOLVED, that the reissue price range at which any treasury shares held by the Company may be reissued off-market shall be as follows:

(a) the maximum price at which such treasury share may be reissued off-market shall be an amount equal to 120% of the market price ; and

(b) the minimum price at which a treasury share may be reissued off-market shall be the nominal value of the share where such a share is required to satisfy an obligation under an employee share plan operated by the Company or, in all other cases, an amount equal to 95% of the market price ; and

(c) for the purposes of this resolution, the market price shall mean the average closing price per ordinary share of the Company, as reported by the New York Stock Exchange, for the thirty (30) trading days immediately preceding the proposed date of re-issuance.

FURTHER RESOLVED, that this authority to reissue treasury shares shall expire at eighteen months from the date of the passing of this resolution unless previously varied or renewed in accordance with the provisions of Section 209 of the Companies Act 1990.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 6

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PROPOSAL 7:

AMEND THE COMPANY S ARTICLES OF ASSOCIATION

TO EXPAND THE AUTHORITY TO EXECUTE AN INSTRUMENT OF TRANSFER

Pursuant to the Irish Companies Acts, the Company may not record a transfer of shares on its register of members unless an executed instrument of transfer has been delivered to the Company. Our Articles of Association currently provide that our Secretary or Assistant Secretary, as agent for a transferor, may execute and deliver an instrument of transfer on behalf of a transferor and that such an instrument of transfer signed by our Secretary or Assistant Secretary shall be a proper instrument of transfer for purposes of the Irish Companies Acts. The proposed amendment to our Articles of Association will provide transferors and the Company with greater efficiency and flexibility in creating the required instruments of transfer by allowing other persons, duly authorized and appointed by the Secretary or Assistant Secretary, to prepare, execute and deliver instruments of transfer on behalf of a transferor.

If approved, the proposed amendment would take effect immediately following shareholder approval.

Special Resolution

The text of the resolution in respect of Proposal 7 (which is proposed as a special resolution) is as follows:

RESOLVED, that the Company s Articles of Association be and hereby are amended by the insertion into Article 13(a) of the underlined language below and deletion of the struck-through language below:

13. (a) The instrument of transfer of any share may be executed for and on behalf of the transferor by the Secretary ~~or,~~ an Assistant Secretary or any duly authorized delegate or attorney of the Secretary or Assistant Secretary (whether an individual, a corporation or other body of persons, whether corporate or not, and whether in respect of specific transfers or pursuant to a general standing authorization), and the Secretary ~~or,~~ Assistant Secretary or a relevant authorized delegate shall be deemed to have been irrevocably appointed agent for the transferor of such share or shares with full power to execute, complete and deliver in the name of and on behalf of the transferor of such share or shares all such transfers of shares held by the members in the share capital of the Company. Any document which records the name of the transferor, the name of the transferee, the class and number of shares agreed to be transferred, the date of the agreement to transfer shares and the price per share, shall, once executed by the transferor or the Secretary or, Assistant Secretary ~~or~~ a relevant authorized delegate as agent for the transferor, be deemed to be a proper instrument of transfer for the purposes of section 81 of the Act. The transferor shall be deemed to remain the Holder of the share until the name of the transferee is entered on the Register in respect thereof, and neither the title of the transferee nor the title of the transferor shall be affected by any irregularity or invalidity in the proceedings in reference to the sale should the Directors so determine.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 7

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PROPOSAL 8:

CREATION OF MALLINCKRODT DISTRIBUTABLE RESERVES

We have disclosed that we plan to spin-off our pharmaceuticals business into a standalone public company. We currently anticipate that the spin-off will involve the transfer of our pharmaceuticals business to a newly formed Irish public limited company called Mallinckrodt plc in return for which Mallinckrodt will issue shares to Covidien shareholders on a pro-rata basis. In order to help ensure that Mallinckrodt has the flexibility to pay dividends if and when its Board of Directors determines to do so following the spin-off, we are asking Covidien shareholders to approve the proposal described below.

Under Irish law, Mallinckrodt must have distributable reserves in its unconsolidated balance sheet (prepared in accordance with the Irish Companies Acts) in order for it to legally make distributions (including the payment of cash dividends) to its shareholders, or to buy back shares. Distributable reserves generally means the accumulated realized profits of Mallinckrodt less accumulated realized losses of Mallinckrodt and can include reserves created by way of capital reductions. Dividends and distributions by Mallinckrodt would also be subject to additional limitations under Irish law.

Immediately following the spin-off, the unconsolidated balance sheet of Mallinckrodt will not contain any distributable reserves, and shareholders equity in such balance sheet will be comprised entirely of share capital (equal to the aggregate par value of the Mallinckrodt shares issued pursuant to the spin-off) and share premium (resulting from the issuance of Mallinckrodt shares as part of the spin-off and equal to (a) the aggregate market value of our pharmaceuticals business at the time of its transfer to Mallinckrodt, less (b) the share capital).

We expect that, as soon as practicable following the completion of the spin-off, Mallinckrodt will seek to obtain the approval of the High Court of Ireland to convert all of its share premium, or such lesser amount as the directors of Mallinckrodt may approve, to distributable reserves, which we refer to as the Mallinckrodt distributable reserves creation. The approval of the High Court of Ireland is required for the Mallinckrodt distributable reserves creation to be effective, and we believe that approval by Covidien shareholders of the Mallinckrodt distributable reserves creation would facilitate obtaining the required order of the High Court of Ireland. Accordingly, we are proposing that Covidien shareholders approve the Mallinckrodt distributable reserves creation at the 2013 Annual General Meeting.

Shareholder approval of the Mallinckrodt distributable reserves creation is not a guarantee that the spin-off will occur or that, if it occurs, Mallinckrodt will pay dividends at any time. The Covidien Board of Directors may decide not to spin-off the pharmaceuticals business, and, even if the spin-off is completed, the Mallinckrodt Board of Directors may decide not to pay dividends. In addition, shareholder approval is not a guarantee that the High Court of Ireland will approve the Mallinckrodt distributable reserves creation. Although we are not aware of any reason why the High Court of Ireland would not approve the Mallinckrodt distributable reserves creation, there is no guarantee that such approval will be forthcoming.

Resolution

The text of the advisory resolution in respect of Proposal 8 is as follows:

IT IS RESOLVED THAT:

(i) a reduction of the share premium of Mallinckrodt created by the issue of shares by Mallinckrodt pursuant to the proposed spin-off (including the proposed transfer of Covidien plc s pharmaceutical business to Mallinckrodt), including a reduction of all of such share premium or such lesser amount as the directors of Mallinckrodt may approve; and

(ii) the treatment of the reserves resulting from such a reduction of share premium as profits available for distribution (as defined by section 45 of the Companies (Amendment) Act 1983 of Ireland) of Mallinckrodt,

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be and are hereby approved, in each case subject to the confirmation of the High Court of Ireland of the reduction of the share premium. For the purposes of this resolution Mallinckrodt means the company to which the pharmaceutical business of Covidien is transferred pursuant to the proposed spin-off.

Unless otherwise instructed, the proxies will vote FOR this resolution.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS

THAT YOU VOTE FOR THE RESOLUTION SET FORTH IN PROPOSAL 8

OTHER MATTERS

Presentation of Irish Statutory Accounts

The Company s Irish Statutory Accounts for the fiscal year ended September 28, 2012, including the reports of the Directors and auditors thereon, will be presented at the Annual General Meeting. The Company s Irish Statutory Accounts have been approved by the Board of Directors of the Company. There is no requirement under Irish law that such statements be approved by shareholders, and no such approval will be sought at the Annual General Meeting. The Company s Irish Statutory Accounts are available with the Proxy Statement, the Company s Annual Report and other proxy materials at *www.proxyvote.com* and in the Investor Relations section of our website at *www.covidien.com.*

Registered and Principal Executive Offices

The registered and principal executive offices of Covidien are located at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland. The telephone number there is +353 1 438-1700.

Shareholder Proposals for the 2014 Annual General Meeting

In accordance with the rules established by the SEC, as well as under the provisions of our Articles of Association, any shareholder proposal submitted pursuant to Rule 14a-8 under the U.S. Securities Exchange Act of 1934 (the Exchange Act) intended for inclusion in the Proxy Statement for next year s Annual General Meeting must be received by us no later than September 26, 2013. Such proposals should be sent to our Secretary at Covidien plc, 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland. To be included in the Proxy Statement, the proposal must comply with the requirements as to form and substance established by the SEC and our Articles of Association and must be a proper subject for shareholder action under Irish law.

A shareholder may otherwise propose business for consideration or nominate persons for election to the Board in compliance with U.S. federal proxy rules, Irish law and other legal requirements, without seeking to have the proposal included in our Proxy Statement pursuant to Rule 14a-8 under the Exchange Act. To bring a proposal before next year s annual general meeting, a shareholder must deliver written notice of the proposed business to the Company s Secretary at our registered office on or before September 26, 2013 and otherwise comply with the requirements of our Articles of Association.

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United States Securities and Exchange Commission Reports

Copies of our Annual Report on Form 10-K for the fiscal year ended September 28, 2012, as filed with the SEC (without exhibits), are available to shareholders free of charge on our website at *www.covidien.com* or by writing to our Secretary at Covidien plc, 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland.

Delivery of Documents to Shareholders Sharing an Address

If you have requested a paper copy of our proxy materials, our Annual Report, including our audited financial statements for the year ended September 28, 2012, is being mailed to you along with this Proxy Statement. In order to reduce printing and postage costs, only one Annual Report and one Proxy Statement will be mailed to multiple shareholders sharing an address unless the Company receives contrary instructions from one or more of the shareholders sharing an address. If your household has received only one Annual Report and one Proxy Statement, the Company will deliver promptly a separate copy of such documents to any shareholder who contacts the Company at +353 1 438-1700 or sends a written request to Covidien plc, 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland, Attention: Company Secretary. If your household is receiving multiple copies of the Company s annual reports or proxy statements and you wish to request delivery of a single copy, you may send a written request to Covidien plc, 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland, Attention: Company Secretary.

General

Your proxy is solicited on behalf of our Board of Directors. Unless otherwise directed, proxies held by the Chief Executive Officer, the Chief Financial Officer and the General Counsel will be voted at the Annual General Meeting (or an adjournment or postponement thereof), FOR Proposals 1 8. If any matter other than those described in this Proxy Statement properly comes before the Annual General Meeting, or with respect to any adjournment or postponement thereof, the Chief Executive Officer, Chief Financial Officer or General Counsel will vote the ordinary shares represented by such proxies in accordance with his discretion.

