MEDICIS PHARMACEUTICAL CORP
Form 10-K
March 02, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the year ended December 31, 2008.

Or

o **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 0-18443

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: Class A common stock, $0.014 par value

New York Stock Exchange	Preference Share Purchase Rights
(Name of each exchange on which registered)	(Title of each Class)

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 þ No o

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 o No þ

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 þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 o.

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

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting stock held on June 30, 2008 by non-affiliates of the registrant was $1,026,926,425 based on the closing price of $20.78 per share as reported on the New York Stock Exchange on June 30, 2008, 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 24, 2009, there were 56,722,705 outstanding shares of Class A common stock.

Documents incorporated by reference:

Portions of the Proxy Statement for the registrant s 2009 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), toge 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 U.S. of products for the treatment of dermatological, aesthetic and podiatric conditions. We believe that the U.S. market for dermatological pharmaceutical sales exceeds $6 billion annually. According to the American Society for Aesthetic Plastic Surgery, a national not-for-profit organization for education and research in cosmetic plastic surgery, nearly 11.7 million cosmetic surgical and non-surgical procedures were performed in the United States during 2007, including approximately 9.6 million non-surgical cosmetic procedures. We also market products in Canada for the treatment of dermatological and aesthetic conditions.

On July 1, 2008, we acquired LipoSonix, Inc. (LipoSonix), an independent, privately-held company that employs a staff of approximately 40 scientists, engineers and clinicians located near Seattle, Washington. LipoSonix is a medical device company developing non-invasive body sculpting technology, and recently launched its first product in Europe, where it is being marketed and sold through distributors. The LipoSonix technology is currently not approved for sale or use in the U.S. We believe the U.S. non-invasive fat ablation market could be several hundred million dollars annually.

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 podiatrists and the leading plastic surgeons in the United States.

We offer a broad range of products addressing various conditions or aesthetic improvements, including facial wrinkles, acne, fungal infections, rosacea, hyperpigmentation, photoaging, psoriasis, skin and skin-structure infections, seborrheic dermatitis and cosmesis (improvement in the texture and appearance of skin). We currently offer 18 branded products. Our primary brands are PERLANE® (hyaluronic acid), RESTYLANE® (hyaluronic acid), SOLODYN® (minocycline HCl, USP), TRIAZ® (benzoyl peroxide), VANOS® (fluocinonide) Cream 0.1%, and ZIANA® (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel. Many of our primary brands currently enjoy branded market leadership in the segments in which they compete. Because of the significance of these brands to our business, we concentrate our sales and marketing efforts in promoting them to physicians in our target markets. We also sell a number of other products that we consider less critical to our business.

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. As a result of our increasing financial strength, we have begun adding long-term projects to our development pipeline. Historically, we have supplemented our research and development efforts by entering into research and development agreements with other pharmaceutical and biotechnology companies.

Currently, except for the LipoSonix technology, we outsource all of our product manufacturing needs. The underlying cost to us for manufacturing our products is established in our agreements with 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.

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Our Products

We currently market 18 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
PERLANE®	Injectable gel for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds	Launched in May 2007 following U.S. Food and Drug Administration (FDA) approval on May 2, 2007
RESTYLANE®	Injectable gel for treatment of moderate to severe facial wrinkles and folds, such as nasolabial folds	The leading worldwide injectable dermal filler, launched in January 2004 following FDA approval on December 12, 2003
SOLODYN®	Once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 and older	Launched in July 2006 following FDA approval on May 8, 2006.
TRIAZ®	Topical patented gel and cleanser and patent-pending pad treatments for acne	A leading branded prescription benzoyl peroxide product, launched during fiscal 1996
VANOS®	Super-high potency topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older	Launched in April 2005 following FDA approval on February 11, 2005
ZIANA®	Once daily topical gel treatment for acne vulgaris in patients 12 and older	Approved by the FDA on November 7, 2006. First commercial sales to wholesalers in December 2006 and launched in January 2007

Dermal Restorative Products

Our principal branded dermal restorative products are described below:

