MEDICIS PHARMACEUTICAL CORP
Form 10-K
February 28, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011.

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 001-14471

MEDICIS PHARMACEUTICAL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	52-1574808
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7720 N. Dobson Road, Scottsdale, Arizona 85256-2740
(Address of principal executive office) (Zip Code)
Registrant s telephone number, including area code: (602) 808-8800

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

Title of each class	Name of each exchange on which registered
Class A common stock, $0.014 par value	New York Stock Exchange
Preference Share Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act: NONE

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) 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 that 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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form or any amendment to this Form 10-K ¨.

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

Large accelerated filer x	Accelerated filer ¨	Non-accelerated filer ¨	Smaller reporting company ¨
		(do not check if a smaller reporting company)	

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

The aggregate market value of the voting stock held on June 30, 2011 by non-affiliates of the registrant was $2,092,313,017 based on the closing price of $38.17 per share as reported on the New York Stock Exchange on June 30, 2011, the last business day of the registrant s most recently completed second fiscal quarter (calculated by excluding all shares held by executive officers, directors and holders known to the registrant of ten percent or more of the voting power of the registrant s common stock, without conceding that such persons are affiliates of the registrant for purposes of the federal securities laws). As of February 22, 2012, there were 58,916,819 outstanding shares of Class A common stock, including 1,916,059 shares of unvested restricted stock awards.

Documents incorporated by reference:

Portions of the Proxy Statement for the registrant s 2012 Annual Meeting of Shareholders (the Proxy Statement) are incorporated herein by reference in Part III of this Form 10-K to the extent stated herein.

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PART I

Item 1. Business

The Company

Medicis Pharmaceutical Corporation (Medicis, the Company, or as used in the context of we, us or our), together with our wholly owned subsidiaries, is a leading independent specialty pharmaceutical company focusing primarily on helping patients attain a healthy and youthful appearance and self-image through the development and marketing in the United States (U.S.) and Canada of products for the treatment of dermatological and aesthetic conditions.

We believe that the U.S. market for dermatological pharmaceutical sales exceeds $6 billion annually. According to the American Society of Plastic Surgeons (ASPS), over 13.8 million cosmetic plastic surgery procedures (both surgical and minimally-invasive) were performed in the U.S. in 2011, an increase of five percent as compared to 2010.

We have built our business by executing a four-part growth strategy: promoting existing brands, developing new products and important product line extensions, entering into strategic collaborations, and acquiring complementary products, technologies and businesses. Our core philosophy is to cultivate high integrity relationships of trust and confidence with the foremost dermatologists and the leading plastic surgeons in the U.S. and Canada.

During the fourth quarter of 2011, we acquired substantially all of the assets of Graceway Pharmaceuticals, LLC (Graceway) for approximately $455.9 million in cash, after our successful bid at a bankruptcy auction. Graceway s commercial pharmaceutical product portfolio includes on-market prescription products and important development projects primarily in dermatology and women s health specialties. Also during the fourth quarter of 2011, we closed the sale of our LipoSonix business to Solta Medical, Inc. (Solta) for aggregate cash consideration of approximately $35.5 million and continuing milestone payments based upon the commercial success of the LipoSonix products.

We offer a broad range of products addressing various conditions or aesthetic improvements, including facial wrinkles, glabellar lines, acne, fungal infections, hyperpigmentation, photoaging, psoriasis, actinic keratosis, bronchospasms, external genital and perianal warts/condyloma acuminata, seborrheic dermatitis and cosmesis (improvement in the texture and appearance of skin). We currently offer 27 branded products. Our primary brands are DYSPORT® (abobotulinumtoxinA) 300 Units for Injection, PERLANE® Injectable Gel, RESTYLANE® Injectable Gel, SOLODYN® (minocycline HCl, USP) Extended Release Tablets, VANOS® (fluocinonide) Cream 0.1%, ZIANA® (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel and ZYCLARA® (imiquimod) Cream 3.75% and 2.5%. Many of our primary brands currently enjoy branded market leadership in the segments in which they compete. We concentrate our sales and marketing efforts in promoting them to physicians in our target markets because of the significance of these brands to our business. We also sell a number of other products that we consider less critical to our business.

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Our current product lines are divided between the dermatological and non-dermatological fields. The dermatological field represents products for the treatment of acne and acne-related dermatological conditions and non-acne dermatological conditions. The non-dermatological field represents products in the respiratory and women s health specialties and products for the treatment of urea cycle disorders. Our non-dermatological field also includes contract revenues associated with licensing agreements and authorized generic agreements. The following table sets forth the percentage of net revenues for each of our product categories for 2011, 2010 and 2009:

Product Category	2011	2010	2009
Acne and acne-related dermatological products	62.1%	69.3%	69.9%
Non-acne dermatological products	31.8%	25.1%	23.4%
Non-dermatological products (including contract revenues)	6.1%	5.6%	6.7%

Less than 5% of our net revenues during 2011, 2010 and 2009 were generated outside the U.S.

Our Products

We currently market 27 branded products. Our sales and marketing efforts are currently focused on our primary brands. The following chart details certain important features of our primary brands:

Brand	Treatment	U.S. Market Impact
DYSPORT®	Temporary improvement in the appearance of moderate to severe glabellar lines in adults younger than 65 years of age	Launched in June 2009 following U.S. Food and Drug Administration (FDA) approval on April 29, 2009
PERLANE®	Implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds	Launched in May 2007 following FDA approval on May 2, 2007; PERLANE-L® was approved by the FDA on January 29, 2010
RESTYLANE®	Implantation into the mid to deep dermis for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds; submucosal implantation for lip augmentation in patients over the age of 21	The first hyaluronic acid dermal filler approved in the U.S., and the most-studied dermal filler in the world; launched in January 2004 following FDA approval on December 12, 2003; RESTYLANE-L® was approved by the FDA on January 29, 2010; the Premarket Approval Application (PMA) supplement to expand the approved use of RESTYLANE® to include lip augmentation was approved by the FDA on October 11, 2011
SOLODYN®	Once daily dosage for the treatment of only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	The #1 dermatology medication by dollars in the world and the #1 most prescribed branded dermatology product in the U.S. by prescriptions and dollars; launched in 2006 following FDA approval on May 8, 2006
VANOS®	Super-high potency topical corticosteroid for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses (e.g., psoriasis) in patients 12 years of age or older	Launched in April 2005 following FDA approval on February 11, 2005

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Brand	Treatment	U.S. Market Impact
ZIANA®	Once daily combination product for topical treatment of acne vulgaris in patients 12 years of age and older	First commercial sales to wholesalers in December 2006 and launched in January 2007 following FDA approval on November 7, 2006
ZYCLARA®	Topical treatment of clinically typical visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults (3.75% and 2.5% strengths), and the topical treatment of external genital and perianal warts/ condyloma acuminate in patients 12 years of age or older (3.75% strength only)	Acquired as part of the purchase of the assets of Graceway on December 2, 2011

Prescription Pharmaceuticals

Our principal branded prescription pharmaceutical products are described below:

SOLODYN®, launched to dermatologists in July 2006 after approval by the FDA on May 8, 2006, is the only branded oral minocycline approved for once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older. SOLODYN® is the first and only extended release minocycline with eight FDA-approved dosing strengths. SOLODYN® is currently available by prescription in 55mg, 65mg, 80mg, 105mg and 115mg extended release tablet dosages. SOLODYN® in 45mg, 90mg and 135mg strengths were approved as a part of the original FDA approval on May 8, 2006, and we stopped shipping these strengths effective July 1, 2011. The 65mg and 115mg dosages were approved by the FDA in July 2009. The 55mg, 80mg and 105mg strengths were approved by the FDA in August 2010. Minocycline, the active ingredient in SOLODYN®, is lipid soluble, and distributes in the skin and sebum. SOLODYN® is not bioequivalent to any immediate release minocycline products, and is in no way interchangeable with any immediate release forms of minocycline. SOLODYN® has four issued patents (see also Item 1A. Risk Factors). U.S. patent No. 5,908,838 (the 838 Patent), which expires in 2018, relates to the use of the SOLODYN® unique dissolution rate. We believe all forms of SOLODYN® currently approved for use are covered by one or more claims of the 838 Patent. The FDA listed this patent in the FDA s Approved Drug Products with Therapeutic Equivalents (the Orange Book) for SOLODYN® in December 2008. U.S. Patent No. 7,541,347 (the 347 Patent), which expires in 2027, relates to the use of the 90mg controlled-release oral dosage form of minocycline to treat acne. U.S. Patent No. 7,544,373 (the 373 Patent), which expires in 2027, relates to the composition of the 90mg dosage form. The FDA listed these two patents in the Orange Book for SOLODYN® in June 2009. On September 8, 2010, the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 7,790,705 (the 705 Patent) related to the use of SOLODYN®. This patent, entitled Minocycline Oral Dosage Forms for the Treatment of Acne, relates to the use of dosage forms of SOLODYN® which provide approximately 1 mg/kg dosing based on the body weight of the person, and expires in 2025. On April 5, 2011, the USPTO issued U.S. Patent No. 7,919,483 (the 483 Patent), entitled Method for the Treatment of Acne, which covers methods of using a controlled-release oral dosage form of minocycline to treat acne, including the use of our product SOLODYN® in all eight currently available dosage forms, and expires in March 2027. Multiple patent applications directed to key dosing, labeling and formulation aspects of SOLODYN® are pending. See also Item 1A. Risk Factors.

VANOS® Cream, launched to dermatologists in April 2005 after approval by the FDA on February 11, 2005, is a super-high potency (Class I) topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses (e.g., psoriasis) in patients 12 years of age or older. The active ingredient in VANOS® is fluocinonide 0.1%, and is the only fluocinonide available in the Class I category of topical corticosteroids. Two double-blind clinical studies have demonstrated the efficacy, safety and tolerability of VANOS®. Its base was formulated to have the cosmetic elegance of a cream with ointment-like ingredients. In addition, physicians have the flexibility of prescribing VANOS® either for once or twice daily

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application for corticosteroid responsive dermatoses. VANOS® Cream is available by prescription in 30 gram, 60 gram and 120 gram tubes. VANOS® Cream is protected by one U.S. patent that expires in 2021, two U.S. patents that expire in 2022 and two U.S patents that expire in 2023. See also Item 1A. Risk Factors.

ZIANA® Gel, which contains clindamycin phosphate 1.2% and tretinoin 0.025%, was approved by the FDA on November 7, 2006. Initial shipments of ZIANA® to wholesalers began in December 2006, with formal promotional launch to dermatologists occurring in January 2007. ZIANA® is a combination of clindamycin and tretinoin approved for once daily use for the topical treatment of acne vulgaris in patients 12 years and older. ZIANA® was also the first approved acne product to combine an antibiotic and a retinoid. ZIANA® is available by prescription in 30 gram and 60 gram tubes. ZIANA® is protected by two U.S. patents for both composition of matter on the aqueous-based vehicle and method that expire in 2015 and 2020. Each of these patents cover aspects of the unique vehicle which are used to deliver the active ingredients in ZIANA®. See also Item 1A. Risk Factors.

ZYCLARA® Cream, which contains imiquimod, was approved by the FDA in the 3.75% strength for the topical treatment of clinically typical visible or palpable actinic keratoses of the full face or balding scalp in immunocompetent adults on March 25, 2010, and for the treatment of external genital warts and perianal warts in patients 12 years or older on March 24, 2011; and was approved in the 2.5% strength for the topical treatment of clinically typical visible or palpable actinic keratoses of the full face or balding scalp in immunocompetent adults on July 15, 2011. ZYCLARA® is available by prescription and is supplied as a cream in the 3.75% strength in single-use packets, and in a pump container system which we began shipping to wholesale customers in February 2012. The 2.5% strength is anticipated to be launched in a pump form during the second half of 2012. ZYCLARA® has several applied-for patents currently under accelerated examination in the U.S. which we believe are to issue before the expiration of regulatory exclusivity. We expect the term of some of these applications to run to 2029 or 2030.

Facial Aesthetic Products

Our principal branded facial aesthetic products are described below:

DYSPORT®, an injectable botulinum toxin type A formulation, is an acetylcholine release inhibitor and a neuromuscular blocking agent. We market DYSPORT® in the U.S. for the aesthetic indication of temporary improvement in the appearance of moderate to severe glabellar lines in adults younger than 65 years of age. DYSPORT® was approved by the FDA on April 29, 2009 and launched by us in June 2009. We acquired the rights to the aesthetic use of DYSPORT® in the U.S., Canada and Japan from Ipsen, S.A. (Ipsen) in March 2006. According to the ASAPS, injections of botulinum toxin type A was the number one nonsurgical cosmetic procedure in 2010, with over 2.4 million total procedures performed.

RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and **RESTYLANE FINE LINES™** are injectable, transparent, stabilized hyaluronic acid gels, which require no patient sensitivity tests in advance of product administration. Their unique particle-based gel formulations offer structural support and lift when implanted into the skin. We acquired the exclusive U.S. and Canadian rights to these facial aesthetic products from Q-Med AB, a Swedish biotechnology and medical device company and its affiliates (collectively, Q-Med) through license agreements in March 2003. On a worldwide basis, more than 11 million treatments of RESTYLANE® have been successfully performed in more than 70 countries since market introduction in 1996. In the U.S., the FDA regulates these products as medical devices. We began offering RESTYLANE® and PERLANE® in the U.S. on January 6, 2004 and May 21, 2007, respectively, following FDA approvals on December 12, 2003 and May 2, 2007, respectively. RESTYLANE® is the most-studied dermal filler, and is the first and only hyaluronic acid dermal filler whose FDA-approved label includes duration data up to 18 months with one follow-up treatment. On January 29, 2010, the FDA approved RESTYLANE-L® and PERLANE-L®, which include the addition of 0.3% lidocaine. We began shipping RESTYLANE-L® and PERLANE-L® during the first quarter of 2010, and these products represented, in aggregate, approximately 88% of RESTYLANE®

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brand family net revenues during 2011. On October 11, 2011, we announced that the FDA had approved our premarket approval application supplement to expand the approved use of RESTYLANE® to include lip augmentation. We offer RESTYLANE®, PERLANE® and RESTYLANE FINE LINES™ in Canada. RESTYLANE FINE LINES ™ is not approved by the FDA for use in the U.S.

Research and Development

We have historically developed and obtained marketing and distribution rights to pharmaceutical agents in various stages of development. We have a variety of products under development, ranging from new products to existing product line extensions and reformulations of existing products. Our product development strategy involves the rapid evaluation and formulation of new therapeutics by obtaining preclinical safety and efficacy data, when possible, followed by rapid safety and efficacy testing in humans. Historically, we have supplemented our research and development efforts by entering into research and development and license agreements with other pharmaceutical and biotechnology companies for the development of new products and the enhancement of existing products. We anticipate that research and development expense will increase as a percentage of net revenues in the next several years as we continue to add important projects to our development portfolio.