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Appendix A

COVIDIEN STOCK AND INCENTIVE PLAN

AS AMENDED AND RESTATED ON NOVEMBER 21, 2008 AND JUNE 4, 2009, ASSUMED BY

COVIDIEN PUBLIC LIMITED COMPANY ON JUNE 4, 2009 AND FURTHER AMENDED AND

RESTATED ON NOVEMBER 15, 2012

ARTICLE I

PURPOSE

1.1. *Purpose.* The purposes of this Covidien Stock and Incentive Plan as amended and restated (the Plan) are to promote the interests of Covidien public limited company (and any successor thereto) by (i) aiding in the recruitment and retention of Directors and Employees, (ii) providing incentives to Directors and Employees by means of performance-related incentives to achieve short-term and long-term performance goals, (iii) providing Directors and Employees with an opportunity to participate in the growth and financial success of the Company, and (iv) promoting the growth and success of the Company s business by aligning the financial interests of Directors and Employees with that of the other shareholders of the Company. Toward these objectives, the Plan provides for the grant of Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards and Other Stock-Based Awards.

1.2. *Effective Date; Shareholder Approval.* The Plan was amended and restated on November 21, 2008, and such amendment and restatement was approved by the shareholders of Covidien Ltd. at its 2009 annual general meeting held on March 18, 2009. The Plan was amended and restated on June 4, 2009, to reflect its assumption by Covidien public limited company. The Plan was further amended and restated on November 15, 2012, subject to approval of the Company s shareholders at the Company s 2013 Annual General Meeting to be held on March 20, 2013.

ARTICLE II

DEFINITIONS

For purposes of the Plan, the following terms have the following meanings, unless another definition is clearly indicated by particular usage and context:

Acquired Company means any business, corporation or other entity acquired by the Company or any Subsidiary.

Acquired Grantee means the grantee of a stock-based award of an Acquired Company and may include a current or former Director of an Acquired Company.

Annual Performance Bonus means an Award of cash or Shares granted under Section 4.4 of the Plan that is paid solely on account of the attainment of a specified performance target in relation to one or more Performance Measures.

Award means any form of incentive or performance award granted under the Plan, whether singly or in combination, to a Participant by the Committee pursuant to any terms and conditions that the Committee may establish and set forth in the applicable Award Certificate. Awards granted under the Plan may consist of:

(a) *Stock Options* awarded pursuant to Section 4.3;

(b) *Stock Appreciation Rights* awarded pursuant to Section 4.3;

(c) *Annual Performance Bonuses* awarded pursuant to Section 4.4;

(d) *Long-Term Performance Awards* awarded pursuant to Section 4.5;

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(e) *Other Stock-Based Awards* awarded pursuant to Section 4.6;

(f) *Director Awards* awarded pursuant to Section 4.7; and

(g) *Substitute Awards* awarded pursuant to Section 4.8.

Award Certificate means the document issued, either in writing or an electronic medium, by the Committee or its designee to a Participant evidencing the grant of an Award and which contains, in the same or accompanying document, the terms and conditions applicable to such Award.

Board means the Board of Directors of the Company.

Cause means, as to any Employee who is a party to an employment agreement with the Company or any Subsidiary which contains a definition of cause, as set forth in such employment agreement and, if there is no applicable employment agreements, means an Employee s or Director s (i) substantial failure or refusal to perform duties and responsibilities of his or her job as required by the Company or Subsidiary, (ii) violation of any fiduciary duty owed to the Company or Subsidiary, (iii) conviction of a misdemeanor (other than a traffic offense) or felony, (iv) dishonesty, (v) theft, (vi) violation of Company or Subsidiary rules or policy, or (vii) other egregious conduct, that has or could have a serious and detrimental impact on the Company or Subsidiary and its employees. The Committee (or the Nominating Committee solely with respect to Director Awards), in its sole and absolute discretion, shall determine Cause.

Change in Control means the first to occur of any of the following events:

(a) any person (as defined in Section 13(d) and 14(d) of the Exchange Act, excluding for this purpose, (i) the Company or any Subsidiary or (ii) any employee benefit plan of the Company or any Subsidiary (or any person or entity organized, appointed or established by the Company for or pursuant to the terms of any such plan that acquires beneficial ownership of voting securities of the Company), is or becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act) directly or indirectly of securities of the Company representing more than 30 percent of the combined voting power of the Company s then outstanding securities; provided, however, that no Change in Control will be deemed to have occurred as a result of a change in ownership percentage resulting solely from an acquisition of securities by the Company; or

(b) persons who, as of the Effective Date constitute the Board (the Incumbent Directors) cease for any reason (including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction) to constitute at least a majority thereof, provided that any person becoming a Director of the Company subsequent to the Effective Date shall be considered an Incumbent Director if such person s election or nomination for election was approved by a vote of at least 50 percent of the Incumbent Directors; but provided further, that any such person whose initial assumption of office is in connection with an actual or threatened proxy contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a person (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director; or

(c) consummation of a reorganization, merger or consolidation or sale or other disposition of at least 80 percent by value of the assets of the Company (a Business Combination), in each case, unless, following such Business Combination, all or substantially all of the individuals and entities who were the beneficial owners of outstanding voting securities of the Company immediately prior to such Business Combination beneficially own directly or indirectly more than 50 percent of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, of the company resulting from such Business Combination (including, without limitation, a company which, as a result of such transaction, owns the Company or all or substantially all of the Company s assets either directly or through one or more Subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Business Combination, of the outstanding voting securities of the Company; or

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(d) approval by the shareholders of the Company of a complete liquidation or dissolution of the Company.

Change in Control Termination means a Participant s involuntary termination of employment that occurs during the twelve (12) month period immediately following a Change in Control. For this purpose, subject to Section 7.11(b)(ii), a Participant s involuntary termination of employment includes only the following:

(a) termination of the Participant s employment by the Company for any reason other than for Cause, Disability or death;

(b) termination of the Participant s employment by the Participant after one of the following events, provided that the Participant s termination of employment occurs within sixty (60) days after the occurrence of any such event:

(i) the Company (1) assigns or causes to be assigned to the Participant duties inconsistent in any material respect with his or her position as in effect immediately prior to the Change in Control; (2) makes or causes to be made any material adverse change in the Participant s position (including titles and reporting relationships and level), authority, duties or responsibilities; or (3) takes or causes to be taken any other action which, in the reasonable judgment of the Participant, would cause him or her to violate his or her ethical or professional obligations, or which results in a significant diminution in such position, authority, duties or responsibilities; or

(ii) the Company, without the Participant s consent, (1) requires the Participant to relocate to a principal place of employment more than fifty (50) miles from his or her existing place of employment and which increases the Participant s commute from his or her principal residence by more than fifty (50) miles; or (2) reduces the Participant s base salary, annual bonus, or retirement, welfare, share incentive, perquisite (if any) and other benefits taken as a whole;

provided, however, that an event described in (i) or (ii) above shall permit a Participant s termination of employment to be deemed a Change in Control Termination only if written notice of such event has been provided by the Participant to the Company and the Company failed to cure such action within a fifteen (15) day period following receipt of such notice.

Code means the United States Internal Revenue Code of 1986, as amended.

Committee means the Compensation and Human Resources Committee of the Board or any successor committee or other committee to which the Compensation and Human Resources Committee delegates its authority under this Plan. The Compensation and Human Resources Committee shall be comprised solely of non-employee directors within the meaning of Rule 16b-3(b)(3) under the Exchange Act and two or more persons who are outside directors within the meaning of Section 162(m)(4)(C)(i) of the Code and the applicable regulations.

Company means Covidien public limited company, a company incorporated in Ireland under registered number 466385, or any successor thereto.

Deferred Stock Unit means a Unit granted under Section 4.6 or 4.7 to acquire Shares upon Termination of Directorship or Termination of Employment, subject to any restrictions that the Committee, in its discretion, may determine.

Director means a member of the Board.

Disabled or *Disability* means, subject to Section 7.11(b)(iii), that the Employee has a permanent and total incapacity from engaging in any employment for the Company or Subsidiary for physical or mental reasons. A Disability shall be deemed to exist if the Employee is designated with an inactive employment status at the end of a disability or medical leave or if the Employee meets the requirements for disability benefits under (i) the Company s or Subsidiary s long-term disability plan or (ii) the Social Security law then in effect, for Employees who are on the payroll of any United States Subsidiary.

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Dividend Equivalent means an amount equal to the cash dividend or the fair market value of the share dividend that would be paid on each Share underlying an Award if the Share were duly issued and outstanding on the date on which the dividend is payable.

Effective Date means June 4, 2009, unless otherwise provided herein.

Employee means any individual who performs services as an officer or employee of the Company or a Subsidiary.

Exchange Act means the United States Securities Exchange Act of 1934, as amended.

Exercise Price means the price of a Share, as fixed by the Committee, which may be purchased under a Stock Option or with respect to which the amount of any payment pursuant to a Stock Appreciation Right is determined.

Fair Market Value of a Share means the closing sales price on the New York Stock Exchange of a Share on the trading day of the grant or on the date as of which the determination of Fair Market Value is being made or, if no sale is reported for such day, on the next preceding day on which a sale of Shares is reported. Notwithstanding anything to the contrary herein, the Fair Market Value of a Share will in no event be determined to be less than par value.

GAAP means United States generally accepted accounting principles.

Incentive Stock Option means a Stock Option granted under Section 4.3 of the Plan that is intended to meet the requirements of Section 422 of the Code and any related regulations and is designated in the Award Certificate as intended to be an Incentive Stock Option.

Key Employee means an Employee who is a covered employee within the meaning of Section 162(m)(3) of the Code or who is reasonably expected to be a covered employee at the time the Company would be entitled to claim a tax deduction in respect of an Award but for Section 162(m) of the Code.

Long-Term Performance Award means an Award granted under Section 4.5 of the Plan that is paid solely on account of the attainment of a specified performance target in relation to one or more Performance Measures or other performance criteria as selected in the sole discretion of the Committee.

Nominating Committee means the Nominating and Governance Committee the Board.

Nonqualified Stock Option means any Stock Option granted under Section 4.3 of the Plan that is not an Incentive Stock Option.

Normal Retirement means Termination of Employment on or after a Participant has attained age 60, provided that the sum of the Participant s age and years of service with the Company or a Subsidiary is 70 or higher.

Ordinary Shares means the ordinary shares of the Company, $0.20 (U.S.) par value, and such other securities or property as may become subject to Awards pursuant to an adjustment made under Section 5.3 of the Plan.

Other Stock-Based Award means an Award granted under Section 4.6 of the Plan and denominated in Shares.

Participant means a Director, Employee or Acquired Grantee who has been granted an Award under the Plan.

Performance Cycle means, with respect to any Award that vests based on Performance Measures, the period of 12 months or longer over which the level of performance will be assessed. The first Performance Cycle under the Plan will begin on such date as is set by the Committee, in its sole discretion.