RESTYLANE®, PERLANE®, RESTYLANE FINE LINES™ and **RESTYLANE SUBQ™** are injectable, transparent, stabilized hyaluronic acid gels, which require no patient sensitivity tests in advance of product administration. These products are the world s leading hyaluronic acid dermal fillers and their unique particle-based gel formulations offer structural support and lift when implanted into the skin. On a worldwide basis, more than ten million treatments have been successfully performed in more than 70 countries since its introduction in 1996. In the United States, the FDA regulates these products as medical devices. Medicis offers all four of these products in Canada, and began offering RESTYLANE® and PERLANE® in the United States on January 6, 2004 and May 21, 2007, respectively. In the U.S., RESTYLANE® 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. RESTYLANE FINE LINES ™ and RESTYLANE SUBQ™ have not yet been approved by the FDA for use in the United States. We acquired the exclusive U.S. and Canadian rights to these dermal restorative products from Q-Med AB, a Swedish biotechnology and medical device company and its affiliates (collectively Q-Med) through license agreements.

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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 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 and older. SOLODYN® is the first approved minocycline in extended release tablet form. SOLODYN® is lipid soluble, and its mode of action occurs in the skin and sebum. SOLODYN® is not bioequivalent to any other minocycline products, and is in no way interchangeable with other forms of minocycline. SOLODYN® is patented until 2018 by a U.S. patent which covers SOLODYN® (see also Item 1A. Risk Factors). Other patent applications covering SOLODYN® are pending (see also Item 1A. Risk Factors). SOLODYN® is available by prescription in 45mg, 90mg and 135mg extended release tablet dosages.

TRIAZ®, a topical therapy prescribed for the treatment of numerous forms and varying degrees of acne, is available as a patented gel or cleanser or in a patent-pending pad in three concentrations. TRIAZ® products are manufactured using the active ingredient benzoyl peroxide in a patented vehicle containing glycolic acid and zinc lactate. Studies conducted by third parties have shown that benzoyl peroxide is the most efficacious agent available for eradicating the bacteria that cause acne with no reported resistance. We introduced the TRIAZ® brand in fiscal 1996. In July 2003, we launched TRIAZ® Pads, the first benzoyl peroxide pad available in the U.S. indicated for the topical treatment of acne vulgaris. TRIAZ® is protected by a U.S. patent that expires in 2015.

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 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, yet behave like an ointment on the skin. In addition, physicians have the flexibility of prescribing VANOS® either for once or twice daily application. VANOS® Cream is protected by one U.S. patent that expires in 2021 and two U.S. patents that expire in 2023. VANOS® Cream is available by prescription in 30 gram, 60 gram and 120 gram tubes.

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 the first and only combination of clindamycin and tretinoin approved for once daily use for the topical treatment of acne vulgaris in patients 12 years and older. ZIANA® is also the first and only approved acne product to combine an antibiotic and a retinoid. ZIANA® is protected by a U.S. patent for both composition of matter on the aqueous-based vehicle and method that expires in 2020. An additional patent covering composition of matter has been placed before the U.S. Patent and Trademark Office to be reissued. Each of these patents cover aspects of the unique vehicle which are used to deliver the active ingredients in ZIANA®. ZIANA® is available by prescription in 30 gram and 60 gram tubes.

Research and Development

We have historically developed and obtained rights to pharmaceutical agents in various stages of development. Currently, 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. As a result of our increasing financial strength, we have begun adding long-term projects to our development pipeline. Historically, we have supplemented our research and development efforts by entering into research and development agreements with other pharmaceutical and biotechnology companies.

We incurred total research and development costs for all of our sponsored and unreimbursed co-sponsored pharmaceutical projects for 2008, 2007 and 2006, of $99.9 million, $39.4 million and $161.8 million, respectively. Research and development costs for 2008 include a $40.0 million payment to IMPAX Laboratories, Inc.

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(IMPAX) related to our development agreement with IMPAX and a $25.0 million payment to Ipsen Ltd., a wholly-owned subsidiary of Ipsen, S.A. (Ipsen) upon the FDA s May 2008 acceptance of filing of Ipsen s Biologics License Application (BLA) for RELOXIN®. Research and development costs for 2007 include $8.0 million related to our option to acquire Revance Therapeutics, Inc. (Revance) or to license Revance s product currently under development. Research and development costs for 2006 include $125.2 million paid to Ipsen pursuant to the RELOXIN® development agreements.