We incurred total research and development costs for all of our sponsored and unreimbursed co-sponsored pharmaceutical projects for 2011, 2010 and 2009, of $68.3 million, $44.3 million and $58.1 million, respectively. Research and development costs include up-front and milestone payments related to product development agreements and other strategic collaborations. During 2011, up-front and/or milestone payments of $20.0 million was paid to Lupin Limited (Lupin), $7.0 million was paid to Anacor Pharmaceuticals, Inc. (Anacor), $5.5 million was paid to a privately-held U.S. biotechnology company, and $2.0 million was paid to a Medicis partner. During 2010, up-front and/or milestone payments of $15.0 million was paid to a privately-held U.S. biotechnology company and $3.9 million was paid to a Medicis partner. During 2009, up-front and/or milestone payments of $12.0 million was paid to Impax Laboratories, Inc. (Impax), $10.0 million was paid to Revance Therapeutics, Inc. (Revance), $5.3 million was paid to Glenmark Generics Ltd. and Glenmark Generics Inc., USA (collectively, Glenmark) and $5.0 million was paid to Perrigo Israel Pharmaceutical Ltd. and Perrigo Company (collectively, Perrigo).

On July 21, 2011, we entered into a joint development agreement with Lupin, whereby Lupin and we will collaborate to develop multiple novel proprietary therapeutic products. Pursuant to the agreement, subject to the terms and conditions contained therein, we made an up-front $20.0 million payment to Lupin and will make additional payments to Lupin of up to $38.0 million upon the achievement of certain research, development, regulatory and other milestones, as well as royalty payments on sales of the products covered under the agreement. In addition, we will receive an exclusive, worldwide (excluding India) license on the sale of the products covered under the agreement. The $20.0 million up-front payment was recognized as research and development expense during the year ended December 31, 2011.

On February 9, 2011, we entered into a research and development agreement with Anacor for the discovery and development of boron-based small molecule compounds directed against a target for the potential treatment of acne. Under the terms of the agreement, we paid Anacor $7.0 million in connection with the execution of the agreement, and will pay up to $153.0 million upon the achievement of certain research, development, regulatory and commercial milestones, as well as royalties on sales by us. Anacor will be responsible for discovering and conducting the early development of product candidates which utilize Anacor s proprietary boron chemistry platform, while we will have an option to obtain an exclusive license for products covered by the agreement. The initial $7.0 million payment was recognized as research and development expense during the year ended December 31, 2011.

On September 10, 2010, we entered into a sublicense and development agreement with a privately-held U.S. biotechnology company to develop an agent for specific dermatological conditions in the Americas and Europe and a purchase option to acquire the privately-held U.S. biotechnology company. Under the terms of the

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agreements, we paid the privately-held U.S. biotechnology company $5.0 million in connection with the execution of the agreement, and will pay additional potential milestone payments totaling approximately $100.5 million upon successful completion of certain clinical, regulatory and commercial milestones. During the three months ended December 31, 2010 and the three months ended June 30, 2011, a development milestone was achieved, and we made a $10.0 million payment and a $5.5 million payment, respectively, to the privately-held U.S. biotechnology company pursuant to the development agreement. The initial $5.0 million payment and the $10.0 million milestone payment were recognized as research and development expense during the year ended December 31, 2010, and the $5.5 million milestone payment was recognized as research and development expense during the year ended December 31, 2011.

On November 14, 2009, we entered into an asset purchase and development agreement with Glenmark. In connection with the agreement, we purchased from Glenmark the North American rights of a dermatology product currently under development, including the underlying technology and regulatory filings. In accordance with the terms of the agreement, we made a $5.0 million payment to Glenmark upon closing of the transaction. The agreement also provided that we would make additional payments to Glenmark of up to $7.0 million upon the achievement of certain development and regulatory milestones, as well as certain royalty payments on sales of the product. The initial $5.0 million payment was recognized as research and development expense during the year ended December 31, 2009. On October 4, 2010, we gave notice to Glenmark that we had determined to stop development of the product in accordance with the terms of the agreement, and on January 6, 2011, we gave notice to Glenmark that the parties obligations under the agreement have been fulfilled and that the agreement has expired.

On July 28, 2009, we entered into a license agreement with Revance granting us worldwide aesthetic and dermatological rights to Revance s novel, investigational, injectable botulinum toxin type A product, referred to as RT002, currently in pre-clinical studies. The objective of the RT002 program is the development of a next-generation neurotoxin with favorable duration of effect and safety profiles. Under the terms of the agreement, we paid Revance $10.0 million upon closing of the agreement, and will pay additional potential milestone payments totaling approximately $94 million upon successful completion of certain clinical, regulatory and commercial milestones, and a royalty based on sales and supply price, the total of which is equivalent to a double-digit percentage of net sales. The initial $10.0 million payment was recognized as research and development expense during the year ended December 31, 2009.

On April 8, 2009, we entered into a joint development agreement with Perrigo whereby we would collaborate with Perrigo to develop a novel proprietary product for which we would have the sole right to commercialize. If and when a New Drug Application (NDA) for a novel proprietary product is submitted to the FDA, we and Perrigo would enter into a commercial supply agreement pursuant to which, among other terms, for a period of three years following approval of the NDA, Perrigo would exclusively supply to us all of our novel proprietary product requirements in the U.S. We made an up-front $3.0 million payment to Perrigo upon execution of the agreement. During the three months ended September 30, 2009, a development milestone was achieved, and we made a $2.0 million payment to Perrigo pursuant to the agreement. The agreement also included additional payments to Perrigo of up to $3.0 million upon the achievement of other certain development and regulatory milestones, as well as royalty payments to Perrigo on sales of the novel proprietary product. The $3.0 million up-front payment and the $2.0 million development milestone payment were recognized as research and development expense during the year ended December 31, 2009. During the three months ended September 30, 2011, we determined that the product under development did not satisfy our criteria for continuing development. The development project was terminated, and we paid Perrigo $1.0 million as part of the termination, which was recognized as research and development expense during the year ended December 31, 2011.

On November 26, 2008, we entered into a joint development agreement with Impax, which was amended on January 21, 2011, whereby we and Impax will collaborate on the development of five strategic dermatology product opportunities, including an advanced-form SOLODYN® product. Under the terms of the agreement, we made an initial payment of $40.0 million upon execution of the agreement. During the three months ended March 31, 2009, September 30, 2009 and December 31, 2009, we paid Impax $5.0 million, $5.0 million and

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$2.0 million, respectively, upon the achievement of three separate clinical milestones, in accordance with the terms of the agreement. In addition, we are required to pay up to $11.0 million upon successful completion of certain other clinical and commercial milestones. We will also make royalty payments based on sales of the advanced-form SOLODYN® product if and when it is commercialized by us upon approval by the FDA. We will share in the gross profit of the other four development products if and when they are commercialized by Impax upon approval by the FDA. The $40.0 million payment was recognized as research and development expense during the year ended December 31, 2008, and the three separate $5.0 million, $5.0 million and $2.0 million clinical milestone achievement payments were recognized as research and development expense during the year ended December 31, 2009.

Sales and Marketing

Our combined dedicated sales force, consisting of 253 employees as of December 31, 2011, focuses on high patient volume dermatologists and plastic surgeons. Since a relatively small number of physicians are responsible for writing a majority of dermatological prescriptions and performing facial aesthetic procedures, we believe that the size of our sales force is appropriate to reach our target physicians. Our therapeutic dermatology sales force consists of 156 employees who regularly call on approximately 10,000 dermatologists. Our facial aesthetic sales force consists of 97 employees who regularly call on leading plastic surgeons, facial plastic surgeons, dermatologists and dermatologic surgeons. We also have four national account managers who regularly call on major drug wholesalers, managed care organizations, large retail chains, formularies and related organizations.

Our strategy is to cultivate relationships of trust and confidence with the high prescribing dermatologists and the leading plastic surgeons in the U.S. We use a variety of marketing techniques to promote our products including sampling, journal advertising, promotional materials, specialty publications, coupons, educational interactions and informational websites. We also promote our facial aesthetic products through television and radio advertising.

We believe we have created an attractive incentive program for our sales force that is based upon goals in prescription growth, market share achievement and customer service.

Warehousing and Distribution

We utilize an independent national warehousing corporation to store and distribute our pharmaceutical products in the U.S. from primarily two regional warehouses in Nevada and Georgia, as well as an additional warehouse in North Carolina. We also utilize independent warehousing companies to store and distribute our pharmaceutical products in Canada from warehouses in Ontario. Upon the receipt of a purchase order through electronic data input (EDI), phone, mail or facsimile, the order is processed through our inventory management systems and is transmitted primarily electronically to the appropriate warehouse for picking and packing. Upon shipment, the warehouse sends back to us, primarily via EDI, the necessary information to automatically process the invoice in a timely manner.

Customers

Our customers include certain of the leading wholesale pharmaceutical distributors in the U.S., such as AmerisourceBergen Corporation (AmerisourceBergen), Cardinal Health, Inc. (Cardinal) and McKesson Corporation (McKesson) along with other major drug chains. During 2011, 2010 and 2009, these customers accounted for the following portions of our net revenues:

	2011	2010	2009
McKesson	44.3%	42.6%	40.8%
Cardinal	38.3%	35.4%	37.1%
AmerisourceBergen	*	10.8%	*

* less than 10%

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McKesson is the sole distributor of our RESTYLANE® and PERLANE® branded products and DYSPORT® in the U.S.

Third-Party Reimbursement

Our operating results and business success depend in large part on the availability of adequate third-party payor reimbursement to patients for our prescription brand products. These third-party payors include governmental entities such as Medicaid, Medicare, private health insurers and managed care organizations. Because of the size of the patient population covered by managed care organizations, marketing of prescription drugs to them and the pharmacy benefit managers that serve many of these organizations has become important to our business.

The trend toward managed healthcare in the U.S. and the growth of managed care organizations, as well as the implementation of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, together known as the Affordable Care Act, could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. Payment or reimbursement of only a portion of the cost of our prescription products could make our products less attractive, from a net-cost perspective, to patients, suppliers and prescribing physicians. As such we continue to actively partner with third-party payors, working towards increasing formulary coverage and accessibility to our products.

Some of our products are covered for Medicare beneficiaries under the expanded prescription drug benefit for all Medicare beneficiaries known as Medicare Part D. This is a voluntary benefit that is implemented through private plans under contractual arrangements with the federal government. These plans negotiate discounts from drug manufacturers and pass some of the savings to Medicare beneficiaries. Effective January 1, 2012, we have entered into several agreements with private plans offering additional savings to Medicare beneficiaries.

Beginning in 2011, the Affordable Care Act made several changes to Medicare Part D to phase-out the patient coverage gap (e.g., doughnut hole) by reducing patient responsibility in the coverage gap from 100% in 2010 to 25% in 2020. Also beginning in 2011, under the Coverage Gap Discount Program, drug manufacturers are obligated to pay quarterly applicable discounts of 50% of the negotiated price of all their branded drugs issued to Medicare Part D patients in the coverage gap. Medicis is obligated to pay these rebates under this Medicare Part D Coverage Gap Discount Program.

Some of our products, such as our facial aesthetics products DYSPORT®, RESTYLANE® and PERLANE®, are not of a type generally eligible for reimbursement. It is possible that products manufactured by others could address the same effects as our products and be subject to reimbursement. If this were the case, some of our products may be unable to compete on a price basis. In addition, decisions by state regulatory agencies, including state pharmacy boards, and/or retail pharmacies may require substitution of generic for branded products, may prefer competitors products over our own, and may impair our pricing and thereby constrain our market share and growth.

Seasonality

Our business, taken as a whole, is not materially affected by seasonal factors. We schedule our inventory purchases to meet anticipated customer demand. As a result, relatively small delays in the receipt of manufactured products by us could result in revenues being deferred or lost.

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Manufacturing

We currently outsource all of our manufacturing needs, and we are required by the FDA to contract only with manufacturers who comply with current Good Manufacturing Practices (cGMP) regulations and other applicable laws and regulations. Typically our manufacturing contracts are short term. We review our manufacturing arrangements on a regular basis and assess the viability of alternative manufacturers and suppliers of key raw materials if our current manufacturers are unable to fulfill our needs. If any of our manufacturing partners are unable to perform their obligations under our manufacturing agreements or if any of our manufacturing agreements are terminated, we may experience a disruption in the manufacturing of the applicable product that would adversely affect our results of operations. In some cases, the sources of our raw materials are outside of the U.S., and as such we cannot always guarantee that the political and industry climate in these countries will always be stable and provide a surety of supply. Also, due to the U.S. environment, certain materials may experience changes in U.S. manufacturing location to an Ex-U.S. location, which could cause unplanned disruptions. We also work though U.S. agents for the supply of active pharmaceutical ingredients brought into the U.S. and in some cases are only able to purchase on a purchase order basis. While we attempt to understand and mitigate risks within the supply chain for manufacturers and suppliers, it is not always feasible and possible to identify willing, qualified alternate sources, often due to the nature of the product lines we produce. In certain cases, we may increase inventory levels as a risk mitigating activity. Additionally, in many cases our manufacturers and suppliers are privately-held or closely-held corporations, so it potentially can be difficult to assess the financial health and viability of our manufacturers and suppliers. We attempt to mitigate this risk through up-front diligence as well as ongoing diligence of the financial status and operational capabilities of our manufacturers and suppliers.

Under several exclusive supply agreements, with certain exceptions, we must purchase most of our product supply from specific manufacturers. If any of these exclusive manufacturer or supplier relationships were terminated, we would be forced to find a replacement manufacturer or supplier. The FDA requires that all manufacturers used by pharmaceutical companies comply with the FDA s regulations, including the cGMP regulations applicable to manufacturing processes. The cGMP validation of a new facility, the qualification of a new supply source and the approval of that manufacturer for a new drug product may take a year or more before commercial manufacture can begin at the facility. Delays in obtaining FDA qualification and validation of a replacement manufacturing facility could cause an interruption in the supply of our products. Although we have business interruption insurance to assist in covering the loss of income for products where we do not have a secondary manufacturer, which may reduce the harm to us from the interruption of the manufacturing of our largest-selling products caused by certain events, the loss of a manufacturer could still cause a significant reduction in our sales, margins and market share, as well as harm our overall business and financial results.

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are currently available from only one source and others may in the future become available from only one source. Also, at times suppliers of raw materials may change their processes and/or components with little advance notice. These occurrences have the potential to impact product availability as well, as we manage these changes in the required regulatory manner and time frames. We try to maintain inventory levels at various in-process stages (e.g., raw material inventory and finished product inventory) that are no greater than necessary to meet our current projections, which could have the effect of exacerbating supply problems. Any interruption in the supply of finished products could hinder our ability to timely distribute finished products and prevent us from increasing raw material and finished product inventory levels to mitigate supply risks as a temporary solution. If we are unable to obtain adequate product supplies to satisfy our customers orders, we may lose those orders and our customers may cancel other orders and stock and sell competing products. This, in turn, could cause a loss of our market share and reduce our revenues. In addition, any disruption in the supply of raw materials or an increase in the cost of raw materials to our manufacturers could have a significant effect on their ability to supply us with our products, which would adversely affect our financial condition and results of operations.

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Our VANOS® and ZIANA® branded products are manufactured by Contract Pharmaceuticals Limited pursuant to a manufacturing agreement that expires three years after delivery of our first order of commercial supply of our ZIANA® branded products, which we anticipate will occur sometime in 2012, or in early 2013. We are also in the process of evaluating alternative manufacturing facilities for some of these products.

Our RESTYLANE® and PERLANE® branded products in the U.S. and Canada are manufactured by Q-Med pursuant to a long-term supply agreement that expires no earlier than 2014.