Performance Measure means, with respect to any Annual Performance Bonus or Long-Term Performance Award, the business criteria selected by the Committee to measure the level of performance of the Company during a Performance Cycle. The Committee may select as the Performance Measure any

operating and maintenance expense targets or financial goals as interpreted by the Committee, either individually, alternatively or in any combination, applied to either the Company as a whole or to a business unit or Subsidiary, either individually, alternatively or in any combination, and that are absolute or relative to the performance of one or more comparable companies or an index of comparable companies, and are measured during the Performance Cycle provided that (i) as to an Annual Performance Bonus or Long-Term Performance Award granted to a Key Employee, Performance Measures shall be limited to the following criteria and (ii) as to an Annual Performance Bonus or Long-Term Performance Award granted to a Participant who is not a Key Employee, Performance Measures may include, but not be limited to, the following criteria: (a) cash flow, (b) earnings per share, (c) earnings before interest, taxes and amortization, (d) return on equity, (e) total shareholder return, (f) share price performance, (g) return on capital, (h) return on assets or net assets, (i) revenue, (j) income or net income, (k) operating income or net operating income, (l) operating profit or net operating profit, (m) operating margin or profit margin, (n) return on operating revenue, (o) return on invested capital, (p) market segment share, (q) product release schedules, (r) new product innovation, (s) product cost reduction through advanced technology, (t) brand recognition/acceptance, (u) product ship targets, or (v) customer satisfaction.

Performance Unit means a Long-Term Performance Award denominated in Units.

Plan means this Covidien Stock and Incentive Plan as most recently amended and restated on November 15, 2012, subject to approval of the Company s shareholders at the Company s Annual General Meeting on March 20, 2012.

Premium-Priced Stock Option means a Stock Option the Exercise Price of which is fixed by the Committee at a price that exceeds the Fair Market Value of a Share on the date of grant.

Reporting Person means a Director or an Employee who is subject to the reporting requirements of Section 16(a) of the Exchange Act.

Restricted Stock means Shares issued pursuant to Section 4.6 that are subject to any restrictions that the Committee, in its discretion, may impose.

Restricted Unit means a Unit granted under Section 4.5 or Section 4.6 to acquire Shares or an equivalent amount in cash, which Unit is subject to any restrictions that the Committee, in its discretion, may impose.

Securities Act means the United States Securities Act of 1933, as amended.

Share means an Ordinary Share of the Company, and *Shares* shall be construed accordingly.

Stock Appreciation Right means a right granted under Section 4.3 of the Plan of an amount in cash or Shares equal to any excess of the Fair Market Value of a Share as of the date on which the right is exercised over the Exercise Price.

Stock Option means a right granted under Section 4.3 of the Plan to purchase from the Company a stated number of Shares at a specified price. Stock Options awarded under the Plan may be in the form of Incentive Stock Options or Nonqualified Stock Options.

Subsidiary means (i) a subsidiary company (wherever incorporated) of the Company, as defined by Section 155 of the Companies Act 1963 of Ireland; (ii) any separately organized business unit, whether or not incorporated, of the Company; (iii) any employer that is required to be aggregated with the Company pursuant to Code Section 414 and the regulations promulgated thereunder; and (iv) any service recipient or employer that is within a controlled group of corporations as defined in Code Sections 1563(a)(1), (2) and (3) which includes the Company, where the phrase at least 50% is substituted in each place at least 80% appears, and any service recipient or employer within trades or businesses under common control as defined in Code Section 414(c) and Treas. Reg. § 1.414(c)-2, which includes the Company, where the phrase at least 50% is substituted in each place at least 80% appears, provided, however, that when the relevant determination is to be based upon legitimate business criteria (as described in Treas. Reg. § 1.409A-1(b)(5)(iii)(E) and § 1.409A-1(h)(3)), the phrase at least 20% shall be substituted in each place at least 80% appears as described above with respect to both a controlled group of corporations and trades or business under common control.

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Target Amount means the amount of Performance Units that will be paid if the applicable Performance Measure is fully (100%) attained, as determined in the sole discretion of the Committee.

Target Bonus means the target Annual Performance Bonus applicable to a Reporting Person in respect of a particular year, as established by the Committee or its delegate.

Target Vesting Percentage means the percentage of performance-based Restricted Units or Shares of Restricted Stock that will vest if the applicable Performance Measure is fully (100%) attained, as determined in the sole discretion of by the Committee.

Termination of Directorship means the date of cessation of a Director s membership on the Board for any reason, with or without Cause, as determined in the sole discretion of the Nominating Committee, provided however that if the Director is a member of the Nominating Committee, such determination shall be made by the full Board (excluding such Director).

Termination of Employment means the date of cessation of an Employee s employment relationship with the Company or a Subsidiary for any reason, with or without Cause, as determined in the sole discretion of the Company.

Unit means, for purposes of Performance Units, the potential right to an Award equal to a specified amount denominated in such form as is deemed appropriate in the discretion of the Committee and, for purposes of Restricted Units or Deferred Stock Units, the potential right to acquire one Share.

ARTICLE III

ADMINISTRATION

3.1. *Committee.* The Plan will be administered by the Committee, except as otherwise provided in Section 4.7.

3.2. *Authority of the Committee.* The Committee or, to the extent required by applicable law, the Board will have the authority, in its sole and absolute discretion and subject to the terms of the Plan, to:

(a) Interpret and administer the Plan and any instrument or agreement relating to the Plan;

(b) Prescribe the rules and regulations that it deems necessary for the proper operation and administration of the Plan, and amend or rescind any existing rules or regulations relating to the Plan;

(c) Select Employees to receive Awards under the Plan;

(d) Determine the form of an Award, the number of Shares subject to each Award, all the terms and conditions of an Award, including, without limitation, the conditions on exercise or vesting, the designation of Stock Options as Incentive Stock Options or Nonqualified Stock Options, and the circumstances under which an Award may be settled in cash or Shares or may be cancelled, forfeited or suspended, and the terms of each Award Certificate;

(e) Determine whether Awards will be granted singly, in combination or in tandem;

(f) Establish and interpret Performance Measures (or, as applicable, other performance criteria) in connection with Annual Performance Bonuses and Long-Term Performance Awards, evaluate the level of performance over a Performance Cycle and certify the level of performance attained with respect to Performance Measures (or other performance criteria, as applicable);

(g) Subject to Sections 6.1 and 7.12, waive or amend any terms, conditions, restriction or limitation on an Award, except that the prohibition on the repricing of Stock Options and Stock Appreciation Rights, as described in Section 4.3(g), may not be waived;

(h) Make any adjustments to the Plan (including but not limited to adjustment of the number of Shares available under the Plan or any Award) and any Award granted under the Plan as shall be appropriate pursuant to Section 5.3;

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(i) Determine and set forth in the applicable Award Certificate the circumstances under which Awards may be deferred and the extent to which a deferral will be credited with Dividend Equivalents and interest thereon;

(j) Determine and set forth in the applicable Award Certificate whether a Nonqualified Stock Option or Restricted Share may be transferable to family members, a family trust or a family partnership;

(k) Establish any subplans and make any modifications to the Plan, without amending the Plan, or to Awards made hereunder (including the establishment of terms and conditions in the Award Certificate not otherwise inconsistent with the terms of the Plan) that the Committee may determine to be necessary or advisable for grants made in countries outside the United States to comply with, or to achieve favorable tax treatment under, applicable foreign laws or regulations or tax policies or customs;

(l) Appoint such agents as it shall deem appropriate for the proper administration of the Plan; and

(m) Take any and all other actions it deems necessary or advisable for the proper operation or administration of the Plan.

3.3. *Effect of Determinations.* All determinations of the Committee will be final, binding and conclusive on all persons having an interest in the Plan.

3.4. *Delegation of Authority.* The Board or, if permitted under applicable corporate law, the Committee, in its discretion and consistent with applicable law and regulations, may delegate to a committee or an officer or group of officers, as it deems to be advisable, the authority to select Employees to receive an Award and to determine the number of Shares under any such Award, subject to any terms and conditions that the Board or the Committee may establish. When the Board or the Committee delegates authority pursuant to the foregoing sentence, it will limit, in its discretion, the number or value of Shares that may be subject to Awards that the delegate may grant. Only the Committee has the authority to grant and administer Awards to Key Employees and other Reporting Persons or to delegates of the Committee, and to establish and certify Performance Measures.

3.5. *Employment of Advisors.* The Committee may employ attorneys, consultants, accountants and other advisors, the fees and other expenses of which shall be paid by the Company, and the Committee, the Company and the officers and directors of the Company may rely upon the advice, opinions or valuations of the advisors employed.

3.6. *No Liability.* No member of the Committee or any person acting as a delegate of the Committee with respect to the Plan will be liable for any losses resulting from any action, interpretation or construction made in good faith with respect to the Plan or any Award granted under the Plan.

ARTICLE IV

AWARDS

4.1. *Eligibility.* All Participants and Employees are eligible to be designated to receive Awards granted under the Plan, except as otherwise provided in this Article IV.

4.2. *Form of Awards.* Awards will be in the form determined by the Committee, in its discretion, and will be evidenced by an Award Certificate. Awards may be granted singly or in combination or in tandem with other Awards.

4.3. *Stock Options and Stock Appreciation Rights.* The Committee may grant Stock Options and Stock Appreciation Rights under the Plan to those Employees whom the Committee may from time to time select, in the amounts and pursuant to the other terms and conditions that the Committee, in its discretion, may determine and set forth in the Award Certificate, subject to the provisions below:

(a)

Form. Stock Options granted under the Plan will, at the discretion of the Committee and as set forth in the Award Certificate, be in the form of Incentive Stock Options, Nonqualified Stock Options or a combination of the two. If an Incentive Stock Option and a Nonqualified Stock Option are granted to

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the same Participant under the Plan at the same time, the form of each will be clearly identified, and they will be deemed to have been granted in separate grants. In no event will the exercise of one Stock Option affect the right to exercise the other Stock Option. Stock Appreciation Rights may be granted either alone or concurrently with Nonqualified Stock Options and the amount of Shares attributable to each Stock Appreciation Right shall be set forth in the applicable Award Certificate on or before the grant date.

(b) *Exercise Price.* The Committee will set the Exercise Price of Stock Options (other than Premium-Priced Stock Options or certain Incentive Stock Options as described below) or Stock Appreciation Rights granted under the Plan at a price that is equal to the Fair Market Value of a Share on the date of grant, subject to adjustment as provided in Section 5.3. The Committee will set the Exercise Price of Premium-Priced Stock Options at a price that is higher than the Fair Market Value of a Share as of the date of grant, provided that such price is no higher than 150 percent of such Fair Market Value. The Exercise Price of Incentive Stock Options will be equal to or greater than 110 percent of the Fair Market Value of a Share as of the date of grant if the Participant receiving the Incentive Stock Options owns shares possessing more than 10 percent of the total combined voting power of all classes of shares of the Company or any subsidiary or parent corporation of the Company, as defined in Section 424 of the Code. The Exercise Price of a Stock Appreciation Right granted in tandem with a Stock Option will equal the Exercise Price of the related Stock Option. The Committee will set forth the Exercise Price of a Stock Option or Stock Appreciation Right in the Award Certificate or accompanying documentation.