On November 26, 2008, we entered into a joint development agreement with IMPAX whereby we and IMPAX will collaborate on the development of five strategic dermatology product opportunities, including an advanced-form SOLODYN® product. Under terms of the agreement, we made an initial payment of $40.0 million upon execution of the agreement. In addition, we are required to pay up to $23.0 million upon successful completion of certain 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 equally 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 a charge to research and development expense during the three months ended December 31, 2008.

On March 17, 2006, we entered into a development and distribution agreement with Ipsen, whereby Ipsen granted to one of our wholly-owned subsidiaries the rights to develop, distribute and commercialize Ipsen s botulinum toxin type A product in the United States, Canada and Japan for aesthetic use by physicians. The product is commonly referred to as RELOXIN® in the U.S. aesthetic market and DYSPORT® in medical and aesthetic markets outside the U.S. The product is not currently approved for use in the U.S., Canada or Japan. Upon execution of the development and distribution agreement, we made an initial payment to Ipsen in the amount of $90.1 million in consideration for the exclusive distribution rights in the U.S., Canada and Japan.

Additionally, on March 17, 2006, Medicis and Ipsen agreed to negotiate and enter into an agreement relating to the exclusive distribution and development rights of the product for the aesthetic market in Europe, and subsequently in certain other markets. Under the terms of the U.S., Canada and Japan agreement, as amended, we were obligated to make an additional $35.1 million payment to Ipsen if this agreement was not entered into by April 15, 2006. On April 13, 2006, Medicis and Ipsen agreed to extend this deadline to July 15, 2006. In connection with this extension, we paid Ipsen approximately $12.9 million in April 2006, which would be applied against the total obligation, in the event an agreement was not entered into by the extended deadline. On July 17, 2006, Medicis and Ipsen agreed that the two companies would not pursue an agreement for the commercialization of the product outside of the U.S., Canada and Japan. On July 17, 2006, we made the additional $22.2 million payment to Ipsen, representing the remaining portion of the $35.1 million total obligation, resulting from the discontinuance of negotiations for other territories.

The initial $90.1 million payment and the $35.1 million obligation were recognized as charges to research and development expense during 2006.

In May 2008, the FDA accepted the filing of Ipsen s BLA for RELOXIN®, and in accordance with the agreement, we paid Ipsen $25.0 million during the three months ended June 30, 2008. In December 2008, we paid Ipsen $1.5 million upon the achievement of an additional regulatory milestone. The $25.0 million payment was recognized as a charge to research and development expense during the three months ended June 30, 2008, and the $1.5 million payment was recognized as a charge to research and development expense during the three months ended December 31, 2008. We will pay Ipsen an additional $75.0 million upon the product s approval by the FDA and $2.0 million upon regulatory approval of the product in Japan. Ipsen will manufacture and provide the product to us for the term of the agreement, which extends to December 2036. Ipsen will receive a royalty based on sales and a supply price, the total of which is equivalent to approximately 30% of net sales as defined under the agreement if and when the product is commercialized by us upon regulatory approval. Under the terms of the agreement, we are responsible for all remaining research and development costs associated with obtaining the product s approval in the U.S., Canada and Japan.

On June 27, 2008, we and a U.S. company entered into a license agreement that provides patent rights for development and commercialization of dermatologic products. Under terms of the agreement, we made an initial

payment of $2.0 million upon execution of the agreement. In addition, we will be required to pay $19.0 million

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upon successful completion of certain clinical milestones, $15.0 million upon the first commercial sales of the products in the U.S. and $30.0 million upon achievement of certain commercial milestones. We will also make royalty payments based on net sales as defined in the license. The $2.0 million payment was recognized as a charge to research and development expense during the three months ended June 30, 2008.

On December 11, 2007, we entered into a strategic collaboration with Revance whereby we made an equity investment in Revance and purchased an option to acquire Revance or to license exclusively in North America Revance s novel topical botulinum toxin type A product currently under clinical development. The consideration to be paid to Revance upon our exercise of the option will be at an amount that will approximate the then fair value of Revance or the license of the product under development, as determined by an independent appraisal. The option period will extend through the end of Phase 2 testing in the United States. In consideration for our $20.0 million payment, we received preferred stock representing an approximate 13.7 percent ownership in Revance, or approximately 11.7 percent on a fully diluted basis, and the option to acquire Revance or to license the product under development. The $20.0 million is expected to be used by Revance primarily for the development of the new product. Approximately $12.0 million of the $20.0 million payment represents the fair value of the investment in Revance at the time of the investment and was included in other long-term assets in our consolidated balance sheets as of December 31, 2007. The remaining $8.0 million, which is non-refundable and is expected to be utilized in the development of the new product, represents the residual value of the option to acquire Revance or to license the product under development and was recognized as a charge to research and development expense during the three months ended December 31, 2007. Additionally, we have committed to make further equity investments in Revance of up to $5.0 million under certain terms, subject to certain conditions and prior to the exercise of the option to acquire Revance or to license exclusively Revance s topical botulinum toxin type A product in North America.