Our DYSPORT® branded product is manufactured by Ipsen pursuant to a long-term supply agreement that expires in 2036.

Our SOLODYN® branded product is manufactured by Wellspring Pharmaceutical Canada Corp. pursuant to a supply agreement that expires in 2014, and also by AAIPharma Services Corp., pursuant to a supply agreement that expires in 2012. We are currently in the process of negotiating a new, long-term supply agreement with AAIPharma, and we are also in the process of evaluating an alternative packaging facility for future SOLODYN® production.

Our ZYCLARA® branded product is manufactured by 3M Corporation pursuant to a supply agreement that terminates in December 2013.

Raw Materials

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are currently available from only one source and others may in the future become available from only one source. Any disruption in the supply of raw materials or an increase in the cost of raw materials to our manufacturers could have a significant effect on their ability to supply us with our products. We are also in the process of evaluating alternative raw material suppliers for some of our products.

License and Royalty Agreements

Pursuant to license agreements with third parties, we have acquired rights to manufacture, use or market certain of our existing products, as well as many of our development products and technologies. Such agreements typically contain provisions requiring us to use our best efforts or otherwise exercise diligence in pursuing market development for such products in order to maintain the rights granted under the agreements and may be canceled upon our failure to perform our payment or other obligations. In addition, we have licensed certain rights to manufacture, use and sell certain of our technologies outside the U.S. and Canada to various licensees.

Trademarks, Patents and Proprietary Rights

We believe that trademark protection is an important part of establishing product and brand recognition. We own a number of registered trademarks and trademark applications. U.S. federal registrations for trademarks remain in force for 10 years and may be renewed every 10 years after issuance, provided the mark is still being used in commerce.

We have obtained and/or in-licensed a number of patents covering key aspects of our products, including a U.S. patent expiring in December 2017 or later covering RESTYLANE®, three U.S. patents expiring, respectively, in February 2018, June 2025 and March 2027, covering multiple strengths of SOLODYN® Tablets; two U.S. patents expiring in April 2027, each covering 90mg SOLODYN® Tablets; two U.S. patents expiring, respectively, in February 2015 and August 2020 covering ZIANA® Gel; one U.S. patent expiring in December 2021, two U.S. patents expiring in January 2023, and two U.S. patents expiring in August and September 2022, respectively, covering VANOS® Cream and two U.S. patents expiring, respectively, in November 2016 and September 2018 covering LOPROX® Shampoo (ciclopirox) 1%. We also have patent applications pending

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relating to most of our products, including SOLODYN® Tablets, ZYCLARA® and LOPROX® Shampoo (ciclopirox) 1%, and we are pursuing several other U.S. and foreign patent applications.

We rely and expect to continue to rely upon unpatented proprietary know-how and technological innovation in the development and manufacture of many of our principal products. Our policy is to require all our employees, consultants and advisors to enter into confidentiality agreements with us, and we employ other security measures to protect our trade secrets and other confidential information. Our success with our products will depend, in part, on our ability to obtain, and successfully defend if challenged, patent or other proprietary protection. Our patents are obtained after examination by the USPTO and are presumed valid. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. Accordingly, our patents may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. As a result, if our patent applications are not approved or, even if approved, patents arising from such patent applications are circumvented or not upheld in a legal proceeding, our ability to competitively exploit our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially exploit these products may be diminished.

Third parties may challenge and seek to invalidate, limit or circumvent our patents and patent applications relating to our products, product candidates and technologies. Such challenges may result in potentially significant harm to our business. The cost of responding to these challenges and the inherent costs of defending the validity of our patents, including the prosecution of infringements and the related litigation, can require a substantial commitment of our management s time, be costly and can preclude or delay the commercialization of products or result in the genericization of markets for our products. See Item 3 of Part I of this report, Legal Proceedings and Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules, for information concerning our current intellectual property litigation.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented.

Competition

The pharmaceutical and facial aesthetics industries are characterized by intense competition, rapid product development and technological change. Numerous companies are engaged in the development, manufacture and marketing of health care products competitive with those that we offer. As a result, competition is intense among manufacturers of prescription pharmaceuticals and dermal injection products, such as for our primary brands.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with our product lines. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Each of our products competes for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by dermatologists and administered by plastic surgeons and aesthetic dermatologists. In addition to product development, other competitive factors affecting the pharmaceutical industry include testing, approval and marketing, industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information.

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The largest competitors for our prescription dermatological products include Allergan, Galderma, Johnson & Johnson, Sanofi, GlaxoSmithKline, plc (Stiefel), Valeant Pharmaceuticals International and Warner Chilcott. There are also prescription dermatological products under development, including products from Leo Pharma. Several of our primary prescription brands compete or may compete in the near future with generic (non-branded) pharmaceuticals, which claim to offer equivalent therapeutic benefits at a lower cost. In some cases, insurers, third-party payors and pharmacies seek to encourage the use of generic products, making branded products less attractive, from a cost perspective, to buyers.

Our facial aesthetics products compete primarily against certain products of Allergan. DYSPORT® competes directly with Allergan s Botox® Cosmetic, an established botulinum toxin product that was approved by the FDA for aesthetic purposes in 2002. Allergan is a larger company than Medicis, and has greater financial resources than those available to us. Another botulinum toxin product on the market is Xeomin®, approved by the FDA for aesthetic purposes in 2011 and marketed by Merz Aesthetics. There are also other botulinum toxin products under development, including products from Johnson & Johnson and its subsidiary Mentor Corporation, which claim to offer equivalent or greater aesthetic benefits than DYSPORT® and, if approved, the companies producing such products could charge less to doctors for their products.

Among other dermal filler products, Allergan markets Juvéderm® Ultra, Juvéderm® Ultra XC, Juvéderm® Ultra Plus and Juvéderm® Ultra Plus XC. Other dermal filler products on the market include: Artefill® by Suneva Medical, Belotero® Balance and Radiesse® by Merz Aesthetics, Elevess™ and Hydrelle™ by Anika Therapeutics, LAVIV™ by Fibrocell Science, Prevelle® Silk by Mentor Corporation and Sculptra® Aesthetic by Valeant Pharmaceuticals International. Patients may differentiate these products from RESTYLANE®, RESTYLANE-L®, PERLANE® and PERLANE-L® based on price, efficacy and/or duration, which may appeal to some patients. In addition, there are several dermal filler products under development and/or in the FDA pipeline for approval, including products from Allergan and Johnson & Johnson and its subsidiary Mentor Corporation, which claim to offer equivalent or greater facial aesthetic benefits than RESTYLANE®, RESTYLANE-L®, PERLANE® and PERLANE-L® and, if approved, the companies producing such products could charge less to doctors for their products.

Government Regulation

The manufacture and sale of medical devices, drugs and biological products are subject to regulation principally by the FDA, but also by other federal agencies, such as the Drug Enforcement Administration (DEA), and state and local authorities in the United States, and by comparable agencies in certain foreign countries. The Federal Trade Commission (FTC), the FDA and state and local authorities regulate the advertising of medical devices, prescription drugs, over-the-counter drugs and cosmetics. The Federal Food, Drug and Cosmetic Act, as amended (FDCA) and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, sale, distribution, advertising and promotion of our products.

The FDA requires a Boxed Warning (sometimes referred to as a Black Box Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Because there have been post-marketing reports of serious adverse events (reported hours to weeks after injection) for botulinum toxin products that are consistent with this class of products, a Boxed Warning is now required for all marketed botulinum toxin products, including our product DYSPORT®, and competitor products Botox®, Botox® Cosmetic, Myobloc® and Xeomin®. This is known as a class label. The FDA s requirement for a Boxed Warning on all marketed botulinum toxin products is the culmination of a safety review of Botox®, Botox® Cosmetic and Myobloc® that the agency announced in early 2008. In addition to the Boxed Warning, the FDA has required implementation of a Risk Evaluation and Mitigation Strategy (REMS) for all marketed botulinum toxin products. The REMS will help ensure that healthcare professionals and patients are adequately informed about product risks. The FDA notified the manufacturers of Botox®, Botox® Cosmetic, Myobloc® and Xeomin® that label changes (e.g., the Boxed Warning) and a REMS are necessary to ensure product risks are adequately communicated to healthcare providers and patients. The Boxed Warning and REMS for DYSPORT® were approved by the FDA as part of the product approval.

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Our RESTYLANE® and PERLANE® dermal filler products are prescription medical devices intended for human use and are subject to regulation by the FDA in the U.S. Unless an exemption applies, a medical device in the U.S. must have a PMA in accordance with the FDCA, or a 510(k) clearance (a demonstration that the new device is substantially equivalent to a device already on the market). RESTYLANE® PERLANE® and non-collagen dermal fillers are subject to PMA regulations that require premarket review of clinical data on safety and effectiveness. FDA device regulations for PMAs generally require reasonable assurance of safety and effectiveness prior to marketing, including safety and efficacy data obtained under clinical protocols approved under an Investigational Device Exemption (IDE) and the manufacturing of the device requires compliance with quality system regulations (QSRs), as verified by detailed FDA inspections of manufacturing facilities. These regulations also require post-approval reporting of alleged product defects, recalls and certain adverse experiences to the FDA. Generally, FDA regulations divide medical devices into three classes. Class I devices are subject to general controls that require compliance with device establishment registration, product listing, labeling, QSRs and other general requirements that are also applicable to all classes of medical devices but, at least currently, most are not subject to premarket review. Class II devices are subject to special controls in addition to general controls and generally require the submission of a premarket notification 510(k) clearance before marketing is permitted. Class III devices are subject to the most comprehensive regulation and in most cases, other than those that remain grandfathered based on clinical use before 1976, require submission to the FDA of a PMA application that includes biocompatibility, manufacturing and clinical data supporting the safety and effectiveness of the device as well as compliance with the same provisions applicable to all medical devices such as QSRs. Annual reports must be submitted to the FDA, as well as descriptions of certain adverse events that are reported to the sponsor within specified timeframes of receipt of such reports. RESTYLANE® and PERLANE® are regulated as Class III PMA-required medical devices. RESTYLANE® and PERLANE® have been approved by the FDA under a PMA.

In general, products falling within the FDA s definition of new drugs, including both drugs and biological products, require premarket approval by the FDA and must comply with a host of marketing requirements, such as product labeling, and post-market regulations, including but not limited to, manufacture under cGMP and adverse experience reporting.

New drug products are thoroughly tested to demonstrate their safety and effectiveness. Preclinical testing is generally conducted on laboratory animals to evaluate the potential safety and toxicity of a drug. The results of these studies are submitted to the FDA as a part of an Investigational New Drug Application (IND), which must be effective before clinical trials in humans can begin. Typically, clinical evaluation of new drugs involves a time consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of healthy subjects to determine the early safety profile, the relationship of safety to dose, and the pattern of drug distribution and metabolism. In Phase II, one or more clinical trials are conducted with groups of patients afflicted with a specific disease or condition to determine preliminary efficacy and expanded evidence of safety; the degree of effect, if any, as compared to the current treatment regimen; and the optimal dose to be used in large scale trials. In Phase III, typically at least two large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease or condition to provide sufficient confirmatory data to support the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical trials and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

The steps required before a new drug may be marketed, shipped or sold in the U.S. typically include (i) preclinical laboratory and animal testing of pharmacology and toxicology; (ii) submission to the FDA of an IND; (iii) at least two adequate and well-controlled clinical trials to establish the safety and efficacy of the drug (for some applications, the FDA may accept one large clinical trial) beyond those human clinical trials necessary to establish a safe dose and to identify the human absorption, distribution, metabolism and excretion of the active ingredient or biological substance as applicable; (iv) submission to the FDA of an NDA or BLA; (v) FDA approval of the NDA or BLA; and (vi) manufacture under cGMPs as verified by a pre-approval inspection (PAI) by the FDA. In addition to obtaining FDA approval for each product, each drug manufacturing establishment must be registered with the FDA.

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Generic versions of new drugs may also be approved by the agency pursuant to an Abbreviated New Drug Application (ANDA) if the product is pharmaceutically equivalent (i.e., it has the same active ingredient, strength, dosage form and route of administration) and bioequivalent to the reference listed drug (RLD). The agency will not approve an ANDA, however, if the RLD has statutory marketing exclusivity. If the RLD has patent protection and the patent is listed in the FDA s Orange Book, the FDA will approve an ANDA generally only if the applicant filed a paragraph IV certification and there is no 30-month stay in place. For oral or parental dosage forms, approval of an ANDA does not generally require the submission of clinical data on the safety and effectiveness of the drug product. For certain topical drug products submitted under ANDAs, clinical studies demonstrating equivalence to the innovator drug product may be required. For solid oral dosage forms, the applicant must provide dissolution and/or bioequivalence studies to show that the generic drug product has comparable bioavailability to the RLD upon which the ANDA is based.

FDA approval is required before a new drug product may be marketed in the U.S. However, many historically over-the-counter (OTC) drugs are exempt from the FDA s premarket approval requirements. In 1972, the FDA instituted the ongoing OTC Drug Review to evaluate the safety and effectiveness of all OTC active ingredients and associated labeling (OTC drugs). Through this process, the FDA issues monographs that set forth the specific active ingredients, dosages, indications and labeling statements for OTC drugs that the FDA will consider generally recognized as safe and effective and therefore not subject to premarket approval. Before issuance of a final OTC drug monograph as a federal regulation, OTC drugs are classified by the FDA in one of three categories: Category I ingredients and labeling which are deemed generally recognized as safe and effective for OTC use; Category II ingredients and labeling, which are deemed not generally recognized as safe and effective for OTC use; and Category III ingredients and labeling, for which available data are insufficient to classify as Category I or II, pending further studies. Based upon the results of these ongoing studies and pursuant to a court order, the FDA is required to reclassify all Category III ingredients as either Category I or Category II before issuance of a final monograph through notice and comment rule-making. Drugs subject to final monographs, as well as drugs that are subject only to proposed monographs, are also and separately subject to various FDA regulations concerning, for example, cGMP, general and specific OTC labeling requirements and prohibitions against promotion for conditions other than those stated in the labeling. OTC drug manufacturing facilities are subject to FDA inspection, and failure to comply with applicable regulatory requirements may lead to administrative or judicially imposed penalties.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a disease or condition that affects populations of fewer than 200,000 individuals in the U.S. or a disease whose incidence rates number more than 200,000 where the sponsor establishes that it does not realistically anticipate that its product sales will be sufficient to recover its costs. The sponsor that obtains the first marketing approval for a designated orphan drug for a given rare disease is eligible to receive marketing exclusivity for use of that drug for the orphan indication for a period of seven years. AMMONUL® (sodium phenylacetate and sodium benzoate) Injection 10%/10%, adjunctive therapy for the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle, has been granted orphan drug status.

We also will be subject to foreign regulatory authorities governing clinical trials and pharmaceutical sales for products we seek to market outside the U.S. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before marketing the product in those countries. The approval process varies from country to country, the approval process time required may be longer or shorter than that required for FDA approval, and any foreign regulatory agency may refuse to approve any product we submit for review.

Our History

We filed our certificate of incorporation with the Secretary of State of Delaware on July 28, 1988. We completed our initial public offering during our fiscal year ended June 30, 1990, and launched our initial pharmaceutical products during our fiscal year ended June 30, 1991.