(c) *Term and Timing of Exercise.* Each Stock Option or Stock Appreciation Right granted under the Plan will be exercisable in whole or in part, subject to the following conditions, unless determined otherwise by the Committee:

(i) The term of each Stock Option shall be determined by the Committee and set forth in the applicable Award Certificate, but in no event shall the term of a Stock Option exceed ten (10) years from the date of its grant.

(ii) A Stock Option or Stock Appreciation Right will become exercisable at such times and in such manner as determined by the Committee and set forth in the applicable Award Certificate.

(iii) Unless the applicable Award Certificate provides otherwise, upon the death, Disability, Normal Retirement or a Change in Control Termination of a Participant who has outstanding Stock Options or Stock Appreciation Rights, the unvested Stock Options or Stock Appreciation Rights will fully vest. Unless the applicable Award Certificate or the remainder of this Section 4.3(c) provides otherwise, the Participant s Stock Options and Stock Appreciation Rights will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is three (3) years after the date on which the Participant dies, incurs a Disability or retires due to Normal Retirement.

(iv) Unless the applicable Award Certificate provides otherwise, upon the Termination of Employment of a Participant for any reason other than the Participant s death, Disability, Normal Retirement or a Change in Control Termination, if the Participant has attained age 55 and the sum of the Participant s age and years of service with the Company or a Subsidiary is 60 or higher, a pro rata portion of the Participant s Stock Options and Stock Appreciation Rights will vest so that the total number of vested Stock Options or Stock Appreciation Rights held by the Participant at Termination of Employment (including those that have already vested as of such date) will be equal to the total number of Stock Options or Stock Appreciation Rights originally granted to the Participant under the applicable Award multiplied by a fraction, the numerator of which is the period of time (in whole months) that have elapsed since the date of grant, and the denominator of which is the number of months set forth in the applicable Award Certificate that is required to attain full vesting. Unless the Award Certificate provides otherwise, such Participant s Stock Options and Stock Appreciation Rights will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is three (3) years after the date of Termination of Employment.

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(v) Unless the applicable Award Certificate provides otherwise, upon the Termination of Employment of a Participant that does not meet the requirements of paragraphs (ii) or (iii) above, any unvested Stock Options or Stock Appreciation Rights will be forfeited. Unless the applicable Award Certificate provides otherwise, any Stock Options or Stock Appreciation Rights that are vested as of such Termination of Employment will lapse, and will not thereafter be exercisable, upon the earlier of (A) their original expiration date or (B) the date that is ninety (90) days after the date of such Termination of Employment.

(vi) Stock Options and Stock Appreciation Rights of a deceased Participant may be exercised only by the estate of the Participant or by the person given authority to exercise the Stock Options or Stock Appreciation Rights by the Participant s will or by operation of law. If a Stock Option or Stock Appreciation Right is exercised by the executor or administrator of a deceased Participant, or by the person or persons to whom the Stock Option or Stock Appreciation Right has been transferred by the Participant s will or the applicable laws of descent and distribution, the Company will be under no obligation to deliver Shares or cash until the Company is satisfied that the person exercising the Stock Option or Stock Appreciation Right is the duly appointed executor or administrator of the deceased Participant or the person to whom the Stock Option or Stock Appreciation Right has been transferred by the Participant s will or by applicable laws of descent and distribution.

(vii) A Stock Appreciation Right granted in tandem with a Stock Option is subject to the same terms and conditions as the related Stock Option and will be exercisable only to the extent that the related Stock Option is exercisable. When either a Stock Option or a Stock Appreciation Right granted in tandem with each other is exercised, the tandem Stock Option or Stock Appreciation Right, as applicable, shall expire.

(d) *Payment of Exercise Price.* The Exercise Price of a Stock Option must be paid in full when the Stock Option is exercised. Shares will be issued and delivered only upon receipt of payment. Payment of the Exercise Price may be made in cash or by certified check, bank draft, wire transfer, or postal or express money order, provided that the format is approved by the Company or a designated third-party administrator. The Committee, in its discretion may also allow payment to be made by any of the following methods, as set forth in the applicable Award Certificate:

(i) Delivering a properly executed exercise notice to the Company or its agent, together with irrevocable instructions to a broker to deliver to the Company, within the typical settlement cycle for the sale of equity securities on the relevant trading market (or otherwise in accordance with the provisions of Regulation T issued by the Federal Reserve Board), the amount of sale proceeds with respect to the portion of the Shares to be acquired having a Fair Market Value on the date of exercise equal to the sum of the applicable portion of the Exercise Price being so paid;

(ii) Subject to any requirements of applicable law and regulations, tendering (actually or by attestation) to the Company or its agent previously acquired Shares that have a Fair Market Value on the day prior to the date of exercise equal to the applicable portion of the Exercise Price being so paid; or

(iii) Subject to any requirements of applicable law and regulations, instructing the Company to reduce the number of Shares that would otherwise be issued by such number of Shares as have in the aggregate a Fair Market Value on the date of exercise equal to the applicable portion of the Exercise Price being so paid.

(e) *Incentive Stock Options.* Incentive Stock Options granted under the Plan will be subject to the following additional conditions, limitations and restrictions:

(i) *Eligibility.* Incentive Stock Options may be granted only to Employees of the Company or a Subsidiary that is a subsidiary or parent corporation of the Company within the meaning of Code Section 424.

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(ii) *Timing of Grant.* No Incentive Stock Option will be granted under the Plan after the 10-year anniversary of the date on which the Plan is adopted by the Board or, if earlier, the date on which the Plan is approved by the stockholders of Covidien Ltd.

(iii) *Amount of Award.* Subject to Section 5.3 of the Plan, no more than 10 million Shares may be available for grant in the form of Incentive Stock Options. The aggregate Fair Market Value (as of the date of grant) of the Shares with respect to which the Incentive Stock Options awarded to any Employee first become exercisable during any calendar year may not exceed $100,000 (U.S.). For purposes of this $100,000 (U.S.) limit, the Employee s Incentive Stock Options under this Plan and all other plans maintained by the Company and its Subsidiaries will be aggregated. To the extent any Incentive Stock Option would exceed the $100,000 (U.S.) limit, the Incentive Stock Option will afterwards be treated as a Nonqualified Stock Option to the extent required by the Code and underlying regulations and rulings.

(iv) *Timing of Exercise.* If the Committee exercises its discretion in the Award Certificate to permit an Incentive Stock Option to be exercised by a Participant more than three months after the Participant has ceased being an Employee (or more than 12 months if the Participant is permanently and totally disabled, within the meaning of Code Section 22(e)), the Incentive Stock Option will afterwards be treated as a Nonqualified Stock Option to the extent required by the Code and underlying regulations and rulings. For purposes of this paragraph (iv), an Employee s employment relationship will be treated as continuing intact while the Employee is on military leave, sick leave or another approved leave of absence if the period of leave does not exceed 90 days, or a longer period to the extent that the Employee s right to reemployment with the Company or a Subsidiary is guaranteed by statute or by contract. If the period of leave exceeds 90 days and the Employee s right to reemployment is not guaranteed by statute or contract, the employment relationship will be deemed to have ceased on the 91st day of the leave.

(v) *Transfer Restrictions.* In no event will the Committee permit an Incentive Stock Option to be transferred by an Employee other than by will or the laws of descent and distribution, and any Incentive Stock Option awarded under this Plan will be exercisable only by the Employee during the Employee s lifetime.

(f) *Exercise of Stock Appreciation Rights.* Upon exercise of a Participant s Stock Appreciation Rights, the Company will pay cash or Shares or a combination of cash and Shares, in the discretion of the Committee and as described in the Award Certificate. Cash payments will be equal to the excess of the Fair Market Value of a Share on the date of exercise over the Exercise Price, for each Share for which a Stock Appreciation Right was exercised. If Shares are paid for the Stock Appreciation Right, the Participant will receive a number of whole Shares equal to the quotient of the cash payment amount divided by the Fair Market Value of a Share on the date of exercise.

(g) *No Repricing.* Except as otherwise provided in Section 5.3, in no event will the Committee decrease the Exercise Price of a Stock Option or Stock Appreciation Right after the date of grant or cancel outstanding Stock Options or Stock Appreciation Rights and grant replacement Stock Options or Stock Appreciation Rights with a lower Exercise Price than that of the replaced Stock Options or Stock Appreciation Rights or other Awards without first obtaining the approval of the holders of a majority of the Shares who are present in person or by proxy at a meeting of the Company s shareholders and entitled to vote.

4.4. *Annual Performance Bonuses.* The Committee may grant Annual Performance Bonuses under the Plan in the form of cash or Shares to the Reporting Persons that the Committee may from time to time select, in the amounts and pursuant to the terms and conditions that the Committee may determine and set forth in the Award Certificate, subject to the provisions below:

(a) *Performance Cycles.* Annual Performance Bonuses will be awarded in connection with a twelve (12) month Performance Cycle, which will be the fiscal year of the Company.

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(b) *Eligible Participants.* Within ninety (90) days after the commencement of a Performance Cycle, the Committee will determine the Reporting Persons who will be eligible to receive an Annual Performance Bonus under the Plan. If an individual becomes a Reporting Person after this ninety (90) day period, the Committee may determine that such Reporting Person is eligible to receive a pro rata Annual Performance Bonus under the Plan.

(c) *Performance Measures; Targets; Award Criteria.*

(i) Within ninety (90) days after the commencement of the service period to which a Performance Cycle relates, the Committee will fix and establish in writing (A) the Performance Measures that will apply to that Performance Cycle; (B) the Target Bonus which may be earned by each Participant; and (C) subject to subsection (d) below, the criteria for computing the amount that will be paid with respect to each level of attained performance. The Committee will also set forth the minimum level of performance, based on the applicable Performance Measures, that must be attained during the Performance Cycle before any Annual Performance Bonus will be paid and the percentage of the Target Bonus that will become payable upon attainment of various levels of performance that equal or exceed the minimum required level.

(ii) The Committee, in its discretion, may, on a case-by-case basis, reduce, but not increase, the amount otherwise payable to any Key Employee with respect to any given Performance Cycle, provided, however, that no reduction will result in an increase in the amount payable under any Annual Performance Bonus of another Key Employee.