Prior to the exercise of the option, Revance will remain primarily responsible for the worldwide development of Revance s topical botulinum toxin type A product in consultation with us in North America. We will assume primary responsibility for the development of the product should consummation of either a merger or a license for topically delivered botulinum toxin type A in North America be completed under the terms of the option. Revance will have sole responsibility for manufacturing the development product and manufacturing the product during commercialization worldwide. Our right to exercise the option is triggered upon Revance s successful completion of certain regulatory milestones through the end of Phase 2 testing in the United States. A license would contain a payment upon exercise of the license option, milestone payments related to clinical, regulatory and commercial achievements, and royalties based on sales, as defined in the license. If we elect to exercise the option, the financial terms for the acquisition or license will be determined through an independent valuation in accordance with specified methodologies.

On October 9, 2007, we entered into a development and license agreement with a company for the development of a dermatologic product. Under terms of the agreement, we made an initial payment of $1.5 million upon execution of the agreement. In addition, we are required to pay $18.0 million upon successful completion of certain clinical milestones and $5.2 million upon the first commercial sales of the product in the U.S. We will also make royalty payments based on net sales as defined in the license. The $1.5 million payment was recognized as a charge to research and development expense during 2007.

On June 19, 2006, we entered into an exclusive start-up development agreement with a company for the development of a dermatologic product. Under terms of the agreement, we made an initial payment of $1.0 million upon execution of the agreement, and are required to pay a milestone payment of $3.0 million upon execution of a development and license agreement between the parties. In addition, we will pay approximately $16.0 million upon successful completion of certain clinical milestones and approximately $12.0 million upon the first commercial sales of the product in the U.S. We also will make additional milestone payments upon the achievement of certain commercial milestones. The $1.0 million payment was recognized as a charge to research and development expense during 2006.

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Sales and Marketing

Our combined dedicated sales force, consisting of 216 employees as of December 31, 2008, 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 dermal aesthetic procedures, we believe that the size of our sales force, including its currently ongoing expansion, is appropriate to reach our target physicians. Our therapeutic dermatology sales forces consist of 105 employees who regularly call on approximately 9,000 dermatologists. Our dermal aesthetic sales force consists of 111 employees who regularly call on leading plastic surgeons, facial plastic surgeons, dermatologists and dermatologic surgeons. We also have eight 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 United States. We use a variety of marketing techniques to promote our products including sampling, journal advertising, promotional materials, specialty publications, coupons, money-back or product replacement guarantees, educational conferences and informational websites. We also promote our dermal 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. 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 electronically to the appropriate warehouse for picking and packing. Upon shipment, the warehouse sends back to us via EDI the necessary information to automatically process the invoice in a timely manner.

Customers

Our customers include certain of the nation s leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc. (Cardinal) and McKesson Corporation (McKesson) and other major drug chains. During 2008, 2007 and 2006, these customers accounted for the following portions of our net revenues:

	2008	2007	2006
McKesson	45.8%	52.2%	56.8%
Cardinal	21.2%	16.9%	19.3%

McKesson is our sole distributor of our RESTYLANE® and PERLANE® products in the United States and Canada.

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, 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 product demand. Managed care organizations and other third party payors try to negotiate the pricing of medical

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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.

Some of our products 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.

Manufacturing

We currently, except for the LipoSonix technology, 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 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.

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 and the approval of that manufacturer for a new drug 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 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 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.

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Our TRIAZ®, VANOS® and ZIANA® branded products are manufactured by Contract Pharmaceuticals Limited pursuant to a manufacturing agreement that automatically renews on an annual basis, unless terminated by either party. We are also in the process of evaluating alternative manufacturing facilities and raw material suppliers 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 2013.