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Employees

At December 31, 2011, we had 646 full-time employees. No employees are subject to a collective bargaining agreement. We believe we have good relationships with our employees.

Available Information

We make available free of charge on or through our Internet website, www.Medicis.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, if any, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission (SEC). We also make available free of charge on or through our website our Code of Business Conduct and Ethics, Corporate Governance Guidelines, Nominating and Governance Committee Charter, Stock Option and Compensation Committee Charter, Audit Committee Charter, Employee Development and Retention Committee Charter and Compliance Committee Charter. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors

Our statements in this report, other reports that we file with the SEC, our press releases and in public statements of our officers and corporate spokespersons contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21 of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. You can identify these statements by the fact that they do not relate strictly to historical or current events, and contain words such as anticipate, estimate, expect, project, intend, will, plan, believe, should, outlook, could, target and other words of similar meaning in connection with discussion of future operating financial performance. These include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings and financial results. These statements are based on certain assumptions made by us based on our experience and perception of historical trends, current conditions, expected future developments and other factors we believe are appropriate in the circumstances. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond our control. These forward-looking statements reflect the current views of senior management with respect to future events and financial performance. No assurances can be given, however, that these activities, events or developments will occur or that such results will be achieved, and actual results may vary materially from those anticipated in any forward-looking statement. Any such forward-looking statements, whether made in this report or elsewhere, should be considered in context of the various disclosures made by us about our businesses including, without limitation, the risk factors discussed below. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this filing except as required by law.

We operate in a rapidly changing environment that involves a number of risks. The following discussion highlights some of these risks and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, prospects, operating results or cash flows.

Risks Related to Our Business

Certain of our primary products could lose patent protection in the near future and become subject to competition from generic forms of such products. If that were to occur, sales of those products would decline significantly and such decline could have a material adverse effect on our results of operations.

We depend upon patents to provide us with exclusive marketing rights for certain of our primary products for some period of time. If patents for our primary products expire, or are successfully challenged by our competitors, in the United States and in other countries, we would face strong competition from lower price

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generic drugs. Loss of patent protection for any of our primary products would likely lead to a rapid loss of sales for that product, as lower priced generic versions of that drug become available. In the case of products that contribute significantly to our sales, the loss of patent protection could have a material adverse effect on our results of operations.

We currently have three issued patents, the 838 Patent, the 705 Patent and the 483 Patent, relating to SOLODYN® that do not expire until 2018, 2025 or later and 2027, respectively, and two other issued patents, the 347 Patent and the 373 Patent, relating to 90mg SOLODYN® tablets that do not expire until 2027. As part of our patent strategy, we are currently pursuing additional patent applications for SOLODYN®. However, we cannot provide any assurance that any additional patents will be issued relating to SOLODYN®. The failure to obtain additional patent protection could adversely affect our ability to deter generic competition, which would adversely affect SOLODYN® revenue and our results of operations. In addition, certain of our products, including ZYCLARA®, do not currently have patent protection. While we are currently pursuing patent applications for several of our products, such as ZYCLARA®, we cannot provide any assurance that patents will be issued. The failure to obtain patent protection on our products could materially affect our sales for those products and could have a material adverse effect on our results of operations. While we have regulatory exclusivity for ZYCLARA® (imiquimod) Cream 3.75% for the treatment of actinic keratosis through March 25, 2013, for ZYCLARA® (imiquimod) Cream 3.75% for the treatment of external genital and perianal warts/condyloma acuminate through March 24, 2014 and for ZYCLARA® (imiquimod) Cream 2.5% for actinic keratosis through July 15, 2014, a failure to have patent protection by such dates could adversely affect our ability to deter generic competition for ZYCLARA®.

We have faced generic competition in the past and expect to face additional generic competition in the near future.

Competition from manufacturers of generic drugs is, and we expect will continue to be, a significant challenge for us. Upon the expiration or loss of patent protection for one of our products, or upon the at-risk launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our products, we can lose a significant portion of sales of that product in a very short period, which can adversely affect our business. In addition, our patent-protected products may face competition in the form of generic versions of branded products of competitors that lose their market exclusivity. Further, the patents covering our products, including SOLODYN®, VANOS® and LOPROX®, continue to be challenged by generic manufacturers and we expect additional challenges. Under the Hatch-Waxman Act, any generic pharmaceutical manufacturer may file an ANDA with a certification, known as a Paragraph IV certification, challenging the validity of or claiming non-infringement of a patent listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, which is known as the FDA s Orange Book, four years after the pioneer company obtains approval of its New Drug Application for new chemical entities (NCEs) and sooner for new drugs including active ingredients that are not classified as NCEs by the FDA. Multiple companies have filed, and we expect additional companies will file, Paragraph IV certifications challenging the patents associated with some of our key products. Companies typically do not advise us as to the timing or status of the FDA s review of their ANDA filings, or whether they have complied with FDA requirements for proving bioequivalence. Paragraph IV certifications commonly allege that one or more of our patents is invalid and/or will not be infringed by the filer s manufacture, use, sale and/or importation of the products for which the ANDA was submitted. If a Paragraph IV challenge were to succeed, any affected product would face generic competition and its sales would likely decline materially. We have from time to time entered into settlement agreements with certain companies that have filed Paragraph IV certifications, but there can be no assurance that we will be able to enter into such settlements in the future. In addition, we have on occasion entered into license and settlement agreements with certain companies, including agreements to market authorized generic versions of our branded products. For example, we have entered into license agreements with certain companies pursuant to which we have granted a license to make and sell generic versions of SOLODYN® in 45mg, 90mg, and 135mg strengths under the SOLODYN® intellectual property rights belonging to us effective in November 2011, as well as future licenses to make and sell generic versions of SOLODYN® in 65mg and 115mg strengths effective in

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February 2018, or earlier under certain conditions, and generic versions of SOLODYN® in 55mg, 80mg and 105mg strengths effective in February 2019, or earlier under certain conditions. We have also entered into license agreements with certain companies pursuant to which we have granted licenses to make and sell generic versions of VANOS® products effective December 15, 2013, or earlier under certain conditions. Although the license agreements require the companies to pay us royalties based on sales of the generic SOLODYN® and VANOS® products, the sale of such generic products could cause our sales of SOLODYN® and VANOS® to decline materially. It is also possible that settlement and license agreements with generic competitors could result in the forfeiture of any marketing exclusivity held by those companies, resulting in the FDA potentially approving additional generic versions of our branded products. If any of our primary products are rendered obsolete or uneconomical by competitive changes, including generic competition, our results of operation would be materially and adversely affected.

See Item 3 of Part I of this report, Legal Proceedings Legal Matters, and Note 12, Commitments and Contingences, in the notes to the consolidated financial statements under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules.

If we are unable to secure and protect our intellectual property and proprietary rights, or if our intellectual property rights are found to infringe upon the intellectual property rights of other parties, our business could suffer.

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks, service marks and other intellectual property rights.

The patents, and patents issuing from our patent applications, in which we have an interest may be challenged as to their validity or enforceability or infringement. Any such challenges may result in potentially significant harm to our business and enable generic entry into markets for our products. The cost of responding to any such challenges and the cost of prosecuting infringement claims and any related litigation, could be substantial. In addition, any such litigation also could require a substantial commitment of our management s time.

See Item 3 of Part I of this report, Legal Proceedings, and Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules, for information concerning our current intellectual property litigation.

We are pursuing several United States patent applications, but we cannot be sure that any of these patents will ever be issued. We also have acquired rights under certain patents and patent applications in connection with our licenses to distribute products and by assignment of rights to patents and patent applications from certain of our consultants and officers. These patents and patent applications may be subject to claims of rights by third parties. If there are conflicting claims to the same patent or patent application, we may not prevail and, even if we do have some rights in a patent or patent application, those rights may not be sufficient for the marketing and distribution of products covered by the patent or patent application.

The ownership of a patent or an interest in a patent does not always provide significant protection. Others may independently develop similar technologies or design around the patented aspects of our products. We only conduct patent searches to determine whether our products infringe upon any existing patents when we think such searches are appropriate. As a result, the products and technologies we currently market, and those we may market in the future, may infringe on patents and other rights owned by others. If we are unsuccessful in any challenge to the marketing and sale of our products or technologies, we may be required to license the disputed rights, if the holder of those rights is willing to license such rights, otherwise we may be required to cease marketing the challenged products, or to modify our products to avoid infringing upon those rights. A claim or finding of infringement regarding one of our products could harm our business, financial condition and results of operations. The costs of responding to infringement claims could be substantial and could require a substantial commitment of our management s time. The expiration of patents may expose our products to additional competition.

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We believe that the protection of our trademarks and service marks is an important factor in product recognition and in our ability to maintain or increase market share. If we do not adequately protect our rights in our various trademarks and service marks from infringement, their value to us could be lost or diminished. If the marks we use are found to infringe upon the trademark or service mark of another company, we could be forced to stop using those marks and, as a result, we could lose the value of those marks and could be liable for damages caused by an infringement.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation in developing and manufacturing many of our primary products. It is our policy to require all of our employees, consultants and advisors to enter into confidentiality agreements prohibiting them from taking or disclosing our proprietary information and technology and we employ other strategies to protect our trade secrets and other confidential information. Nevertheless, these agreements may not provide meaningful protection for our trade secrets and proprietary know-how if they are used or disclosed. Despite all of the precautions we may take, people who are not parties to confidentiality agreements may obtain access to our trade secrets or proprietary know-how. In addition, others may independently develop similar or equivalent trade secrets or proprietary know-how.

The FDA may authorize sales of certain prescription pharmaceuticals on an over-the-counter drug or a non-prescription basis, which would reduce the profitability of our prescription products.

From time to time, the FDA may elect to permit sales of certain pharmaceuticals currently sold on a prescription basis, without a prescription. FDA approval of the sale of our products without a prescription would reduce demand for our competing prescription products and, accordingly, reduce our profits. The FDA may also require us to stop selling our product as a prescription drug and obtain approval of the product for OTC sale or require us to comply with an OTC monograph, which may materially and adversely affect our business, financial condition and results of operations. For example, in 2010, the FDA classified benzoyl peroxide, the active ingredient in our TRIAZ® products, as a Category III ingredient under a final FDA monograph for OTC use in treatment of labeled conditions, effective March 4, 2011. Because our TRIAZ® products, which we sold on a prescription basis, have the same ingredients at the same dosage levels as the OTC products, as of the effective date of the final monograph, TRIAZ® is no longer available by prescription.

In addition to the impact described above relating to the FDA s approval of the sale of certain pharmaceutical products on an OTC drug or a non-prescription basis, the FDA imposes certain composition and labeling requirements on OTC products, which may also have an adverse effect on the profitability of any affected pharmaceutical products.

We depend on licenses from others, and any loss of such licenses could harm our business, market share and profitability.

We have acquired the rights to manufacture, use and market certain products, including certain of our primary products. We also expect to continue to obtain licenses for other products and technologies in the future. Our license agreements generally require us to develop a market for the licensed products. If we do not develop these markets within specified time frames, the licensors may be entitled to terminate these license agreements.

We may fail to fulfill our obligations under any particular license agreement for various reasons, including insufficient resources to adequately develop and market a product, lack of market development despite our diligence and lack of product acceptance. Our failure to fulfill our obligations could result in the loss of our rights under a license agreement.

Our inability to continue the distribution of any particular licensed product could harm our business, market share and profitability. Also, certain products we license are used in connection with other products we own or license. A loss of a license in such circumstances could materially harm our ability to market and distribute these other products.

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Obtaining FDA and other regulatory approvals is time consuming, expensive and uncertain.

The research, development and marketing of our products are subject to extensive regulation by government agencies in the U.S, particularly the FDA, and other countries. The process of obtaining FDA and other regulatory approvals is time consuming and expensive. Clinical trials are required, and the manufacturing of pharmaceutical and medical device products is subject to rigorous testing procedures. We may not be able to obtain FDA approval to conduct clinical trials or to manufacture or market any of the products we develop, acquire or license on a timely basis or at all. Moreover, the costs to obtain approvals could be considerable, and the failure to obtain or delays in obtaining an approval could significantly harm our business performance and financial results. Marketing approval or clearance of a new product or new indication for an approved product may be delayed, restricted, or denied for many reasons, including:

- determination by the FDA that the product is not safe and effective;
- a different interpretation of preclinical and clinical data by the FDA;
- failure to obtain approval of the manufacturing process or facilities;
- results of post-marketing studies;
- changes in FDA policy or regulations related to product approvals; and
- failure to comply with applicable regulatory requirements.

No amount of time, effort, or resources invested in a new product or new indication for an approved product can guarantee that regulatory approval will be granted.

The FDA vigorously monitors the ongoing safety of products, which can affect the approvability of our products or the continued ability to market our products. If adverse events are associated with products that have already been approved or cleared for marketing, such products could be subject to increased regulatory scrutiny, changes in regulatory approval or labeling, or withdrawal from the market. Even if pre-marketing approval from the FDA is received, the FDA is authorized to impose post-marketing requirements such as:

- testing and surveillance to monitor the product and its continued compliance with regulatory requirements, including cGMPs for drug and biologic products and the QSRs for medical device products;
- submitting products, facilities and records for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products from the same lot;
- suspending manufacturing;
- switching status from prescription to over-the-counter drug;

completion of post-marketing studies;

changes to approved product labeling;

advertising or marketing restrictions, including direct-to-consumer advertising;

REMS;

recalling products; and

withdrawing marketing clearance.

In their regulation of advertising, the FDA and FTC from time to time issue correspondence to pharmaceutical companies alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and the receipt of correspondence from the FDA alleging these practices could result in the following:

incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA s requirements;

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changes in the methods of marketing and selling products;

taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians rescinding previous advertisements or promotion; and

disruption in the distribution of products and loss of sales until compliance with the FDA s position is obtained.

In addition to the potential impact of any FDA allegations or enforcement described above, the FTC has the power to impose a number of sanctions, including prohibiting us from making certain claims about our products or requiring us to stop selling certain products.

In recent years, various legislative proposals have been offered in Congress and in some state legislatures that include major changes in the health care system. These proposals have included price or patient reimbursement constraints on medicines, restrictions on access to certain products, re-importation of products from Canada or other sources and mandatory substitution of generic for branded products. We cannot predict the outcome of such initiatives, and it is difficult to predict the future impact of the broad and expanding legislative and regulatory requirements affecting us.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

Federal health care program anti-kickback statutes prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on one hand and prescribers, purchasers and formulary managers on the other. In March 2010, the President of the United States signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the Affordable Care Act, which, among other things, amends the intent requirement of the federal anti-kickback statute. In particular, a person or entity no longer needs to have actual knowledge of the anti-kickback statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. From time to time we may enter into business arrangements (e.g., loans or investments) involving our customers and those arrangements may be reviewed by federal and state regulators. Although we believe that we are in compliance, our practices may be determined to fail to meet all of the criteria for safe harbor protection from anti-kickback liability.

The Affordable Care Act also imposes new reporting and disclosure requirements on pharmaceutical and device manufacturers for any transfer of value made or distributed to prescribers and other health care providers, effective March 30, 2013. Such information will be made available on the Internet in a searchable format beginning on September 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. The failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failure), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Effective April 1, 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians.