(d) *Payment, Certification.* No Annual Performance Bonus will be paid to any Reporting Person until the Committee certifies in writing the level of performance attained for the Performance Cycle in relation to the applicable Performance Measures. In applying Performance Measures, the Committee (i) shall make adjustments for events listed in Section 5.3 in accordance therewith and (ii) may, in its discretion, exclude the effect of unusual or infrequently occurring items, the cumulative effect of changes in the law, regulations or accounting rules, and other items, all determined in accordance with GAAP (to the extent applicable) and identified in financial statements, notes to the financial statements or discussion and analysis of management; provided that the determination by the Committee that Performance Measures shall be adjusted for items in accordance with this clause (ii) shall be made no later than ninety (90) days after the commencement of any applicable Performance Cycle in respect of Annual Performance Bonuses awarded to Key Employees.

(e) *Form of Payment.* Annual Performance Bonuses will be paid in cash or Shares. All such Performance Bonuses shall be paid no later than the 15th day of the third month following the end of the calendar year (or, if later, following the end of the Company s fiscal year) in which such Performance Bonuses are no longer subject to a substantial risk of forfeiture (as determined for purposes of Section 409A of the Code), except to the extent that a Participant has elected to defer payment under the terms of a duly authorized deferred compensation arrangement, in which case the terms of such arrangement shall govern.

(f) *Section 162(m) of the Code.* It is the intent of the Company that Annual Performance Bonuses made to Key Employees be performance-based compensation for purposes of Section 162(m) of the Code, that this Section 4.4 be interpreted in a manner that satisfies the applicable requirements of Section 162(m)(4)(C) of the Code and related regulations, and that the Plan be operated so that the Company may take a full tax deduction for Annual Performance Bonuses. If any provision of this Plan or any Annual Performance Bonus would otherwise frustrate or conflict with this intent, the provision will be interpreted and deemed amended so as to avoid this conflict.

(g) *Acceleration.* Each Participant who is eligible to receive an Annual Performance Bonus with respect to a Performance Cycle during which a Change of Control occurs will, except as otherwise provided below, be deemed to have achieved a level of performance, as of the date of Change in Control, that would cause all (100%) of the Participant s Target Bonus to become payable at such times and in such manner as determined in the sole discretion of the Committee. Notwithstanding the previous sentence,

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if (i) a surviving entity maintains the Performance Cycle in which a Change in Control occurs, or otherwise provides for the payment of an Annual Performance Bonus based on the level of performance attained for such Performance Cycle in relation to the Performance Measures established for such Performance Cycle (including Performance Measures that were adjusted or modified as a result of the Change in Control) and (ii) the Annual Performance Bonus based on the level of performance attained for such Performance Cycle exceeds all (100%) of the Participant s Target Bonus, then each Participant who is eligible to receive an Annual Performance Bonus with respect to such Performance Cycle shall receive an Annual Performance Bonus based on the level of performance attained for such Performance Cycle at such times and in such manner as determined in the sole discretion of the Committee, or successor to the Committee. Notwithstanding the above, the time and manner of any payments made pursuant to this Section 4.4(g) shall comply with Section 4.4(e) above.

4.5. *Long-Term Performance Awards.* The Committee may grant Long-Term Performance Awards under the Plan in the form of Performance Units, Restricted Units or Restricted Stock to any Employee who the Committee may from time to time select, in the amounts and pursuant to the terms and conditions that the Committee may determine and set forth in the Award Certificate, subject to the provisions below:

(a) *Performance Cycles.* Long-Term Performance Awards will be awarded in connection with a Performance Cycle, as determined by the Committee in its discretion, provided, however, that a Performance Cycle may be no shorter than twelve (12) months and no longer than five (5) years.

(b) *Eligible Participants.* Within ninety (90) days after the commencement of a Performance Cycle, the Committee will determine the Employees who will be eligible to receive a Long-Term Performance Award for the Performance Cycle, provided that the Committee may determine the eligibility of any Employee other than a Key Employee after the expiration of this ninety (90) day period.

(c) *Performance Measures; Targets; Award Criteria.*

(i) Within ninety (90) days after the commencement of the service period to which a Performance Cycle relates, the Committee will fix and establish in writing (A) the Performance Measures that will apply to that Performance Cycle; (B) with respect to Performance Units, the Target Amount payable to each Participant; (C) with respect to Restricted Units and Restricted Stock, the Target Vesting Percentage for each Participant; and (D) subject to subsection (d) below, the criteria for computing the amount that will be paid or will vest with respect to each level of attained performance. The Committee will also set forth the minimum level of performance, based on the applicable Performance Measures, that must be attained during the Performance Cycle before any Long-Term Performance Award will be paid or vest, and the percentage of Performance Units that will become payable and the percentage of performance-based Restricted Units or Shares of Restricted Stock that will vest upon attainment of various levels of performance that equal or exceed the minimum required level.

(ii) The Committee, in its discretion, may, on a case-by-case basis, reduce, but not increase, the amount of Long-Term Performance Awards otherwise payable to any Key Employee with respect to any given Performance Cycle, provided, however, that no reduction will result in an increase in the dollar amount or number of Shares payable under any Long-Term Performance Award of another Key Employee.

(d) *Payment, Certification.* Long-Term Performance Awards shall vest and be paid within the sixty (60) day period following the end of the applicable Performance Cycle, and shall only be paid if, within such sixty (60) day period, the Committee certifies in writing the level of performance attained for the Performance Cycle in relation to the applicable Performance Measures. Long-Term Performance Awards awarded to Participants who are not Key Employees will be based on the Performance Measures, or other applicable performance criteria, and payment formulas that the Committee, in its discretion, may establish for these purposes. These Performance Measures, or other performance criteria, and formulas may be the same as or different than the Performance Measures and formulas that apply to Key Employees.

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(e) *Form of Payment.* Long-Term Performance Awards in the form of Performance Units may be paid in cash or full Shares, in the discretion of the Committee, and as set forth in the applicable Award Certificate. Performance-based Restricted Units and Restricted Stock will be paid in full Shares. Payment with respect to any fractional Share will be in cash in an amount based on the Fair Market Value of the Share as of the date the Performance Unit becomes payable. All Long-Term Performance Awards shall be paid no later than the 15th day of the third month following the end of the calendar year (or, if later, following the end of the Company s fiscal year) in which such Long-Term Performance Awards are no longer subject to a substantial risk of forfeiture (within the meaning of Code Section 409A), except to the extent that a Participant has elected to defer payment under the terms of a duly authorized deferred compensation arrangement, in which case the terms of such arrangement shall govern, or as otherwise provided in Section 4.5(g) below.

(f) *Section 162(m) of the Code.* It is the intent of the Company that Long-Term Performance Awards made to Key Employees be performance-based compensation for purposes of Section 162(m) of the Code, that this Section 4.5 be interpreted in a manner that satisfies the applicable requirements of Section 162(m)(4)(C) of the Code and related regulations with respect to Long-Term Performance awards made to Key Employees, and that the Plan be operated so that the Company may take a full tax deduction for Long-Term Performance Awards. If any provision of this Plan or any Long-Term Performance Award would otherwise frustrate or conflict with this intent, the provision will be interpreted and deemed amended so as to avoid this conflict.

(g) *Special Vesting Provisions.* Unless the applicable Award Certificate provides otherwise, upon the death, Disability, Normal Retirement or a Change in Control Termination of a Participant who has an outstanding Long-Term Performance Award, the unvested Long-Term Performance Award will fully vest and be paid as if the Participant had continued in active employment with the Company through the date such Long-Term Performance Award would have vested and been paid in the absence of such event. Unless the applicable Award Certificate provides otherwise, upon the Termination of Employment of a Participant for any reason other than the Participant s death, Disability, Normal Retirement or a Change in Control Termination, the unvested Long-Term Performance Award will be forfeited unless the Participant has attained age 55 and the sum of the Participant s age and years of service with the Company or a Subsidiary is 60 or higher, in which case a pro rata portion of the Participant s Long-Term Performance Awards will vest and be paid as if the Participant had continued in active employment with the Company through the date such Long-Term Performance Award would have vested and been paid in the absence of such event; provided that the number of Long-Term Performance Awards held by the Participant which shall vest under those circumstances shall equal the total number of Long-Term Performance Awards in which such Participant would have vested multiplied by a fraction, the numerator of which is the period of time (in whole months) that have elapsed since the date of grant, and the denominator of which is the number of total months set forth in the applicable Award Certificate for such Performance Period.

4.6. *Other Stock-Based Awards.* The Committee may, from time to time, grant Awards (other than Stock Options, Stock Appreciation Rights, Annual Performance Bonuses or Long-Term Performance Awards) to any Employee who the Committee may from time to time select, which Awards consist of, or are denominated in, payable in, valued in whole or in part by reference to, or otherwise related to, Shares. These Awards may include, among other forms, Restricted Stock, Restricted Units, or Deferred Stock Units. The Committee will determine, in its discretion, the terms and conditions that will apply to Awards granted pursuant to this Section 4.6, which terms and conditions will be set forth in the applicable Award Certificate.

(a) *Vesting.* Restrictions on Other Stock-Based Awards granted under this Section 4.6 will lapse at such times and in such manner as determined by the Committee and set forth in the applicable Award Certificate. Unless the applicable Award Certificate provides otherwise, if the restrictions on Other Stock-Based Awards have not lapsed or been satisfied as of the Participant s Termination of Employment, the Shares will be forfeited by the Participant if the termination is for any reason other than the Normal Retirement, death or Disability of the Participant or a Change in Control Termination,

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except that the Award will vest pro rata with respect to the portion of the vesting term set forth in the applicable Award Certificate that the Participant has completed if the Participant has attained age 55 and the sum of the Participant s age and years of service with the Company is 60 or higher. All restrictions on Other Stock-Based Awards granted pursuant to this Section 4.6 will lapse upon the Normal Retirement, death or Disability of the Participant or a Change in Control Termination.

(b) *Grant of Restricted Stock.* The Committee may grant Restricted Stock to any Employee, which Shares will be registered in the name of the Participant and held for the Participant by the Company. The Participant will have all rights of a shareholder with respect to the Shares, including the right to vote and to receive dividends or other distributions (subject to Section 4.6(e)), except that the Shares may be subject to a vesting schedule and will be forfeited if the Participant attempts to sell, transfer, assign, pledge or otherwise encumber or dispose of the Shares before the restrictions are satisfied or lapse.

(c) *Grant of Restricted Units.* The Committee may grant Restricted Units to any Employee, which Units will be paid in cash or whole Shares or a combination of cash and Shares, in the discretion of the Committee, when the restrictions on the Units lapse and any other conditions set forth in the Award Certificate have been satisfied. For each Restricted Unit that vests, one Share will be paid or an amount in cash equal to the Fair Market Value of a Share as of the date on which the Restricted Unit vests.