Our SOLODYN® branded product is manufactured by Wellspring Pharmaceutical and AAIPharma pursuant to long-term supply agreements that expire in 2011 and 2010, respectively, unless extended by mutual agreement. We are also in the process of evaluating an alternative manufacturing facility for future SOLODYN® production.

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 available from only one source and others may 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.

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 United States 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 licensed a number of patents covering key aspects of our products, including a U.S. patent expiring in October of 2015 covering various formulations of TRIAZ®, a U.S. patent expiring in December 2017 covering RESTYLANE®, a U.S. patent expiring in February 2018 covering SOLODYN® Tablets, two U.S. patents expiring in February 2015 and August 2020 covering ZIANA® Gel, one U.S. patent expiring in December 2021 and two U.S. patents expiring in January 2023 covering VANOS® Cream, and two U.S. patents expiring in September 2009 and December 2024 covering LipoSonix technology. We have patent applications pending relating to SOLODYN® Tablets, LOPROX® Shampoo and ZIANA® Gel. We are also pursuing several other U.S. and foreign patent applications. We hold additional LipoSonix patents, and have numerous LipoSonix patent applications pending in the U.S. and in other countries.

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.

Our success with our products will depend, in part, on our ability to obtain, and successfully defend if challenged, patent or other proprietary protection. 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, such patents are

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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 or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges may result in potentially significant harm to our business. The cost of responding to these challenges and the inherent costs to defend 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. For example, on January 13, 2009, we filed suit against Mylan, Inc., Matrix Laboratories Ltd., Matrix Laboratories Inc., Sandoz, Inc. and Barr Laboratories, Inc. (collectively Defendants) in the United States District Court for the District of Delaware seeking an adjudication that Defendants have infringed one or more claims of Medicis U.S. Patent No. 5,908,838 (the 838 Patent) by submitting to the Food And Drug Administration their respective Abbreviated New Drug Applications for generic versions of SOLODYN®. See Item 3 of Part I of this report, Legal Proceedings and Note 14, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and 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 dermal 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 podiatrists 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.

The largest competitors for our prescription dermatological products include Allergan, Galderma, Johnson & Johnson, Sanofi-Aventis, Stiefel Laboratories and Warner Chilcott. 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 Allergan. Among other dermal filler products, Allergan markets Juvéderm® Ultra and Juvéderm® Ultra Plus. Allergan is a larger company than Medicis, and has greater financial, marketing, sales and technical resources than those available to us. Other dermal filler products, such as OrthoNeutrogena s Evolence®, Mentor s Prevelle® Silk, BioForm Medical s Radiesse®, Sanofi-Aventis Sculptra®, and Anika Therapeutics Elevess® have also recently been approved by the FDA. Patients may differentiate these products from RESTYLANE® and PERLANE® based on price, efficacy and/or duration, which

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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 Johnson & Johnson and Mentor Corporation, 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.

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 over-the-counter drugs and cosmetics. The Federal Food, Drug and Cosmetic Act (FDCA), as amended, 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.

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 United States. Unless an exemption applies, a medical device in the U.S. must have a Premarket Approval Application (PMA) in accordance with the FDCA, as amended, 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 (501(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. Products falling within the FDA s definition of cosmetics or drugs and that are generally recognized as safe and effective (and therefore not new drugs) do not require premarketing clearance although all drugs must comply with a host of post-market regulations, including manufacture under cGMP and adverse experience reporting.

New drug products are thoroughly tested to demonstrate their safety and effectiveness. Preclinical or biocompatibility 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

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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 United States typically include (i) preclinical laboratory and animal testing of pharmacology and toxicology; (ii) manufacture under cGMPs as verified by a pre-approval inspection (PAI) by the FDA; (iii) submission to the FDA of an IND; (iv) 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; (v) submission to the FDA of a New Drug Application (or NDA) or BLA; and (vi) FDA approval of the NDA or BLA. In addition to obtaining FDA approval for each product, each drug-manufacturing establishment must be registered with the FDA.

New drugs may also be approved by the agency pursuant to an Abbreviated New Drug Application (ANDA) for generic drugs if the same active ingredient has previously been approved by the agency and the original sponsor of the NDA no longer has patent protection or statutory marketing exclusivity. Approval of an ANDA does not generally require the submission of clinical data on the safety and effectiveness of the drug product if in an oral or parental dosage form. Clinical studies demonstrating equivalence to the innovator drug product may be required for certain topical drug products submitted under ANDAs. However, even if no clinical studies are required, the applicant must provide dissolution and/or bioequivalence studies to show that the active ingredient in an oral generic drug sponsor s application is comparably available to the patient as the original product in the NDA upon which the ANDA is based.