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Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical and medical device companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines, and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

On April 25, 2007, we entered into a Settlement Agreement with the Justice Department, the Office of Inspector General of the Department of Health and Human Services (OIG) and the TRICARE Management Activity (collectively, the United States) and private complainants to settle all outstanding federal and state civil suits against us in connection with claims related to our alleged off-label marketing and promotion of LOPROX® and LOPROX® TS products to pediatricians during periods prior to our May 2004 disposition of our pediatric sales division (the Settlement Agreement). The settlement is neither an admission of liability by us nor a concession by the United States that its claims are not well founded. Pursuant to the Settlement Agreement, we agreed to pay approximately $10 million to settle the matter. Pursuant to the Settlement Agreement, the United States released us from the claims asserted by the United States and agreed to refrain from instituting action seeking exclusion from Medicare, Medicaid, the TRICARE Program and other federal health care programs for the alleged conduct. These releases relate solely to the allegations related to us and do not cover individuals. The Settlement Agreement also provides that the private complainants release us and our officers, directors and employees from the asserted claims, and we release the United States and the private complainants from asserted claims.

As part of the settlement, we have entered into a five-year Corporate Integrity Agreement (the CIA) with the OIG to resolve any potential administrative claims the OIG may have arising out of the government s investigation. The CIA acknowledges the existence of our comprehensive existing compliance program and provides for certain other compliance-related activities during the term of the CIA, including the maintenance of a compliance program that, among other things, is designed to ensure compliance with the CIA, federal health care programs and FDA requirements. Pursuant to the CIA, we are required to notify the OIG, in writing, of: (i) any ongoing government investigation or legal proceeding involving an allegation that we have committed a crime or have engaged in fraudulent activities; (ii) any other matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws; (iii) any written report, correspondence, or communication to the FDA that materially discusses any unlawful or improper promotion of our products; and (iv) any change in location, sale, closing, purchase, or establishment of a new business unit or location related to items or services that may be reimbursed by Federal health care programs. We are also subject to periodic reporting and certification requirements attesting that the provisions of the CIA are being implemented and followed, as well as certain document and record retention mandates. We have hired a Chief Compliance Officer and created an enterprise-wide compliance function to administer our obligations under the CIA. Failure to comply under the CIA could result in substantial civil or criminal penalties and being excluded from government health care programs, which could materially reduce our sales and adversely affect our financial condition and results of operations.

On or about October 12, 2006, we and the United States Attorney s Office for the District of Kansas entered into a Nonprosecution Agreement wherein the government agreed not to prosecute us for any alleged criminal violations relating to the alleged off-label marketing and promotion of LOPROX®. In exchange for the

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government s agreement not to pursue any criminal charges against us, we agreed to continue cooperating with the government in its ongoing investigation into whether past and present employees and officers may have violated federal criminal law regarding alleged off-label marketing and promotion of LOPROX® to pediatricians. As a result of the investigation, prosecutions and other proceedings, certain past and present sales and marketing employees and officers separated from the Company. See Item 3 of Part I of this report, Legal Proceedings and Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules, for information concerning our current litigation.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations.

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, is subject to extensive federal and state regulation in the United States and in foreign countries. While we have developed and instituted a corporate compliance program based on what we believe to be current best practices, we cannot assure you that we or our employees are or will be in compliance with all potentially applicable federal, state or foreign regulations and/or laws or the CIA we entered into with the OIG. If we fail to comply with the CIA or any of these regulations and/or laws, a range of actions could result, including, but not limited to, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

We depend on a limited number of customers for a substantial portion of our revenues, and if we lose any of them, our business could be harmed.

Our customers include some of the United States leading wholesale pharmaceutical distributors, such as Cardinal, McKesson, and major drug chains. We are party to distribution services agreements with McKesson and Cardinal. During 2011, McKesson and Cardinal accounted for 44.3% and 38.3%, respectively, of our net revenues. During 2010, McKesson and Cardinal accounted for 42.6% and 35.4%, respectively, of our net revenues. During 2009, McKesson and Cardinal accounted for 40.8% and 37.1%, respectively, of our net revenues. The loss of either of these customers accounts or a material reduction in their purchases could harm our business, financial condition or results of operations. McKesson is our sole distributor of our RESTYLANE® and PERLANE® branded products and DYSPORT® in the U.S.

The consolidation of drug wholesalers could increase competition and pricing pressures throughout the pharmaceutical industry.

We sell our pharmaceutical products primarily through major wholesalers. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions. As a result, a smaller number of large wholesale distributors control a significant share of the market. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. Further consolidation among, or any financial difficulties of, distributors or retailers could result in the combination or elimination of warehouses which may result in product returns to us, cause a reduction in the inventory levels of distributors and retailers, result in reductions in purchases of our products or increase competitive and pricing pressures on pharmaceutical manufacturers, any of which could harm our business, financial condition and results of operations.

We derive a majority of our sales revenue from our primary products, and any factor adversely affecting sales of these products would harm our business, financial condition and results of operations.

We believe that the prescription volume of our primary prescription products, in particular, SOLODYN®, VANOS®, ZIANA® and ZYCLARA®, and sales of our facial aesthetic products, DYSPORT®, RESTYLANE®

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and PERLANE®, will continue to constitute a significant portion of our sales revenue for the foreseeable future. Accordingly, any factor adversely affecting our sales related to these products, individually or collectively, could harm our business, financial condition and results of operations.

DYSPORT® competes directly with Allergan s Botox® Cosmetic, an established botulinum toxin product that was approved by the FDA for aesthetic purposes in 2002.

We are experiencing intense competition in the dermal filler market. Other dermal filler products on the market include: Juvéderm®, Artefill®, Belotero® Balance, Radiesse®, Elevess™, Hydrelle™, LAVIV™, Prevelle® Silk, and Sculptra® Aesthetic. Patients may differentiate these products from our RESTYLANE® and PERLANE® branded products based on price, efficacy and/or duration, which may appeal to some patients. In addition, there are several dermal filler products under development and/or in the FDA pipeline for approval which claim to offer equivalent or greater facial aesthetic benefits to RESTYLANE® and PERLANE® and, if approved, the companies producing such products could charge less to doctors for their products.

We are involved in patent litigation with certain competitors, primarily related to our ZIANA® and VANOS® branded products. See the previously listed Risk Factor, *Certain of our primary products could lose patent protection in the near future and become subject to competition from generic forms of such products. If that were to occur, sales of those products would decline significantly and such decline could have a material adverse effect on our results of operations,* Item 3 of Part I of this report, Legal Proceedings, and Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules for information concerning our current intellectual property litigation. There can be no assurance that we will prevail in patent litigation or that these competitors will not successfully introduce products that would cause a loss of our market share and reduce our revenues.

Sales related to our primary prescription drug products, including SOLODYN®, VANOS®, ZIANA® and ZYCLARA®, and sales of our facial aesthetic products, DYSPORT®, RESTYLANE® and PERLANE® could also be adversely affected by other factors, including:

- manufacturing or supply interruptions;
- the development of new competitive pharmaceuticals and technological advances to treat the conditions addressed by our primary products, including the introduction of new products into the marketplace;
- generic competition;
- marketing or pricing actions by one or more of our competitors;
- regulatory action by the FDA and other government regulatory agencies;
- importation of other dermal fillers;
- changes in the prescribing or procedural practices of dermatologists and/or plastic surgeons;
- changes in the reimbursement or substitution policies of third-party payors or retail pharmacies;

product liability claims;

the outcome of disputes relating to trademarks, patents, license agreements and other rights;

changes in state and federal law that adversely affect our ability to market our products to dermatologists and/or plastic surgeons;

restrictions on travel affecting the ability of our sales force to market to prescribing physicians and plastic surgeons in person; and

restrictions on promotional activities.

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Our continued growth depends upon our ability to develop new products.

Our ability to develop new products is the key to our continued growth. Our research and development activities, as well as the clinical testing and regulatory approval process, which must be completed before commercial sales can commence, will require significant commitments of personnel and financial resources. We cannot assure you that we will be able to develop products or technologies in a timely manner, or at all. Delays in the research, development, testing or approval processes will cause a corresponding delay in revenue.

We may not be able to identify and acquire products, technologies and businesses on acceptable terms, if at all, which may constrain our growth.

Our strategy for continued growth includes the acquisition of products, technologies and businesses. These acquisitions could involve acquiring other pharmaceutical companies assets, products or technologies. In addition, we may seek to obtain licenses or other rights to develop, manufacture and distribute products. We cannot be certain that we will be able to identify suitable acquisition or licensing candidates, if they will be accretive in the near future, or if any will be available on acceptable terms. Other pharmaceutical companies, with greater financial, marketing and sales resources than we have, are also attempting to grow through similar acquisition and licensing strategies. Because of their greater resources, our competitors may be able to offer better terms for an acquisition or license than we can offer, or they may be able to demonstrate a greater ability to market licensed products. In addition, even if we identify potential acquisitions and enter into definitive agreements relating to such acquisitions, we may not be able to consummate planned acquisitions on the terms originally agreed upon or at all.

We reevaluate our research and development efforts regularly to assess whether our efforts to develop a particular product or technology are progressing at a rate that justifies our continued expenditures. On the basis of these reevaluations, we have abandoned in the past, and may abandon in the future, our efforts on a particular product or technology. Products that we research or develop may not be successfully commercialized. If we fail to take a product or technology from the development stage to market on a timely basis, we may incur significant expenses without a near-term financial return.

We have in the past, and may in the future, supplement our internal research and development by entering into research and development agreements with other pharmaceutical companies. We may, upon entering into such agreements, be required to make significant up-front payments to fund the projects. We cannot be sure, however, that we will be able to locate adequate research partners or that supplemental research will be available on terms acceptable to us in the future. If we are unable to enter into additional research partnership arrangements, we may incur additional costs to continue research and development internally or abandon certain projects. Even if we are able to enter into collaborations, we cannot assure you that these arrangements will result in successful product development or commercialization.

Our products may not gain market acceptance.

There is a risk that our products may not gain market acceptance among physicians, patients and the medical community generally. The degree of market acceptance of any medical device or other product that we develop will depend on a number of factors, including demonstrated clinical efficacy and safety, cost-effectiveness, potential advantages over alternative products, and our marketing and distribution capabilities. Physicians will not recommend our products until clinical data or other factors demonstrate their safety and efficacy compared to other competing products. Even if the clinical safety and efficacy of using our products is established, physicians may elect to not recommend using them for any number of other reasons, including whether our products best meet the particular needs of the individual patient.

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Our operating results and financial condition may fluctuate.

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in our financial performance from period to period:

- development and launch of new competitive products, including OTC or generic competitor products;
- the timing and receipt of FDA approvals or lack of approvals;
- the timing and receipt of patent claim issuances or lack of issuances or rejections in prosecution or reexamination proceedings before the USPTO;
- changes in the amount we spend to develop, acquire or license new products, technologies or businesses;
- costs related to business development transactions;
- untimely contingent research and development payments under our third-party product development agreements;
- changes in the amount we spend to promote our products;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;
- changes in treatment practices of physicians that currently prescribe our products;
- changes in reimbursement policies of health plans and other similar health insurers, including changes that affect newly developed or newly acquired products;
- increases in the cost of raw materials used to manufacture our products;
- manufacturing and supply interruptions, including failure to comply with manufacturing specifications;
- changes in prescription levels and the effect of economic changes in hurricane and other natural disaster-affected areas;
- the impact on our employees, customers, patients, manufacturers, suppliers, vendors, and other companies we do business with and the resulting impact on the results of operations associated with a large-scale outbreak of contagious diseases;

the mix of products that we sell during any time period;

lower than expected demand for our products;

our responses to price competition;

expenditures as a result of legal actions, including the defense of our patents and other intellectual property;

market acceptance of our products;

the impairment and write-down of goodwill or other intangible assets;

implementation of new or revised accounting or tax rules or policies;

disposition of primary products, technologies and other rights;

termination or expiration of, or the outcome of disputes relating to, trademarks, patents, license agreements and other rights;

increases in insurance rates for existing products and the cost of insurance for new products;

general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand, and our ability to recover quickly from such economic and industry conditions;

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changes in seasonality of demand for our products;

our level of research and development activities;

new accounting standards and/or changes to existing accounting standards that would have a material effect on our consolidated financial position, results of operations or classification of cash flows;

costs and outcomes of any tax audits or any litigation involving intellectual property, customers or other issues;

failure by us or our contractors to comply with all applicable FDA and other regulatory requirements;

the imposition of a REMS program requirement on any of our products;

adverse decisions by FDA advisory committees related to any of our products; and

timing of payments and/or revenue recognition related to licensing agreements and/or strategic collaborations.

As a result, we believe that period-to-period comparisons of our results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. The above factors may cause our operating results to fluctuate and adversely affect our financial condition and results of operations.

We face significant competition within our industry.

The pharmaceutical and facial aesthetics industries are highly competitive. Competition in our industry occurs on a variety of fronts, including:

developing and bringing new products to market before others;

developing new technologies to improve existing products;

developing new products to provide the same benefits as existing products at less cost; and

developing new products to provide benefits superior to those of existing products.

The intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively. Consequently, we must continue to develop and introduce products in a timely and cost-efficient manner to effectively compete in the marketplace and maintain our revenue and gross margins.

Our competitors vary depending upon product categories. Many of our competitors are large, well-established companies in the fields of pharmaceuticals, chemicals, cosmetics and health care. Among our largest competitors are Allergan, Galderma, Johnson & Johnson, Sanofi-Aventis, GlaxoSmithKline, plc (Stiefel Laboratories), Warner Chilcott and others.

Many of these companies have greater resources than we do to devote to marketing, sales, research and development and acquisitions. As a result, they have a greater ability to undertake more extensive research and development, marketing and pricing policy programs. It is possible that our competitors may develop new or improved products to treat the same conditions as our products or make technological advances reducing their cost of production so that they may engage in price competition through aggressive pricing policies to secure a greater market share to our detriment. These competitors also may develop products that make our current or future products obsolete. Any of these events could significantly harm our business, financial condition and results of operations, including reducing our market share, gross margins, and cash flows.

We sell and distribute prescription brands, medical devices and over-the-counter products. Each of these products competes with products produced by others to treat the same conditions. Several of our prescription

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products compete with generic pharmaceuticals, which claim to offer equivalent benefit at a lower cost. In some cases, insurers and other health care payment organizations try to encourage the use of these less expensive generic brands through their prescription benefits coverage and reimbursement policies. These organizations may make the generic alternative more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic product to the patient is less than the net cost of our prescription brand product. Aggressive pricing policies by our generic product competitors and the prescription benefits policies of third-party payors could cause us to lose market share or force us to reduce our gross margins in response.

There are several dermal filler products under development and/or in the FDA pipeline for approval which claim to offer equivalent or greater facial aesthetic benefits to RESTYLANE® and PERLANE® branded products, and if approved, the companies producing such products could charge less to doctors for their products.

Our investments in other companies and our collaborations and strategic alliances with companies could adversely affect our results of operations and financial condition.

We have made substantial investments in, and entered into significant collaborations and strategic alliances with, other companies. We may use these and other methods to develop or commercialize products in the future. These arrangements typically involve other pharmaceutical companies as partners that may be competitors of ours in certain markets. In many instances, we will not control these companies, collaborations or strategic alliances, and cannot assure you that these ventures will be profitable or that we will not lose any or all of our invested capital. If these investments, collaborations and strategic alliances are unsuccessful, our results of operations could materially suffer.