(d) *Grant of Deferred Stock Units.* The Committee may grant Deferred Stock Units to any Employee, which Units will be paid in whole Shares upon the Employee s Termination of Employment if the restrictions on the Units have lapsed. One Share will be paid for each Deferred Stock Unit that becomes payable.

(e) *Dividends and Dividend Equivalents.* At the discretion of the Committee and as set forth in the applicable Award Certificate, dividends paid on Shares may be paid immediately or withheld and deferred in the Participant s account. In the event of a payment of dividends on the Ordinary Shares, the Committee may credit Restricted Units with Dividend Equivalents in accordance with terms and conditions established in the discretion of the Committee. Dividend Equivalents will be subject to such vesting terms as is determined by the Committee and may be distributed immediately or withheld and deferred in the Participant s account as determined by the Committee and set forth in the applicable Award Certificate. Deferred Stock Units may, in the discretion of the Committee and as set forth in the Award Certificate, be credited with Dividend Equivalents or additional Deferred Stock Units. The number of any Deferred Stock Units credited to a Participant s account upon the payment of a dividend will be equal to the quotient produced by dividing the cash value of the dividend by the Fair Market Value of one Share as of the date the dividend is paid. The Committee will determine any terms and conditions on deferral of a dividend or Dividend Equivalent, including the rate of interest to be credited on deferral and whether interest will be compounded.

4.7. *Director Awards.*

(a) Notwithstanding anything herein to the contrary, the Nominating Committee shall have the exclusive authority to issue awards to Directors who are not also employees of the Company or any Subsidiary (Director Awards), which may consist of, but not be limited to, Stock Options, Stock Appreciation Rights, or Other Stock-Based Awards. Each Director Award shall be governed by an Award Certificate approved by the Nominating Committee.

(b) The Nominating Committee shall have the exclusive authority to administer Director Awards, and shall have the authority set forth in Section 3.2 and the indemnification set forth in Section 7.7, solely as such provisions apply to the Director Awards. All determinations made by the Nominating Committee hereunder shall be final, binding and conclusive.

4.8. *Substitute Awards.* The Committee may make Awards under the Plan to Acquired Grantees through the assumption of, or in substitution for, outstanding stock-based awards previously granted to such Acquired Grantees. Such assumed or substituted Awards will be subject to the terms and conditions of the original awards

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made by the Acquired Company, with such adjustments therein as the Committee considers appropriate to give effect to the relevant provisions of any agreement for the acquisition of the Acquired Company. Any grant of Incentive Stock Options pursuant to this Section 4.8 will be made in accordance with Section 424 of the Code and any final regulations published thereunder.

4.9. *Limit on Individual Grants.* Subject to Sections 5.1 and 5.3, no Employee may be granted more than six (6) million Shares over any calendar year pursuant to Awards of Stock Options, Stock Appreciation Rights and performance-based Restricted Stock and Restricted Units, except that an incentive Award of no more than ten (10) million Shares may be made pursuant to Stock Options, Stock Appreciation Rights and performance-based Restricted Stock and Restricted Units to any person who has been hired within the calendar year as a Key Employee. The maximum amount that may be paid in cash or Shares pursuant to Annual Performance Bonuses or Long-Term Performance Awards paid in Performance Units to any one Employee is $15 million (U.S.) for any Performance Cycle of twelve (12) months. For any longer Performance Cycle, this maximum will be adjusted proportionally.

4.10. *Termination for Cause.* Notwithstanding anything to the contrary herein and unless the applicable Award Certificate provides otherwise, if a Participant incurs a Termination of Directorship or Termination of Employment for Cause, then all Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards, Restricted Units, Restricted Stock and Other Stock-Based Awards will immediately be cancelled. The exercise of any Stock Option or Stock Appreciation Right or the payment of any Award may be delayed, in the Committee s discretion, in the event that a potential termination for Cause is pending. Unless the applicable Award Certificate provides otherwise, if a Participant incurs a Termination of Directorship or Termination of Employment for Cause, then the Participant will be required to deliver to the Company (i) Shares (or, in the discretion of the Committee, cash) equal in value to the amount of any profit the Participant realized upon the exercise of an Option or Stock Appreciation Right during the twelve (12) month period occurring immediately prior to the Participant s Termination of Directorship or Termination of Employment for Cause; and (ii) the number of Shares (or, in the discretion of the Committee, the cash value of Shares) the Participant received for Other Stock Based Awards (including Restricted Stock, Restricted Units and Deferred Stock Units) that vested during the period specified in (i) above. Unless the applicable award certificate provides otherwise, if, after a Participant s Termination of Directorship or Termination of Employment, the Committee determines in its sole discretion that while the Participant was a Company or Subsidiary employee or a Director, such Participant engaged in activity that would have been grounds for a Termination of Directorship or Termination of Employment for Cause, then the Company will immediately cancel all Stock Options, Stock Appreciation Rights, Annual Performance Bonuses, Long-Term Performance Awards, Restricted Units, Restricted Stock and Other Stock-Based Awards and the Participant will be required to deliver to the Company (A) Shares (or, in the discretion of the Committee, cash) equal in value to the amount of any profit the Participant realized upon the exercise of an Option or Stock Appreciate Right during the period that begins twelve (12) months immediately prior to the Participant s Termination of Directorship or Termination of Employment and ends on the date of the Committee s determination that the Participant s conduct would have constituted grounds for a Termination of Directorship or Termination of Employment for Cause; and (B) the number of Shares (or, in the discretion of the Committee, the cash value of said shares) the Participant received for Other Stock Based Awards (including Restricted Stock, Restricted Units and Deferred Stock Units) that vested during the period specified in (A) above.

ARTICLE V

SHARES SUBJECT TO THE PLAN; ADJUSTMENTS

5.1. *Shares Available.*

(a) The Shares issuable under the Plan will be authorized but unissued Shares, and, to the extent permissible under applicable law, Shares acquired by the Company, any Subsidiary or any other person or entity designated by the Company and held as treasury shares.

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(b) Subject to the counting rules set forth in Section 5.2 and adjustment in accordance with Section 5.3, the total number of Shares with respect to which Awards may be issued under the Plan shall equal 97,497,609 (24,843,452 of which were originally authorized in connection with the adoption of the Plan, 27,654,157 of which were authorized in connection with the amendment and restatement of the Plan approved by shareholders at the Company s Annual General Meeting held on March 18, 2009, and 45 million of which were authorized in connection with the amendment and restatement of the Plan on November 15, 2012, subject to approval of the Company s shareholders at the Company s 2013 Annual General Meeting to be held on March 20, 2013).

(c) Incentive Stock Options may be granted under the Plan in respect of no more than 10 million Shares.

5.2. *Counting Rules.*

(a) The total number of Shares with respect to which Awards may be issued under the Plan, as described in Section 5.1(b), shall be reduced by 2.2 Shares per each Share subject to an Award of Restricted Stock, Restricted Units, Deferred Stock Units, Performance Units or Other Stock-Based Awards, or as payment of an Annual Performance Bonus, in each case granted on or after March 20, 2013.

(b) The following Shares related to Awards under the Plan will again be available for issuance under the Plan:

(i) Shares related to Awards paid in cash;

(ii) Shares related to Awards that expire, are forfeited or cancelled or terminate for any other reason without issuance of Shares and any Shares of Restricted Stock that are returned to the Company upon a Participant s Termination of Employment or, if applicable, a Director s Termination of Directorship (including, for clarity, at a rate of 2.2 Shares per each Share related to such an Award in the form of Restricted Stock, Restricted Units, Deferred Stock Units, Performance Units or Other Stock-Based Awards, or as payment of an Annual Performance Bonus); and

(iii) Any Shares issued in connection with Awards that are assumed, converted or substituted as a result of the acquisition of an Acquired Company by the Company or a combination of the Company with another company.

5.3. *Adjustments.* In the event of a change in the outstanding Shares by reason of a share split, reverse share split, dividend or other distribution (whether in the form of cash, Shares, other securities or other property), extraordinary cash dividend, recapitalization, merger, consolidation, split-up, spin-off, reorganization, combination, repurchase or exchange of Shares or other securities or similar corporate transaction or event, the Committee shall make an appropriate adjustment to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan. Any adjustment made by the Committee under this Section 5.3 will be conclusive and binding for all purposes under the Plan.

5.4. *Change in Control.*

(a) *Acceleration.* Unless the applicable Award Certificate provides otherwise, (i) all outstanding Stock Options and Stock Appreciation Rights will become exercisable as of the effective date of a Participant s Change in Control Termination if the Awards are not otherwise vested, and all conditions will be waived with respect to outstanding Restricted Stock and Restricted Units (other than Long-Term Performance Awards) and Deferred Stock Units and (ii) each Participant who has been granted a Long-Term Performance Award that is outstanding as of the date of such Participant s Change in Control Termination will be deemed to have achieved a level of performance, as of the Change in Control Termination, that would cause all (100%) of the Participant s Target Amounts to become payable and all restrictions on the Participant s performance-based Restricted Units and Shares of Restricted Stock to lapse. Unless the Committee determines otherwise in its discretion (either when an Award is granted or any time thereafter), in the event that Awards outstanding as of the date of a Change in Control that are payable in Ordinary Shares of the Company will not be substituted with

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comparable awards payable or redeemable in shares of publicly-traded stock after the Change in Control, each such outstanding Award (A) will become fully vested (at target, where applicable) immediately prior to the Change in Control and (B) each such Award that is a Stock Option will be settled in cash, without the Participant s consent, for an amount equal to the amount that could have been attained upon the exercise of such Award immediately prior to the Change in Control had such Award been exercisable or payable at such time.

(b) *Permissive Actions*. In addition to the actions described in Section 5.4(a)(A) and (B), in the event of a Change in Control, the Committee may take any one or more of the following actions with respect to any or all outstanding Awards, without the consent of Participants: (i) the Committee may determine that outstanding Stock Options and Stock Appreciation Rights shall be fully vested and exercisable and restrictions on Restricted Stock, Restricted Units, Deferred Stock Units and Other Stock-Based Awards shall lapse as of the date of the Change in Control or such other time (prior to a Participant s Change in Control Termination) as the Committee determines; (ii) the Committee may require that a Participant surrender his or her outstanding Stock Options and Stock Appreciation Rights in exchange for one or more payments by the Company, in cash or Ordinary Shares, as determined by the Committee, in an amount equal to the amount by which the then Fair Market Value of the Shares subject to the Participant s unexercised Stock Options and Stock Appreciation Rights exceeds the Exercise Price, if any, and on such terms as the Committee determines; (iii) after giving Participants an opportunity to exercise any outstanding Stock Options and Stock Appreciation Rights, the Committee may terminate any or all unexercised Stock Options and Stock Appreciation Rights at such time as the Committee deems appropriate; (iv) the Committee may determine that Annual Performance Bonuses and/or Long-Term Performance Awards will be paid out at their target level, in cash or Ordinary Shares as determined by the Committee; or (v) the Committee may determine that Awards that remain outstanding after the Change in Control shall be converted to similar grants of, or assumed by, the surviving corporation (or a parent or subsidiary of the surviving corporation or successor). Such acceleration, surrender, termination, settlement, payment or conversion shall take place as of the date of the Change in Control or such other date as the Committee determines. The Committee may specify how an Award will be treated in the event of a Change in Control either when the Award is granted or at any time thereafter.