FDA approval is required before a new drug product may be marketed in the United States. 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. For certain categories of OTC drugs not yet subject to a final monograph, the FDA usually permits such drugs to continue to be marketed until a final monograph becomes effective, unless the drug will pose a potential health hazard to consumers. Stated differently, the FDA generally permits continued marketing only of any Category I products and Category III products that are safe but unknown efficacy products during the pendency of a final monograph. 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.

The active ingredient in the LOPROX® (ciclopirox) products has been approved by the FDA under multiple NDAs. The active ingredient in the DYNACIN® (minocycline HCl) branded products has been approved by the FDA under multiple ANDAs. Benzoyl peroxide, the active ingredient in the TRIAZ® products, has been classified as a Category III ingredient under a tentative final FDA monograph for OTC use in treatment of labeled conditions. The FDA has requested, and a task force of the Non-Prescription Drug Manufacturers Association (or NDMA), a trade association of OTC drug manufacturers, has undertaken further studies to confirm that benzoyl peroxide is not a tumor promoter when tested in conjunction with UV light exposure. The TRIAZ® products, which we sell on a prescription

basis, have the same ingredients at the same dosage levels as the OTC products. When the

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FDA issues the final monograph, one of several possible outcomes that may occur is that we may be required by the FDA to discontinue sales of TRIAZ® products until and unless we file an NDA covering such product. There can be no assurance as to the results of these studies or any FDA action to reclassify benzoyl peroxide. In addition, there can be no assurance that adverse test results would not result in withdrawal of TRIAZ® products from marketing. An adverse decision by the FDA with respect to the safety of benzoyl peroxide could result in the assertion of product liability claims against us and could have a material adverse effect on our business, financial condition and results of operations.

Our TRIAZ® branded products must meet the composition and labeling requirements established by the FDA for OTC products containing their respective basic ingredients. We believe that compliance with those established standards avoids the requirement for premarket clearance of these products. There can be no assurance that the FDA will not take a contrary position in the future. Our PLEXION® branded products, which contain the active ingredients sodium sulfacetamide and sulfur, are marketed under the FDA compliance policy entitled Marketed New Drugs without Approved NDAs or ANDAs.

We believe that certain of our products, as they are promoted and intended by us for use, are exempt from being considered new drugs and therefore do not require premarket clearance. There can be no assurance that the FDA will not take a contrary position in the future. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or withdraw such products from the market. We believe that these products are compliant with applicable regulations governing product safety, use of ingredients, labeling, promotion and manufacturing methods.

We also will be subject to foreign regulatory authorities governing clinical trials and pharmaceutical sales for products we seek to market outside the United States. 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.

Change in Fiscal Year

Effective December 31, 2005, we changed our fiscal year end from June 30 to December 31. This change was made to align our fiscal year end with other companies within our industry. This Form 10-K is intended to cover the audited calendar year January 1, 2008 to December 31, 2008, which we refer to as 2008. We refer to the audited calendar year January 1, 2007 to December 31, 2007 as 2007. We refer to the audited calendar year January 1, 2006 to December 31, 2006 as 2006. Comparative financial information to 2006 is provided in this Form 10-K with respect to the calendar year January 1, 2005 to December 31, 2005, which is unaudited and we refer to as 2005. Additional audited information is provided with respect to the transition period July 1, 2005 through December 31, 2005, which we refer to as the Transition Period. We refer to the period beginning July 1, 2004 and ending June 30, 2005 as fiscal 2005.

Employees

At December 31, 2008, we had 578 full-time employees. No employees are subject to a collective bargaining agreement. We believe we have a good relationship 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

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reports, if any, filed or furnished pursuant to Section 13(a) of 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 Business Code of Conduct and Ethics, Corporate Governance Guidelines, Nominating and Governance Committee Charter, Stock Option and Compensation Committee Charter and Audit 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 amended 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 with discussion of future operating or 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 amended 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 amended 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 product 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 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.