In addition, certain of our collaborations and strategic alliances with other companies provide companies with purchase or buyout rights. For example, our wholly-owned subsidiary, Ucyclyd Pharma, Inc. (Ucyclyd), entered into a collaboration agreement, dated April 23, 2007 (as amended, the Collaboration Agreement) with Hyperion Therapeutics, Inc. (Hyperion) under which Hyperion has certain purchase and buyout rights with respect to a Ucyclyd development product referred to as HPN-100 (formerly known as GT4P), as well as Ucyclyd s existing on-market products, AMMONUL® and BUPHENYL®. If such other companies, including Hyperion, decide to exercise such rights, our results of operations may be adversely affected.

Further, our collaborations and strategic alliances with other companies may give rise to legal disputes, including, but not limited to potential disputes concerning ownership of intellectual property under such collaborations and strategic alliances, which can lead to lengthy, expensive litigation or arbitration, and may materially and adversely affect our business and results of operations. For example, Ucyclyd and Hyperion are currently engaged in negotiations to resolve a dispute between them with respect to their rights under the Collaboration Agreement, as more fully described in Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements under Item 15 of Part IV of this report, Exhibits, Financial Statement Schedules. While it is the opinion of our management that this matter will not result in a material adverse effect on our business or results of operations, there can be no assurance of a successful resolution of the matter or that we will not incur additional significant expenses in connection with the matter.

Our profitability is impacted by our continued participation in governmental pharmaceutical pricing programs.

A condition of federal funds being made available to pay for our products under the Medicaid and Medicare Part B programs is that we must participate in the Medicaid drug rebate program. Participation in the program requires us to provide a rebate to each state for each unit of our products that is reimbursed by Medicaid. The Affordable Care Act increased the minimum rebate percentage for all drugs, modified the rebate formula for certain drugs that are line extensions of existing drugs, and expanded the rebate obligation, which previously had applied only to utilization under fee-for-service arrangements, to also apply to drug utilization under capitated Medicaid managed care arrangements. Rebate amounts for our products are determined by a statutory formula that is based on prices defined by statute: average manufacturer price (AMP), which we must calculate for all

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products that are covered outpatient drugs under the Medicaid program, and best price, which we must calculate only for those of our covered outpatient drugs that are innovator products. The Affordable Care Act capped the rebate amount for innovator products at 100% of AMP, and the Affordable Care Act along with other legislation enacted in 2010 revised the definition of AMP, effective October 1, 2010. We are required to report AMP and best price for each of our covered outpatient drugs to the government on a regular basis. Under the Affordable Care Act, AMP now also will be used to calculate the federal upper limits (FULs) on pharmacy reimbursement amounts under the Medicaid program. These FULs are used to determine ceilings placed on the amounts that state Medicaid programs can pay for certain prescription drugs using federal dollars. Under the Affordable Care Act, FULs shall be no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule to implement these aspects of the Affordable Care Act on February 2, 2012 and CMS has indicated that it expects to issue a final regulation in 2013. We cannot predict the full impact of these changes on our business nor can we predict whether there will be additional federal legislative or regulatory proposals to modify current Medicaid rebate rules. These and other cost containment measures and health care reforms could adversely affect our business.

To receive reimbursement under the Medicaid programs and the Medicare Part B program for our products, we also are required by federal law to provide discounts under other pharmaceutical pricing programs. For example, we are required to enter into a Federal Supply Schedule (FSS) contract with the Department of Veterans Affairs (VA) under which we must make our covered drugs available to the Big Four federal agencies the VA, the Department of Defense (DoD), the Public Health Service, and the Coast Guard at pricing that is capped pursuant to a statutory Federal ceiling price (FCP) formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average wholesaler price known as the non-federal average manufacturer price, which manufacturers are required to report on a quarterly and annual basis to the VA. FSS contracts are federal procurement contracts that include standard government terms and conditions and separate pricing for each product. In addition to the Big Four agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies negotiated pricing for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor s commercial most favored customer pricing. Medicis chooses to offer one single FCP-based FSS contract price for each product to the Big Four agencies as well as to all other FSS purchasers. In addition, all items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing to an agreed tracking customer is reduced.

Pursuant to regulations issued by the DoD TRICARE Management Activity (TMA) to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, Medicis has entered into an agreement with TMA under which it has agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and Medicis agreement and is based on the difference between the Annual Non-FAMP and the FCP.

To receive reimbursement under state Medicaid programs and the Medicare Part B program for our products, we also are required by federal law to provide discounted purchase prices under the Public Health Service Drug Pricing Program to certain categories of entities defined by statute. The formula for determining the discounted purchase price is defined by statute and is based on the AMP and rebate amount for a particular product as calculated under the Medicaid drug rebate program, discussed above. The Affordable Care Act s changes to the Medicaid rebate formula and the definition of AMP also could impact the discounted purchase prices that we are obligated to provide under this program. In addition, under the Affordable Care Act, additional categories of entities are eligible for these discounts, potentially increasing the volume of sales for which we must pay discounts, although orphan drugs are exempt from the discount requirement as to the new entity types. These discounts currently apply to outpatient utilization by eligible covered entities, but historically there have been

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efforts to expand the program to apply the discounting obligation to drugs used in the inpatient setting as well. We cannot predict the full impact of these changes on our business, nor can we predict whether there will be additional federal legislative or regulatory proposals to modify this program or current Medicaid rebate rules which then could impact this program as well.

In addition to the changes to these rebate and discount programs, the Affordable Care Act requires manufacturers of branded prescription drugs to pay an annual fee to the federal government beginning in 2011. Each manufacturer s fee is calculated based on the dollar value of its sales to certain federal programs and the aggregate dollar value of all branded prescription drug sales by covered manufacturers. A manufacturer s fee will be its prorated share of the industry s total fee obligation (approximately $2.8 billion in 2012 and 2013 and set to increase in following years), based on the ratio of its sales to the total sales by manufacturers to these same programs. We cannot predict our share of this fee because it is determined in part on other entities sales to the relevant programs.

Our profitability may be impacted by ongoing changes under certain Federal pharmaceutical pricing programs.

Under the terms of our Medicaid drug rebate program agreement and our VA FSS contract and related pricing agreements required under the VHCA, we are required to accurately report our pharmaceutical pricing data, which is based, in part, on accurate classifications of our customers classes of trade. On May 1, 2007, and on May 15, 2007, we notified the U.S. Department of Health and Human Services and the VA, respectively, that we may have misclassified certain of our customers classes of trade, which could affect the prices previously reported under the Medicaid drug rebate program and/or prices on our VA FSS contract. We have reviewed this issue and have identified certain customer class of trade misclassifications.

Based on this finding, we undertook a review and recalculation of our Non-Federal Average Manufacturer Prices (Non-FAMPs) and related FCPs, AMPs, and Best Prices (BPs) for a period going back at least (3) years from the expected completion date of the recalculation to determine the impact, if any, that reclassification of customers to appropriate classes of trade might have on these reported prices. In doing the recalculation, we generally reviewed the methodologies for computing the reported prices, the classification of products under the various programs, and any other potentially significant issues identified in the course of the review. In April 2009, we completed the voluntary review of pricing data submitted to the Medicaid Drug Rebate Program (the Program) for the period from the first quarter of 2006 through the fourth quarter of 2007. In July 2009, we completed the extension of this review to the pricing data submitted to the Program for the period from the first quarter of 2008 through the fourth quarter of 2008. The review identified certain actions that were needed in relation to the reviewed data. We disclosed the results of the review and the resulting revised rebate liability to CMS, which administers the Program, and received permission, where necessary, to file the revised pricing data. Our submission to CMS also included a request that CMS approve a change in drug category for certain of our products, which CMS approved in December 2009. We accrued $3.1 million for the 2006 and 2007 liability, which was recognized as a reduction of net revenues during the three months ended March 31, 2009, and $0.7 million for the 2008 and 2009 liability, which was recognized as a reduction of net revenues during the three months ended March 31, 2010.

Upon submission of the revised pricing figures under the Medicaid program, we determined that additional amounts were owed under the PHS Drug Pricing Program of approximately $415,700 for the period spanning from the first quarter of 2006 through the second quarter of 2010 based on the restated AMP and BP figures filed with CMS for the period January 1, 2006 through December 31, 2009. Of this amount, $188,700 and $227,000 was accrued for during 2009 and 2010, respectively, and was recognized as a reduction of net revenues.

In addition, we conducted a review and recalculation of our Non-FAMPs and FCPs for a period spanning the duration of our applicable FSS contract to determine what, if any, impact reclassification of customers to appropriate classes of trade and any other issues identified in the course of the review might have on these reported prices. In doing the recalculation, we assigned all customers to an appropriate class of trade,

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implemented a revised calculation methodology, and addressed all other issues identified in the course of the review. Our review also involved assessment of compliance with the FSS Price Reductions Clause for the products on FSS contract.

On September 15, 2008, we submitted a report to the VA detailing the recalculations and the impact figures associated with overcharges under the current FSS contract. The submission showed liability in the amount of $121,646, resulting from overcharges under our FSS contract through July 31, 2008. On December 18, 2008, we submitted a supplement to the September 15, 2008 submission, which, based on certain issues uncovered subsequent to the September 15, 2008 submission, showed an additional $61,459 in overcharges. Based on subsequent communications, the VA requested that Medicis make payment for FSS overcharges for the period through December 31, 2008 in the amount of $307,205 pursuant to a bill of collection dated January 5, 2011. Medicis made payment under the bill of collection on January 27, 2011.

The Company is reviewing FSS sales transactions from January 1, 2009 through the conclusion of its prior FSS contract (February 14, 2011) to identify any potential additional overcharges under the contract. To the extent that additional overcharges are identified, Medicis will calculate the FSS price impact and report accordingly to the VA. Medicis has received additional chargeback data from the wholesalers and is in the process of validating the data and performing additional impact calculations. Medicis expects to submit revised impact figures to the VA during the first quarter of 2012.

On March 17, 2009, the DoD TMA issued a final rule (2009 Final Rule) pursuant to Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA) to establish a program under which it seeks FCP-based rebates from drug manufacturers on TRICARE retail utilization. Under the 2009 Final Rule, DoD claimed an entitlement to rebates on TRICARE Retail Pharmacy utilization from January 28, 2008 forward, unless TMA grants a waiver or compromise of amounts due from utilization in quarters that have passed prior to execution of a voluntary agreement with DoD. Pursuant to the 2009 Final Rule, rebates are computed by subtracting the applicable FCP from the corresponding Annual Non-FAMP.

DoD asserted in the 2009 Final Rule the right to apply offsets and/or proceeds under the Debt Collection Act, in the event that a company does not pay rebates or request a waiver of rebate liability in a timely fashion. DoD also required voluntary rebate agreement proposals to be submitted by manufacturers on or before June 1, 2009, under which manufacturers would be obligated to pay rebates on TRICARE retail utilization. Medicis submitted a proposed voluntary pricing agreement in a timely manner. The agreement offered to provide FCP-based rebates on utilization occurring on or after the effective date of the agreement. The agreement was signed and executed by the DoD and Medicis, with an effective date of June 29, 2009. Medicis also submitted a waiver, pursuant to the terms of the 2009 Final Rule, for amounts due prior to execution of that agreement.

The Coalition for Common Sense in Government Procurement (Coalition) filed a lawsuit in the U.S. District Court for the District of Columbia, challenging the validity of DoD s assertion in the 2009 Final Rule that Section 703 mandated a manufacturer rebate program to allow DoD to access FCPs. In response to a ruling by the Court that DoD did not follow proper procedures in issuing its Final Rule, *Coal. for Common Sense in Gov t Procurement v. United States*, 671 F. Supp. 2d 48 (D.D.C. 2009), DoD reissued the Final Rule on October 15, 2010. 75 Fed. Reg. 63,383 (Oct. 15, 2010). The revised Final Rule is nearly identical in substance to the 2009 Final Rule and re-adopts DoD s approach of requesting voluntary agreements obligating manufacturers to pay rebates on TRICARE retail utilization.

In response to the reissued Final Rule, the Coalition amended its complaint to include challenges to the 2010 reissued Final Rule. On October 25, 2011, the United States District Court for the District of Columbia issued a decision granting summary judgment in favor of the DoD and denying relief to the Coalition. *Coalition for Common Sense in Gov t Procurement (the Coalition) v. United States,* No. 08-996, 2011 WL 5042007 (D.C. Dist. Ct. Oct. 25, 2011). The Coalition has filed an appeal at the Court of Appeals for the District of Columbia. The standard of review on appeal is *de novo*, which allows for independent consideration of the legal issues by the Court of Appeals.

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The calculated estimated liability for 2008 TRICARE retail utilization is $1,560,878 and was accrued for in the Company s financial statements as of the quarter ending March 31, 2009. Additionally, TRICARE retail utilization for Q1 2009 has been received and the estimated liability for Q1 2009 of $756,043 was accrued for in the Company s financial statements as of the quarter ending March 31, 2009. As of September 30, 2009, TRICARE retail utilization data for Q2 2009 was received and the liability calculated to the government for the time period of April 1, 2009 through June 28, 2009 is $565,316, and this amount is accrued for in the Company s financial statements as of the quarter ending June 30, 2009. As of the quarter ending September 30, 2009, the Company added an additional $98,816 to the accrual for the time period of April 1, 2009 through June 28, 2009.

DoD has not responded to the Company s waiver requests. Pursuant to the terms of the 2009 Final Rule, during the pendency of the waiver requests, Medicis is not required to pay rebates subject to the requests and is considered to be in compliance with the 2009 Final Rule with respect to the requirement to pay such amounts. In the event DoD does not grant the Company s request in full, Medicis has reserved the right to challenge DoD s asserted right to rebates on pre-voluntary agreement TRICARE retail utilization. Should DoD reject the Company s waiver request in full, under the 2009 Final Rule, DoD would seek payment under the TRICARE retail program of $2,316,921 for the period including 2008 and Q1 2009, plus payment of $565,316 for Q2 2009.

We will be unable to meet our anticipated development and commercialization timelines if clinical trials for our products are unsuccessful, delayed, or additional information is required by the FDA.

The production and marketing of our products and our ongoing research and development, pre-clinical testing and clinical trials activities are subject to extensive regulation and review by numerous governmental authorities. Before obtaining regulatory approvals for the commercial sale of any products, we and/or our partners must demonstrate through pre-clinical testing and clinical trials that our products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process that may be subject to unexpected delays.

In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling and record-keeping procedures.

Completion of clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- lack of efficacy during the clinical trials;
- unforeseen safety issues;
- severe or harmful side effects;
- failure to obtain necessary proprietary rights;
- shortage or lack of supply sufficient to complete studies;
- the decision to modify the product;
- lack of economical pathway to manufacture and commercialize product;
- cost-effectiveness of continued product development;

slower than expected patient recruitment;

failure of Medicis, investigators, or other contractors to strictly adhere to federal regulations governing the conduct and data collection procedures involved in clinical trials;

development of issues that might delay or impede performance by a contractor;

errors in clinical documentation or at the clinical locations;

non-acceptance by the FDA of our NDAs, ANDAs or BLAs;

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government or regulatory delays; and

unanticipated requests from the FDA for new or additional information.