5.5. *Fractional Shares.* No fractional Shares will be issued under the Plan. Except as otherwise provided in Section 4.5(e) and unless otherwise provided by the Committee, if a Participant acquires the right to receive a fractional Share under the Plan, the Participant will receive, in lieu of the fractional Share, a cash payment equal to the Fair Market Value of such fractional share on the date of settlement of the related Award.

ARTICLE VI

AMENDMENT AND TERMINATION

6.1. *Amendment.* The Plan may be amended at any time and from time to time by the Board or authorized Board committee without the approval of shareholders of the Company, except that no material revision to the terms of the Plan will be effective until the amendment is approved by the shareholders of the Company. A revision is material for this purpose if it materially increases the number of Shares that may be issued under the Plan (other than an increase pursuant to Section 5.3 of the Plan), expands the types of Awards available under the Plan, materially expands the class of persons eligible to receive Awards under the Plan, materially extends the term of the Plan, materially decreases the Exercise Price at which Stock Options or Stock Appreciation Rights may be granted, reduces the Exercise Price of outstanding Stock Options or Stock Appreciation Rights, results in the replacement of outstanding Stock Options and Stock Appreciation Rights with new Awards that have an Exercise Price that is lower than the Exercise Price of the replaced Stock Options and Stock Appreciation Rights, or is otherwise an amendment requiring shareholder approval pursuant to any law or the rules of any exchange on which the Company s Ordinary Shares are listed for trading. No amendment of the Plan or any outstanding Award Certificate made without the Participant s written consent may adversely affect any right of a Participant with respect to an outstanding Award.

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6.2. *Termination.* The Plan will terminate upon the earlier of the following dates or events to occur:

(a) The adoption of a resolution of the Board terminating the Plan; or

(b) November 14, 2022, the day before the tenth (10^{th}) anniversary of the adoption of the November 15, 2012 amendment and restatement of the Plan which was approved by the Company s shareholders at its 2013 Annual General Meeting held on March 20, 2013.

No Awards will be granted under this Plan after it has terminated. The termination of the Plan, however, will not alter or impair any of the rights or obligations of any person under any Award previously granted under the Plan without such person s consent. After the termination of the Plan, any previously granted Awards will remain in effect and will continue to be governed by the terms of the Plan and the applicable Award Certificate.

ARTICLE VII

GENERAL PROVISIONS

7.1. *Nontransferability of Awards.* No Award under the Plan will be subject in any manner to alienation, anticipation, sale, assignment, pledge, encumbrance or transfer, and no other persons will otherwise acquire any rights therein, except as provided below.

(a) Any Award may be transferred by will or by the laws of descent or distribution.

(b) Unless the applicable Award Certificate provides otherwise, all or any part of a Nonqualified Stock Option or Shares of Restricted Stock may be transferred to a family member without consideration. For purposes of this subsection (b), family member includes any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the Participant, including adoptive relationships, any person sharing the Participant s household (other than a tenant or employee), a trust in which these persons have more than fifty percent (50%) of the beneficial interest, a foundation in which these persons (or the Participant) control the management of assets, and any other entity in which these persons (or the Participant) own more than fifty percent (50%) of the voting interests.

Any transferred Award will be subject to all of the same terms and conditions as provided in the Plan and the applicable Award Certificate. The Participant or the Participant s estate will remain liable for any withholding tax that may be imposed by any federal, state or local tax authority. The Company may, in its sole discretion, disallow all or a part of any transfer of an Award pursuant to this Subsection 7.1(b) unless and until the Participant makes arrangements satisfactory to the Company for the payment of any withholding tax. The Participant must immediately notify the Company, in the form and manner required by the applicable Award Certificate or as otherwise required by the Company, of any proposed transfer of an Award pursuant to this Subsection 7.1(b). No transfer will be effective until the Company consents to the transfer.

(c) Unless the applicable Award Certificate provides otherwise, any Nonqualified Stock Option transferred by a Participant pursuant to subsection (b) may be exercised by the transferee only to the extent that the Award would have been exercisable by the Participant had no transfer occurred. The transfer of Shares upon exercise of the Award will be conditioned on the payment of any withholding tax.

(d) Restricted Stock may be freely transferred after the restrictions lapse or are satisfied and the Shares are delivered, provided, however, that Restricted Stock awarded to an affiliate of the Company may be transferred only pursuant to Rule 144 under the Securities Act, or pursuant to an effective registration for resale under the Securities Act. For purposes of this subsection (d), affiliate will have the meaning assigned to that term under Rule 144.

(e) In no event may a Participant transfer an Incentive Stock Option other than by will or the laws of descent and distribution.

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7.2. *Withholding of Taxes.* The Committee, in its discretion, may require the satisfaction of a Participant s tax withholding obligations by any of the following methods or any method as it determines to be in accordance with the laws of the jurisdiction in which the Participant resides, has domicile or performs services.

(a) *Stock Options and Stock Appreciation Rights.* As a condition to the delivery of Shares pursuant to the exercise of a Stock Option or Stock Appreciation Right, the Committee may require that the Participant, at the time of exercise, pay to the Company by cash, certified check, bank draft, wire transfer or postal or express money order an amount sufficient to satisfy any applicable tax withholding obligations. The Committee may also, in its discretion, accept payment of tax withholding obligations through any of the Exercise Price payment methods described in Section 4.3(d).

(b) *Other Awards Payable in Shares.* The Participant shall satisfy the Participant s tax withholding obligations arising in connection with the release of restrictions on Restricted Units, Restricted Stock and Other Stock-Based Awards by payment to the Company in cash or by certified check, bank draft, wire transfer or postal or express money order, provided that the format is approved by the Company or a designated third-party administrator. However, subject to any requirements of applicable law, the Company may also satisfy the Participant s tax withholding obligations by other methods, including selling or withholding Shares that would otherwise be available for delivery.

(c) *Cash Awards.* The Company may satisfy a Participant s tax withholding obligation arising in connection with the payment of any Award in cash by withholding cash from such payment.

7.3. *No Implied Rights.* The establishment and operation of the Plan, including the eligibility of a Participant to participate in the Plan, will not be construed as conferring any legal or other right upon any Director for any continuation of directorship or any Employee for the continuation of employment through the end of any Performance Cycle or other period. The Company expressly reserves the right, which may be exercised at any time and in the Company s sole discretion, to discharge any individual or treat him or her without regard to the effect that discharge might have upon him or her as a Participant in the Plan.

7.4. *No Obligation to Exercise Awards.* The grant of a Stock Option or Stock Appreciation Right will impose no obligation upon the Participant to exercise the Award.

7.5. *No Rights as Shareholders.* A Participant who is granted an Award under the Plan will have no rights as a shareholder of the Company with respect to the Award unless and until certificates for the Shares underlying the Award are registered in the Participant s name and (other than in the case of Restricted Stock) delivered to the Participant. The right of any Participant to receive an Award by virtue of participation in the Plan will be no greater than the right of any unsecured general creditor of the Company.

7.6. *Indemnification of Committee.* The Company will indemnify, to the fullest extent permitted by law, each person made or threatened to be made a party to any civil or criminal action or proceeding by reason of the fact that the person, or the executor or administrator of the person s estate, is or was a member of the Committee or an authorized delegate of the Committee including, for purposes of Director Awards, the Nominating Committee.

7.7. *No Required Segregation of Assets.* Neither the Company nor any Subsidiary will be required to segregate any assets that may at any time be represented by Awards granted pursuant to the Plan.

7.8. *Nature of Payments.* All Awards made pursuant to the Plan are in consideration of services for the Company or a Subsidiary. Any gain realized pursuant to Awards under the Plan constitutes a special incentive payment to the Participant and will not be taken into account as compensation for purposes of any other employee benefit plan of the Company or a Subsidiary, except as the Committee otherwise provides. The adoption of the Plan will have no effect on Awards made or to be made under any other benefit plan covering an employee of the Company or a Subsidiary or any predecessor or successor of the Company or a Subsidiary.

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7.9. *Securities Law Compliance.* Awards under the Plan are intended to satisfy the requirements of Rule 16b-3 under the Exchange Act. If any provision of this Plan or any grant of an Award would otherwise frustrate or conflict with this intent, that provision will be interpreted and deemed amended so as to avoid conflict. No Participant will be entitled to a grant, exercise, transfer or payment of any Award if the grant, exercise, transfer or payment would violate the provisions of the Sarbanes-Oxley Act of 2002 or any other applicable law.

7.10. *Coordination with Other Plans.* If this Plan provides a level of benefits with respect to Awards that differs from the level of benefits provided under the Covidien Severance Plan for U.S. Officers and Executives, the Covidien Change in Control Severance Plan for Certain U.S. Officers and Executives or the Covidien Severance Plan for U.S. Employees, then the terms of the plan that provides for the more favorable benefit to the Participant shall govern

7.11. *Section 409A Compliance.* Notwithstanding any other provision of this Plan or an applicable Award Certificate to the contrary, the provisions of this Section 7.12 shall apply to all Awards that were issued or became vested on or after January 1, 2005 and that are subject to Code Section 409A, but only with respect to the portion of such Award that is subject to Code Section 409A.

(a) *General*. To the extent the Committee (or Nominating Committee with respect to Director Awards) determines that any Award granted under the Plan is subject to Code Section 409A, the Award Certificate evidencing such Award will incorporate the terms and conditions required by Code Section 409A. To the extent applicable, the Plan and the Award Certificate will be interpreted in accordance with Code Section 409A and the applicable regulations and rulings thereunder. Notwithstanding any other provision of the Plan to the contrary, in the event that the Committee (or Nominating Committee with respect to Director Awards) determines that any Award may be subject to Code Section 409A, the Committee may adopt such amendments to the Plan and/or the applicable Award Certificate or adopt policies and procedures or take any other action or actions, including an action or amendment with retroactive effect, that the Committee (or Nominating Committee with respect to Director Awards) determines is necessary or appropriate to (i) exempt the Award from the application of Code Section 409A or (ii) comply with the requirements of Code Section 409A.

(b) *Modifications to Defined Terms*. The following modifications to Plan provisions (and, if necessary, applicable Award Certificate provisions) shall apply.

(i) Any payment of deferred compensation subject to Code Section 409A that is to be made under an Award other than an Annual Performance Bonus upon the occurrence of a Change in Control or any change in the timing and/or form of such payment as a direct result of a Change in Control (including payments made upon a specified date or event occurring after a Change in Control) shall not be made, or such change in timing and/or form shall not occur, unless such Change in Control is also a change in ownership or effective control of the Company within the meaning of Code Section 409A(a)(2)(A)(v) and applicable regulations and rulings thereunder and such payment, or such change in timing and/or form, occurs no later than two (2) years after the date of such change in ownership or effective control of the Company, in each case to the extent required to avoid the recipient of such Award from incurring tax penalties under Code Section 409A in respect of such Award. Notwithstanding the foregoing, if the Committee takes an action pursuant to Section 5.4(b) to accelerate the payment of deferred compensation upon a Change in Control, then any accelerated payment shall occur on a date specified in the applicable Award Certificate, which date shall be no later than ninety (90) days after a change in ownership or effective control of the Company. The payment of an Annual Performance Bonus that is to be accelerated pursuant to Subsection 4.4(g) shall occur within thirty (30) days after a change in ownership or effective control of the Company within the meaning of Code Section 409A(a)(2)(A)(v).

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(ii) The definition of Change in Control Termination in subsection (b) of that definition shall be deleted in its entirety and replaced with the following:

(b) termination of the Participant s employment by the Participant after one of the following events:

(i) the Company (1) assigns or causes to be assigned to the Participant duties inconsistent in any material respect with his or her position as in effect immediately prior to the Change in Control; (2) makes or causes to be made any material adverse change in the Participant s position (including titles and reporting relationships and level), authority, duties or responsibilities, or the budget over which the Participant retains authority; or (3) takes or causes to be taken any other action which results in a material diminution in such position, authority, duties or responsibilities or the budget over which the Participant retains authority; or

(ii) the Company, without the Participant s consent, (1) requires the Participant to relocate to a principal place of employment more than fifty (50) miles from his or her existing place of employment, which increases the Participant s commute from his or her principal residence by more than fifty (50) miles; or (2) materially reduces the Participant s base salary, annual bonus, or retirement, welfare, share incentive, perquisite (if any) and other benefits taken as a whole;

provided that an event described in (i) or (ii) above shall permit a Participant s termination of employment to be deemed a Change in Control Termination only if (x) the Participant provides written notice to the Company specifying in reasonable detail the event upon which the Participant is basing his termination within ninety (90) days after the occurrence of such event, (y) the Company fails to cure such event within thirty (30) days after its receipt of such notice, and (z) the Participant terminates his employment within sixty (60) days after the expiration of such cure period.

(iii) The definition of Disabled or Disability shall be deleted in its entirety and replaced with the following:
Disabled or Disability means that the Employee is receiving income replacement benefits for a period of not less than three (3) months under a Company or Subsidiary accident and health plan covering the Employee by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

(iv) A Termination of Directorship or Termination of Employment shall only occur where such Termination of Directorship or Termination of Employment is a separation from service within the meaning of Code Section 409A(a)(2)(A)(i) and the applicable regulations and rulings thereunder. For purposes of determining whether a Termination of Directorship has occurred under this Subsection 7.12(b)(iii), services provided in the capacity of an employee or otherwise shall be excluded.

(c) *Modifications to or Adjustments of Awards*. Any modifications to an Award pursuant to Subsection 3.2(g) or adjustments of an Award pursuant to Subsections 4.8 or 5.3 shall comply with the requirements of Section 409A.

(d) *Specified Employees*. Payments to any Participant who is a specified employee of deferred compensation that is subject to Code Section 409A(a)(2) and that becomes payable upon, or that is accelerated upon, such Participant s Termination of Employment (as modified by Subsection 7.12(b)(iv)), shall not be made on or before the date which is six (6) months following such Participant s Termination of Employment (or, if earlier, such Participant s death). A specified employee for this purpose shall be determined by the Committee or its delegate in accordance with the provisions of Code Section 409A and the regulations and rulings thereunder.

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7.12. *Section 457A Compliance*. To the extent the Committee (or Nominating Committee with respect to Director Awards) determines that any Award granted under the Plan is subject to Code Section 457A, the Award Certificate evidencing such Award will incorporate the terms and conditions required by Code Section 457A in order to avoid accelerated taxation or tax penalties to the holder thereof in respect of such Award. To the extent applicable, the Plan and the Award Certificate will be interpreted in accordance with Code Section 457A and applicable guidance issued thereunder. Notwithstanding any other provision of the Plan to the contrary, in the event that the Committee (or Nominating Committee with respect to Director Awards) determines that any Award may be subject to Code Section 457A, the Committee may adopt such amendments to the Plan and/or the applicable Award Certificate or adopt policies and procedures or take any other action or actions, including an action or amendment with retroactive effect, that the Committee (or Nominating Committee with respect to Director Awards) determines is necessary or appropriate to (i) exempt the Award from the application of Code Section 457A or (ii) comply with the requirements of Code Section 457A.

7.13. *Governing Law, Severability.* The Plan and all determinations made and actions taken under the Plan will be governed by the law of Ireland and construed accordingly. If any provision of the Plan is held unlawful or otherwise invalid or unenforceable in whole or in part, the unlawfulness, invalidity or unenforceability will not affect any other parts of the Plan, which parts will remain in full force and effect.

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Annual General Meeting of Shareholders

Wednesday, March 20, 2013, 11:00 a.m., local time

The Conrad Dublin Hotel

Earlsfort Terrace

Dublin 2, Ireland

Important Notice Regarding the Internet Availability of Proxy Materials for the Annual Meeting:

Notice and Proxy Statement, including resolutions; Annual Report, including Form 10-K; and Irish Statutory Accounts, including related reports, are available at *www.proxyvote.com.*

THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

ANNUAL GENERAL MEETING OF SHAREHOLDERS

MARCH 20, 2013

The undersigned hereby appoints José E. Almeida, Charles J. Dockendorff and John H. Masterson, or any of them, as proxies, each with full power of substitution, and hereby authorizes them to represent and to vote all of the Ordinary Shares of Covidien plc that the shareholder(s) is/are entitled to vote at the Annual General Meeting of Shareholders to be held at 11:00 a.m., local time on Wednesday, March 20, 2013 at the Conrad Dublin Hotel, Earlsfort Terrace, Dublin 2, Ireland, and any adjournment or postponement thereof, as indicated on the reverse side of this proxy card with respect to the proposals set forth in the proxy statement and in their discretion upon any matter that may properly come before the meeting or any adjournment of the meeting.

THIS PROXY, WHEN PROPERLY EXECUTED, WILL BE VOTED AS DIRECTED BY THE SHAREHOLDER(S). IF NO SUCH DIRECTIONS ARE MADE, THIS PROXY WILL BE VOTED IN ACCORDANCE WITH THE RECOMMENDATIONS OF THE BOARD OF DIRECTORS.

IF YOU ARE NOT VOTING ON THE INTERNET OR BY TELEPHONE, PLEASE MARK, SIGN, DATE AND RETURN THIS PROXY CARD PROMPTLY USING THE ENCLOSED REPLY ENVELOPE.

Address Changes/Comments: _____

(If you noted any Address Changes/Comments above, please mark corresponding box on the reverse side.)

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c/o Covidien plc

Company Secretary

20 on Hatch

Lower Hatch Street

Dublin 2, Ireland

VOTE BY INTERNET - www.proxyvote.com

Use the Internet to transmit your voting instructions and for electronic delivery of information up until 5:00 p.m. U.S. Eastern Time on March 19, 2013. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

VOTE BY PHONE - 1-800-690-6903

Use any touch-tone telephone to transmit your voting instructions up until 5:00 p.m. U.S. Eastern Time on March 19, 2013. Have your proxy card in hand when you call and then follow the instructions.

VOTE BY MAIL

Mark, sign and date your proxy card and return it in the postage-paid envelope provided or return it to Covidien plc, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

ELECTRONIC DELIVERY OF FUTURE PROXY MATERIALS

If you would like to reduce the costs incurred by our company in mailing proxy materials, you can consent to receiving all future proxy statements, proxy cards and annual reports electronically via e-mail or the Internet. To sign up for electronic delivery, please follow the instructions above to vote using the Internet and, when prompted, indicate that you agree to receive or access proxy materials electronically in future years.

If you transmit your voting instructions by the Internet or by telephone,

you do NOT need to mail back your proxy card.

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS:

KEEP THIS PORTION FOR YOUR RECORDS

DETACH AND RETURN THIS PORTION ONLY

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED.

COVIDIEN PLC

The Board of Directors recommends a vote **FOR** the nominees listed under Item 1.

Item 1 - Election of Directors

		For	**Against**	**Abstain**
NOMINEES:				
1(a)	José E. Almeida	¨	¨	¨
1(b)	Joy A. Amundson	¨	¨	¨
1(c)	Craig Arnold	¨	¨	¨
1(d)	Robert H. Brust	¨	¨	¨
1(e)	John M. Connors, Jr.	¨	¨	¨
1(f)	Christopher J. Coughlin	¨	¨	¨
1(g)	Randall J. Hogan, III	¨	¨	¨
1(h)	Martin D. Madaus	¨	¨	¨
1(i)	Dennis H. Reilley	¨	¨	¨
1(j)	Joseph A. Zaccagnino	¨	¨	¨

Please date and sign name exactly as it appears hereon. Executors, administrators, trustees, etc. should so indicate when signing. If the shareholder is a corporation, the full corporate name should be inserted and the proxy signed by an officer of the corporation indicating his/her title.

The Board of Directors recommends a vote **FOR** Items 2, 3, 4, 5, 6, 7 and 8

		For	**Against**	**Abstain**
Item 2	Appoint the Independent Auditors and authorize the Audit Committee to set the auditors remuneration.	¨	¨	¨
Item 3 -	Advisory vote on executive compensation.	¨	¨	¨
Item 4 -	Approve the amended and restated Covidien Stock and Incentive Plan.	¨	¨	¨
Item 5 -	Authorize the Company and/or any subsidiary to make market purchases of Company shares.	¨	¨	¨
Item 6 -	Authorize the price range at which the Company can reissue shares it holds as treasury shares. (Special Resolution)	¨	¨	¨
Item 7 -	Amend Articles of Association to expand the authority to execute instruments of transfer. (Special Resolution)	¨	¨	¨
Item 8 -	Advisory vote on the creation of Mallinckrodt distributable reserves.	¨	¨	¨

	Yes	**No**
Please indicate if you plan to attend the meeting.	¨	¨

For address changes and/or comments, please check this box and write them on the back where indicated. ¨

Signature [PLEASE SIGN WITHIN BOX] Date Signature (Joint Owners) Date