The results from pre-clinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. A number of new products have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including perceived defects in the design of the clinical trials and changes in regulatory policy during the period of product development. Any delays in, or termination of, our clinical trials could materially and adversely affect our development and commercialization timelines, which could adversely affect our financial condition, results of operations and cash flows.

Compliance with the requirements of federal and state laws pertaining to the privacy and security of health information may be time consuming, difficult and costly, and if we are unable to or fail to comply with such laws, our financial condition, results of operations and cash flows may be adversely affected.

We are subject to various privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (as amended, HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions (e.g., health care claims information and plan eligibility, referral certification and authorization, claims status, plan enrollment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could adversely affect our financial condition, results of operations and cash flows.

Downturns in general economic conditions may adversely affect our financial condition, results of operations and cash flows.

Our business, and in particular our facial aesthetic and branded prescription products, have been and are expected to continue to be adversely affected by downturns in general economic conditions. Economic conditions such as employment levels, business conditions, interest rates, energy and fuel costs, consumer confidence and tax rates could change consumer purchasing habits or reduce personal discretionary spending. A reduction in consumer spending may have an adverse impact on our financial condition, results of operations and cash flows. In addition, our ability to meet our expected financial performance is dependent upon our ability to rapidly recover from downturns in general economic conditions.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2012. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to

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reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have led to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business consumer spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

The current condition of the credit markets may not allow us to secure financing for potential future activities on satisfactory terms, or at all.

Our existing cash and short-term investments are available for dividends, strategic investments, acquisitions of companies or products complementary to our business, the repayment of outstanding indebtedness, repurchases of our outstanding securities and other potential large-scale needs. We may consider incurring additional indebtedness and issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt or for general corporate purposes. As a result of the volatility and disruption of the capital and credit markets since the latter part of 2008, the markets have exerted downward pressure on the availability of liquidity and credit capacity; therefore, we may not be able to secure additional financing for future activities on satisfactory terms, or at all, which may adversely affect our financial condition and results of operations.

Negative conditions in the credit markets may impair the liquidity of a portion of our short-term and long-term investments.

Our short-term and long-term investments consist of corporate and various government agency and municipal debt securities and auction rate floating securities. As of December 31, 2011, our investments included $12.8 million of auction rate floating securities. Our auction rate floating securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The negative conditions in the credit markets in recent years have prevented some investors from liquidating their holdings, including their holdings of auction rate floating securities. Since early 2008, there has been insufficient demand at auction for auction rate floating securities. As a result, these affected auction rate floating securities are now considered illiquid, and we could be required to hold them until they are redeemed by the holder at maturity. We may not be able to liquidate the securities until a future auction on these investments is successful. We could be required to record impairment losses in the future, depending on market conditions.

In conducting our business operations outside the U.S., we may be subject to risks associated with doing business internationally.

As we engage in and expand our operations internationally, our business will be subject to certain risks inherent in international business, many of which are beyond our control. These risks include, among other things:

adverse changes in tariff and trade protection measures;

reductions in the reimbursement amounts we receive for our products from foreign governments and foreign insurance providers;

unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;

potentially negative consequences from changes in or interpretations of tax laws;

differing labor regulations;

changing economic conditions in countries where our products are sold or manufactured or in other countries;

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differing local product preferences and product requirements;

exchange rate risks;

restrictions on the repatriation of funds;

political unrest and hostilities;

product liability, intellectual property and other claims;

new export license requirements;

differing degrees of protection for intellectual property;

difficulties in coordinating and managing foreign operations, including ensuring that foreign operations comply with foreign laws as well as U.S. laws applicable to U.S. companies with foreign operations, such as export laws and the U.S. Foreign Corrupt Practices Act, or FCPA; and

difficulties with licensees, contract counterparties, or other commercial partners.

Any of these factors, or any other international factors, could have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that we may be able to successfully manage these risks or avoid their effects.

We may be subject to risks arising from currency exchange rates, which could increase our costs and may cause our profitability to decline.

As we expand our international business operations, we may collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates may affect our operating results. We cannot assure you that future exchange rate movements, inflation or other related factors will not have a material adverse effect on our sales or operating expenses.

If Q-Med is unable to protect its intellectual property and proprietary rights with respect to our dermal filler products, our business could suffer.

The exclusivity period of the license granted to us by Q-Med for RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™ will terminate on the later of (i) the expiration of the last patent covering the products (estimated to be 2017) or (ii) upon the licensed know-how becoming publicly known. If the validity or enforceability of our patents is successfully challenged, the cost to us could be significant and our business may be harmed. For example, if any such challenges are successful, Q-Med may be unable to supply products to us. As a result, we may be unable to market, distribute and commercialize the products or it may no longer be profitable for us to do so.

We depend upon our key personnel and our ability to attract, train and retain employees.

Our success depends significantly on the continued individual and collective contributions of our senior management team, and Jonah Shacknai, our Chairman and Chief Executive Officer, in particular. While we have entered into employment agreements with many members of our senior management team, including Mr. Shacknai, the loss of the services of any member of our senior management for any reason or the inability to hire and retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. In addition, our future success depends on our ability to hire, train and retain skilled employees. Competition for these employees is intense.

We have a significant amount of intangible assets, which may never generate the returns we expect.

Our identifiable intangible assets, which include trademarks and trade names, license agreements and patents acquired in acquisitions, were $502.5 million at December 31, 2011, representing approximately 34.6% of our

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total assets of $1.45 billion. Goodwill, which relates to the excess of cost over the fair value of the net assets of the businesses acquired, was $202.6 million at December 31, 2011, representing approximately 14.0% of our total assets. Goodwill and identifiable intangible assets are recorded at fair value on the date of acquisition. Under Accounting Standards Codification (ASC) No. 350 Intangibles Goodwill and Other, goodwill is reviewed at least annually for impairment and definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. Future impairment may result from, among other things, deterioration in the performance of the acquired business or product line, adverse market conditions and changes in the competitive landscape, adverse changes in applicable laws or regulations, including changes that restrict the activities of the acquired business or product line, changes in accounting rules and regulations, and a variety of other circumstances. The amount of any impairment is recorded as a charge to the statement of operations. We may never realize the full value of our intangible assets, and any determination requiring the write-off of a significant portion of intangible assets may have an adverse effect on our financial condition and results of operations. See Management s Discussion and Analysis of Financial Condition and Results of Operations.

We may acquire technologies, products and companies in the future and these acquisitions could disrupt our business and harm our financial condition and results of operations. In addition, we may not obtain the benefits that the acquisitions were intended to create and this may cause us to undertake certain strategic alternatives and changes, which may include the discontinuation of certain aspects of our business and/or the divestiture of certain of our product lines.

As part of our business strategy, we regularly consider and, as appropriate, make acquisitions (whether by acquisition, license or otherwise) of technologies, products and companies that we believe are complementary to our business. For example, on December 2, 2011, we completed an asset acquisition pursuant to that certain asset purchase agreement, dated as of November 18, 2011 (the Asset Purchase Agreement), by and among us, Graceway Pharmaceuticals, LLC (Graceway) and certain of Graceway s subsidiaries (together with Graceway, the Sellers). Pursuant to the Asset Purchase Agreement, we acquired substantially all of the assets of the Sellers for an aggregate purchase price of approximately $455.9 million and agreed to assume certain limited post-closing liabilities, primarily associated with contracts for commercial operations assumed by us and also certain liabilities relating to Graceway s Canadian operations (the Graceway Acquisition). Acquisitions, such as the Graceway Acquisition, typically entail many risks, including, but not limited to, the inability to maintain relationships with customers and partners of the acquired business, unexpected difficulties encountered when entering new markets in which we have limited or no experience, and the potential unknown liabilities associated with an acquired business or investment. Another risk related to acquisitions includes difficulties in integrating the operations, personnel, technologies, products and companies acquired, which may result in significant charges to earnings. If we are unable to successfully integrate our acquisitions with our existing business, or we otherwise make an acquisition that does not result in the benefits that we anticipated, our business, results of operations, financial condition and cash flows could be materially and adversely affected, which would adversely affect our ability to develop and introduce new products and the market price of our stock. In addition, in connection with acquisitions, we could experience disruption in our business or employee base, including the diversion of management attention or other resources from other business operations and strategic priorities, or key employees of companies that we acquire may seek employment elsewhere, including with our competitors. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the combined businesses.

In the event that we are unable to obtain the benefits that our acquisitions were intended to create, we may be required to consider strategic alternatives and changes, including the discontinuation of certain aspects of our business and/or the divestiture of certain product lines, which may subject us to a number of risks, including causing strains on our ongoing operations by distracting our management and by causing us to incur substantial exit costs, losses and liabilities. For example, as a result of our strategic planning process and the current regulatory and commercial capital equipment environment, we sold our LipoSonix business in 2011.

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Further, there is no guarantee that we will be able to successfully undertake such strategic alternatives and changes. The inability to do so will create a number of risks, including the diversion of management s attention, a negative impact on our customer relationships and the potential costs associated with retaining the targeted divestiture.

We may discontinue existing product lines, which may adversely impact our business and results of operations.

We continually evaluate the performance of our product lines, and may determine that it is in the best interest of the Company to discontinue certain of our product lines. For example, we decided to discontinue TRIAZ® and PLEXION® in early 2011. We cannot guarantee that we have correctly forecasted, or will correctly forecast in the future, the appropriate product lines to discontinue or that our decision to discontinue various products lines is prudent if market conditions change. In addition, there are no assurances that the discontinuance of product lines will reduce our operating expenses or will not cause us to incur material charges associated with such a decision. Furthermore, the discontinuance of existing product lines entails various risks, including, in the event that we decide to sell the discontinued product, the risk that we will not be able to find a purchaser for a product line or that the purchase price obtained will not be equal to at least the book value of the net assets for the product line. Other risks include managing the expectations of, and maintaining good relations with, our customers who previously purchased products from our discontinued product lines, which could prevent us from selling other products to them in the future. Moreover, we may incur other significant liabilities and costs associated with our discontinuance of product lines.

We rely on third parties to conduct business operations outside of the U.S., and we may be adversely affected if they act in violation of the U.S. Foreign Corrupt Practices Act or other anti-bribery laws.

The FCPA and similar anti-bribery laws in other jurisdictions prohibit companies and their agents from making improper payments to government officials for the purpose of obtaining or retaining business. These laws are complex and often difficult to interpret and apply, and in certain cases, local business practices may conflict with strict adherence to anti-bribery laws. Our policies and contractual arrangements are designed to maintain compliance with these anti-bribery laws. We perform, on a periodic basis, an extensive background check to verify several aspects of compliance, including but not limited to, national and international black lists. We also provide training to relevant employees and agents regarding compliance with anti-bribery laws. We cannot guarantee that our policies and procedures, contractual obligations, background checks and training programs will prevent reckless or criminal acts committed by our employees or agents. Violations may result in criminal and civil penalties, including fines, imprisonment, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products, and exclusion from participation in government healthcare programs. Allegations or evidence that we or our agents have violated these laws could disrupt our business and subject us to criminal or civil enforcement actions. Such action could have a material adverse effect on our business.

Our success depends on our ability to manage our growth.

We have experienced a period of rapid growth from both acquisitions and internal expansion of our operations. This growth has placed significant demands on our personnel and financial resources. We must continue to improve our operational, financial and management information controls and systems and effectively motivate, train and manage our employees to properly manage this growth. If we do not manage this growth effectively, maintain the quality of our products despite the demands on our resources and retain key personnel, our business could be harmed.

We rely on others to manufacture our products.

Currently, we rely on third-party manufacturers for much of our product manufacturing needs. All third-party manufacturers are required by law to comply with the FDA s regulations, including the cGMP regulations (for

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drugs and biologics) and the QSR (for medical devices), as applicable. These regulations set forth standards for both quality assurance and quality control. Third-party manufacturers also must maintain records and other documentation as required by applicable laws and regulations. In addition to a legal obligation to comply, our third-party manufacturers are contractually obligated to comply with all applicable laws and regulations. However, we cannot guarantee that third-party manufacturers will ensure compliance with all applicable laws and regulations. Failure of a third-party manufacturer to maintain compliance with applicable laws and regulations could result in decreased sales of our products and decreased revenues. Failure of a third-party manufacturer to maintain compliance with applicable laws and regulations also could result in reputational harm to us and potentially subject us to sanctions, including:

- delays, warning letters and fines;
- product recalls or seizures;
- injunctions on sales;
- refusal of the FDA to review pending applications;
- total or partial suspension of production;
- withdrawal of prior marketing approvals or clearances; and
- civil penalties and criminal prosecutions.

Typically, our manufacturing contracts are short term. We are dependent upon renewing agreements with our existing manufacturers or finding replacement manufacturers to satisfy our requirements. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of our products on reasonable or acceptable terms.

The underlying cost to us for manufacturing our products is established in our agreements with these outside manufacturers. Because of the short-term nature of these agreements, our expenses for manufacturing are not fixed and could change from contract to contract. If the cost of production increases, our gross margins could be negatively affected.

In addition, we rely on outside manufacturers to provide us with an adequate and reliable supply of our products on a timely basis and in accordance with good manufacturing standards and applicable product specifications. As a result, we are subject to and have little or no control over delays and quality control lapses that our third-party manufacturers and suppliers may suffer. For example, in early May 2008, we became aware that our third-party manufacturer and supplier of SOLODYN® mistakenly filled at least one bottle labeled as SOLODYN® with a different pharmaceutical product. As a result of this occurrence, we initiated a voluntary recall of the two affected lots. We were able, however, to recoup some of our losses from this voluntary recall during 2009 as a result of an indemnification claim against the manufacturer.

Loss of a supplier or any difficulties that arise in the supply chain could significantly affect our inventories and supply of products available for sale. We do not have alternative sources of supply for all of our products. If a primary supplier of any of our primary products is unable to fulfill our requirements for any reason, it could reduce our sales, margins and market share, as well as harm our overall business and financial results. If we are unable to supply sufficient amounts of our products on a timely basis, our revenues and market share could decrease and, correspondingly, our profitability could decrease.

Under several exclusive supply agreements, with certain exceptions, we must purchase most of our product supply from specific manufacturers. If any of these exclusive manufacturer or supplier relationships were terminated, we would be forced to find a replacement manufacturer or supplier. Manufacturing facilities must be approved by the FDA before they are used to manufacture our products. The validation of a new facility and the approval of that manufacturer for a new product may take a year or more before manufacture can begin at the facility. Delays in

obtaining FDA validation of a replacement manufacturing facility could cause an interruption

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in the supply of our products. The new facility also may be subject to follow-up inspections. Although we have business interruption insurance to assist in covering the loss of income for products where we do not have a secondary manufacturer, which may mitigate the harm to us from the interruption of the manufacturing of our largest selling products caused by certain events, the loss of a manufacturer could still cause a reduction in our sales, margins and market share, as well as harm our overall business and financial results.

We and our third-party manufacturers rely on a limited number of suppliers of the raw materials of our products. A disruption in supply of raw material would be disruptive to our inventory supply.

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are available from only one source and others may become available from only one source. We try to maintain inventory levels that are no greater than necessary to meet our current projections, which could have the effect of exacerbating supply problems. Any interruption in the supply of finished products could hinder our ability to timely distribute finished products. If we are unable to obtain adequate product supplies to satisfy our customers orders, we may lose those orders and our customers may cancel other orders and stock and sell competing products. This, in turn, could cause a loss of our market share and reduce our revenues. In addition, any disruption in the supply of raw materials or an increase in the cost of raw materials to our manufacturers could have a significant effect on their ability to supply us with our products, which would adversely affect our financial condition and results of operations.

We could experience difficulties in obtaining supplies of RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™.

The manufacturing process to create bulk non-animal stabilized hyaluronic acid necessary to produce RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™ products is technically complex and requires significant lead-time. Any failure by us to accurately forecast demand for finished products could result in an interruption in the supply of RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™ products and a resulting decrease in sales of the products.

We depend exclusively on Q-Med for our supply of RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™ products. There are currently no alternative suppliers of these products. Q-Med has committed to supply RESTYLANE® to us under a long-term license that is subject to customary conditions and our delivery of specified milestone payments. Q-Med manufactures RESTYLANE®, RESTYLANE-L®, PERLANE®, PERLANE-L® and RESTYLANE FINE LINES™ at its facility in Uppsala, Sweden. We cannot be certain that Q-Med will be able to meet our current or future supply requirements. Any impairment of Q-Med s manufacturing capacities could significantly affect our inventories and our supply of products available for sale, which would materially and adversely affect our results of operations.

Supply interruptions may disrupt our inventory levels and the availability of our products.

Numerous factors could cause interruptions in the supply of our finished products, including:

- timing, scheduling and prioritization of production by our contract manufacturers;
- labor interruptions;
- changes in our sources for manufacturing;
- the timing and delivery of domestic and international shipments;
- our failure to locate and obtain replacement manufacturers as needed on a timely basis;

conditions affecting the cost and availability of raw materials; and

hurricanes and other natural disasters.

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We estimate customer demand for our prescription products primarily through use of third-party syndicated data sources which track prescriptions written by health care providers and dispensed by licensed pharmacies. The data represents extrapolations from information provided only by certain pharmacies, and are estimates of historical demand levels. We estimate customer demand for our non-prescription products primarily through internal data that we compile. We observe trends from these data, and, coupled with certain proprietary information, prepare demand forecasts that are the basis for purchase orders for finished and component inventory from our third-party manufacturers and suppliers. Our forecasts may fail to accurately anticipate ultimate customer demand for products. Overestimates of demand may result in excessive inventory production and underestimates may result in an inadequate supply of our products in channels of distribution.

We sell our products primarily to major wholesalers and retail pharmacy chains. Approximately 75-80% of our gross revenues are typically derived from two major drug wholesale concerns. We have distribution services agreements with our two largest wholesale customers. We review the supply levels of our significant products sold to major wholesalers by reviewing periodic inventory reports supplied by our major wholesalers. We rely wholly upon our wholesale and drug chain customers to effect the distribution allocation of substantially all of our products.

We periodically offer promotions to wholesale and chain drugstore customers to encourage dispensing of our prescription products, consistent with prescriptions written by licensed health care providers. Because many of our prescription products compete in multi-source markets, it is important for us to ensure the licensed health care providers dispensing instructions are fulfilled with our branded products and are not substituted with a generic product or another therapeutic alternative product which may be contrary to the licensed health care providers recommended prescribed Medicis brand. We believe that a critical component of our brand protection program is maintenance of full product availability at drugstore and wholesale customers. We believe such availability reduces the probability of local and regional product substitutions, shortages and backorders, which could result in lost sales. We expect to continue providing favorable terms to wholesale and retail drug chain customers as may be necessary to ensure the fullest possible distribution of our branded products within the pharmaceutical chain of commerce. From time to time, we may enter into business arrangements (e.g., loans or investments) involving our customers and those arrangements may be reviewed by federal and state regulators.

Purchases by any given customer, during any given period, may be above or below actual prescription volumes of any of our products during the same period, resulting in fluctuations in product inventory in the distribution channel. Any decision made by management to reduce wholesale inventory levels will decrease our product revenue.

Fluctuations in demand for our products create inventory maintenance uncertainties.

We schedule our inventory purchases to meet anticipated customer demand. As a result, miscalculation of customer demand or relatively small delays in our receipt of manufactured products could result in revenues being deferred or lost. Our operating expenses are based upon anticipated sales levels, and a high percentage of our operating expenses are relatively fixed in the short term. Depending on the customer, we recognize revenue at the time of shipment to the customer, or at the time of receipt by the customer, net of estimated provisions. Consequently, variations in the timing of revenue recognition could cause significant fluctuations in operating results from period to period and may result in unanticipated periodic earnings shortfalls or losses.

We selectively outsource certain non-sales and non-marketing services, and cannot assure you that we will be able to obtain adequate supplies of such services on acceptable terms.

To enable us to focus on our core marketing and sales activities, we selectively outsource certain non-sales and non-marketing functions, such as laboratory research, manufacturing and warehousing. As we expand our activities, we expect to expend additional financial resources in these areas. We typically do not enter into long-term manufacturing contracts with third-party manufacturers. Whether or not such contracts exist, we cannot assure you that we will be able to obtain adequate supplies of such services or products in a timely fashion, on acceptable terms, or at all.

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Importation of products from Canada and other countries into the United States may lower the prices we receive for our products.

Our products are subject to competition from lower priced versions of our products and competing products from Canada and other countries where government price controls or other market dynamics result in lower prices. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere targeted to American purchasers, the increase in United States-based businesses affiliated with Canadian pharmacies marketing to American purchasers, and other factors. Most of these foreign imports are illegal under current United States law. However, the volume of imports continues to rise due to the limited enforcement resources of the FDA and the United States Customs Service, and there is increased political pressure to permit the imports as a mechanism for expanding access to lower priced medicines.

In December 2003, Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This law contains provisions that may change United States import laws and expand consumers ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to United States import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. To date, the former Secretary of Health and Human Services has not made such a certification. However, it is possible that the current Secretary or a subsequent Secretary could make the certification in the future. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for United States consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted, and the current Secretary has not announced any plans to make the required certification. In addition, federal legislative proposals have been made to implement the changes to the United States import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the United States import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the United States Customs Service and other government agencies.

The importation of foreign products adversely affects our profitability in the United States. This impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to facilitate the importation of products from abroad.

If we become subject to product liability claims, our earnings and financial condition could suffer.

We are exposed to risks of product liability claims from allegations that our products resulted in adverse effects to the patient or others. These risks exist even with respect to those products that are approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA.

In addition to our desire to reduce the scope of our potential exposure to these types of claims, many of our customers require us to maintain product liability insurance as a condition of conducting business with us. We currently carry product liability insurance on a claims-made basis. Nevertheless, this insurance may not be sufficient to cover all claims made against us. Insurance coverage is expensive and may be difficult to obtain. As a result, we cannot be certain that our current coverage will continue to be available in the future on reasonable terms, if at all. If we are liable for any product liability claims in excess of our coverage or outside of our coverage, the cost and expense of such liability could cause our earnings and financial condition to suffer.

If we suffer negative publicity concerning the safety of our products, our sales may be harmed and we may be forced to withdraw products.

Physicians and potential patients may have a number of concerns about the safety of our products, whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. Negative

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publicity, whether accurate or inaccurate, concerning our products could reduce market or governmental acceptance of our products and could result in decreased product demand or product withdrawal. In addition, significant negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law.

Rising insurance costs could negatively impact profitability.

The cost of insurance, including workers compensation, product liability and general liability insurance, has been relatively stable in recent years but may increase in the future. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our results of operations, financial condition and cash flows.

DYSPORT® , RESTYLANE® and PERLANE® are consumer products and as such, are susceptible to changes in popular trends and applicable laws, which could adversely affect sales or product margins of DYSPORT®, RESTYLANE® and PERLANE®.

DYSPORT®, RESTYLANE® and PERLANE® are consumer products. If we fail to anticipate, identify or react to competitive products or if consumer preferences in the cosmetic marketplace shift to other treatments for the treatment of glabellar lines and moderate to severe facial wrinkles and folds, respectively, we may experience a decline in demand for DYSPORT®, RESTYLANE® and PERLANE®. In addition, the popular media has at times in the past produced, and may continue in the future to produce, negative reports regarding the efficacy, safety or side effects of facial aesthetic products. Consumer perceptions of DYSPORT®, RESTYLANE® and PERLANE® may be negatively impacted by these reports and other reasons.

Demand for DYSPORT®, RESTYLANE® and PERLANE® may be materially adversely affected by changing economic conditions. Generally, the costs of cosmetic procedures are borne by individuals without reimbursement from their medical insurance providers or government programs. Individuals may be less willing to incur the costs of these procedures in weak or uncertain economic environments, and demand for DYSPORT®, RESTYLANE® and PERLANE® could be adversely affected.

The restatement of our consolidated financial statements has subjected us to a number of additional risks and uncertainties, including increased costs for accounting and legal fees and the increased possibility of legal proceedings.

As discussed in our Form 10-K/A for the year ended December 31, 2007 filed with the SEC on November 10, 2008, and in Note 2 to our consolidated financial statements therein, we determined that our consolidated financial statements for the annual, transition and quarterly periods in fiscal years 2003 through 2007 and the first and second quarters of 2008 should be restated due to an error in our interpretation and application of Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48), as it applies to a component of our sales return reserve calculations. SFAS 48 is now part of ASC 605, *Revenue Recognition* (ASC 605). As a result of the restatement, we have become subject to a number of additional risks and uncertainties, including:

We incurred substantial unanticipated costs for accounting and legal fees in connection with the restatement. Although the restatement is complete, we expect to continue to incur accounting and legal costs as noted below.

As a result of the restatement, we have been named in a putative stockholder class action complaint, and certain stockholder derivative complaints, as discussed in Note 12, Commitments and Contingencies Legal Matters, in the notes to the consolidated financial statements under Item 15 of Part IV of this report Exhibits, Financial Statement Schedules.

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There may be reputational harm to us as a result of the restatement or the stockholder class action or derivative suits.

Management may identify material weaknesses in our internal control over financial reporting, including with respect to our accounting assumptions, that could adversely affect investor confidence, impair the value of our common stock and increase our cost of raising capital.

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. There can be no assurance that material weaknesses in our internal control over financial reporting will not be identified in the future. Any failure to remedy deficiencies in our internal control over financial reporting that may be discovered could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure could, in turn, affect the future ability of our management to certify that our internal control over our financial reporting is effective and, moreover, affect the results of our independent registered public accounting firm s attestation report regarding our management s assessment. Inferior internal control over financial reporting could also subject us to the scrutiny of the SEC and other regulatory bodies and could cause investors to lose confidence in our reported financial information, which could have an adverse effect on the trading price of our common stock.

In addition, if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting, the disclosure of that fact, even if quickly remedied, could reduce the market s confidence in our financial statements and harm our share price. Furthermore, deficiencies could result in non-compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Such non-compliance could subject us to a variety of administrative sanctions, including the suspension or delisting of our ordinary shares from the NYSE and review by the NYSE, the SEC, or other regulatory authorities.

We may not be able to repurchase the Old Notes when required.

We have $169.1 million principal amount of outstanding 2.5% Contingent Convertible Senior Notes due 2032 (the Old Notes). On June 4, 2012 and 2017 or upon the occurrence of a change in control, holders of the Old Notes may require us to offer to repurchase their Old Notes for cash.

The source of funds for any repurchase required as a result of any such event will be our available cash or cash generated from operating activities or other sources, including borrowings, sales of assets, sales of equity or funds provided by a new controlling entity. We cannot assure you, however, that sufficient funds will be available at the time of any such event to make any required repurchases of the Notes tendered. If sufficient funds are not available to repurchase the Old Notes, we may be forced to incur other indebtedness or otherwise reallocate our financial resources. Furthermore, the use of available cash to fund the repurchase of the Old Notes may impair our ability to obtain additional financing in the future.

Unanticipated changes in our tax rates or exposure to additional income tax liabilities could affect our profitability.

We are subject to income taxes in both the U.S. and other foreign jurisdictions. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in or interpretations of tax laws including pending tax law changes (such as the research and development credit and the deductibility of executive compensation), changes in the application of state tax laws, changes in our manufacturing activities and changes in our future levels of research and development spending. In addition, we are subject to the periodic examination of our income tax returns by the Internal Revenue Service and other tax authorities, including state tax authorities. We regularly

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assess the likelihood of outcomes resulting from these examinations to determine the adequacy of our provision for income taxes. There can be no assurance that the outcomes from these periodic examinations will not have an adverse effect on our provision for income taxes and estimated income tax liabilities.

Risks Related to Our Industry

The growth of managed care organizations, other third-party reimbursement policies, state regulatory agencies and retailer fulfillment policies may harm our pricing, which may reduce our market share and margins.

Our operating results and business success depend in large part on the availability of adequate third-party payor reimbursement to patients for our prescription-brand products. These third-party payors include governmental entities such as Medicaid, private health insurers and managed care organizations. Because of the size of the patient population covered by managed care organizations, marketing of prescription drugs to them and the pharmacy benefit managers that serve many of these organizations has become important to our business.

The trend toward managed healthcare in the United States and the growth of managed care organizations could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in demand for products such as SOLODYN®. Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. Payment or reimbursement of only a portion of the cost of our prescription products could make our products less attractive, from a net-cost perspective, to patients, suppliers and prescribing physicians. We cannot be certain that the reimbursement policies of these entities will be adequate for our pharmaceutical products to compete on a price basis. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be harmed, as could our business, financial condition, results of operations and cash flows. We are actively engaged in a strategy to reduce our exposure to managed care restrictions for SOLODYN® and our other therapeutic products. This strategy includes, among other things, negotiating new, multi-year contracts with targeted managed care organizations and pharmacy benefit managers. There can be no assurance that such negotiations will be successful or that the strategy will achieve its desired result. Even if such negotiations are successful, they may result in increased managed care rebates, which may have a negative impact on sales, reserves, profitability and the average selling price for affected products, such as SOLODYN®, and result in a reduction in reimbursement amounts for such products from other third-party payors, including the Medicare and Medicaid programs.

In addition, healthcare reform could affect our ability to sell our products and may have a material adverse effect on our business, results of operations, financial condition and cash flows. In particular, the Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, subjects biologic products to potential competition by lower-cost biosimilars, and significantly impacts the U.S. pharmaceutical and medical device industries. Among other things, the Affordable Care Act:

- Establishes annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics, effective 2011;

- Establishes a deductible excise tax on any entity that manufactures or imports certain medical devices offered for sale in the United States, beginning 2013;

- Increases minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1 percent of the AMP for most innovator products (17.1 percent for certain pediatric and clotting factor innovator products) and 13 percent of the AMP for generic drugs;

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Redefines a number of terms used in determining Medicaid drug rebate liability, including average manufacturer price and retail community pharmacy, effective October 2010;

Extends manufacturers Medicaid rebate liability to covered drugs dispensed to enrollees in certain Medicaid managed care organizations, effective March 23, 2010;

Expands eligibility criteria for Medicaid programs by, among other things, permitting states to offer Medicaid coverage to additional individuals beginning April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133 percent of the Federal Poverty Level beginning 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

Establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research;