In addition, SOLODYN® may face generic competition in the near future. We currently have one issued patent relating to SOLODYN® that does not expire until 2018. 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®. For example, on December 24, 2008, we received a non-final rejection from the USPTO in SOLODYN® application number 11/695,514. During January and February of 2009, responses to final rejection were filed in applications serial numbers 11/166,817 and 11/695,539, a response to a non-final rejection was filed in application serial number 11/944,186, and a request for continuing examination was filed in application serial number 11/776,676. The failure to obtain additional patent protection could adversely

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affect our ability to deter generic competition, which would adversely affect SOLODYN® revenue and our results of operations.

On January 15, 2008, we announced that IMPAX sent us a letter advising that IMPAX has filed an ANDA seeking FDA approval to market a generic version of SOLODYN® (minocycline HCl) extended-release capsules. Also on January 15, 2008, IMPAX filed a lawsuit against us in the United States District Court for the Northern District of California seeking a declaratory judgment that our U.S. Patent No. 5,908,838 (the 838 Patent) related to SOLODYN® is invalid and is not infringed by IMPAX s ANDA for a generic version of SOLODYN®. On April 16, 2008, the Court granted Medicis motion to dismiss the IMPAX complaint for lack of jurisdiction. IMPAX appealed the Court s order dismissing the case to the United States Court of Appeals for the Federal Circuit. On November 26, 2008, we entered into a License and Settlement Agreement and a Joint Development Agreement with IMPAX. In connection with the License and Settlement Agreement, Medicis and IMPAX agreed to terminate all legal disputes between them relating to SOLODYN®. Additionally, under terms of the License and Settlement Agreement, IMPAX has confirmed that Medicis patents relating to SOLODYN® are valid and enforceable, and cover IMPAX s activities relating to its generic product under ANDA #90-024. Under the terms of the License and Settlement Agreement, IMPAX has a license to market its generic versions of SOLODYN® 45mg, 90mg and 135mg under the SOLODYN® intellectual property rights belonging to Medicis upon the occurrence of certain events. Upon launch of its generic formulations of SOLODYN®, IMPAX may be required to pay Medicis a royalty, based on sales of those generic formulations by IMPAX under terms described in the License and Settlement Agreement. On December 12, 2008, we announced that we had received a Paragraph IV Patent Certification from IMPAX, advising it had filed an ANDA with the FDA for generic SOLODYN® in its current forms of 45mg, 90mg and 135mg strengths. IMPAX s certification alleged that the 838 Patent will not be infringed by IMPAX s manufacture, use or sale of the product for which the ANDA was submitted because it has been granted a patent license by us for the 838 Patent. On February 3, 2009, the FDA approved IMPAX s ANDA for generic SOLODYN®. IMPAX has not yet launched a generic formulation of SOLODYN®.

On August 18, 2008, we announced that the United States Patent and Trademark Office (USPTO) has granted a Request for Ex Parte Reexamination of our 838 Patent. During the reexamination process, the USPTO will review the 838 Patent and could determine that the patent claims, as written, were properly allowed. This determination would assist us in defending challenges to the validity of the 838 Patent. Alternatively, the USPTO could narrow or reject certain or all of the claims of the 838 Patent. Depending upon the specifics of what narrowing amendments are required and the claims rejected, these determinations of the USPTO could result in the loss of patent protection on SOLODYN®, which would have a material adverse impact on our results of operations. The timing of the USPTO s completion of the reexamination is uncertain. We believe that the USPTO should reconfirm the validity of the 838 Patent. However, there can be no guarantee as to the outcome.

Pursuant to Section 125 of the Food and Drug Administration Modernization Act (FDAMA), several statutory provisions added to the FD&C Act by the Hatch-Waxman Amendments of 1984, including the patent listing, certification and notice provisions and the 30-month stay provision, did not apply to so-called old antibiotics such as minocycline HCl, the active ingredient in SOLODYN®. On October 8, 2008, the President signed into law the QI Program Supplemental Funding Act of 2008, Pub. L. No. 110-379, 122 Stat. 4075 (2008) (the Antibiotic Act), which provides that notwithstanding section 125 of FDAMA or any other provision of law, the provisions of the Hatch-Waxman Amendments shall apply to old antibiotics. On December 3, 2008, in accordance with and pursuant to the Antibiotic Act and FDA s recently issued Draft Guidance for Industry entitled *Submission of Patent Information for Certain Old Antibiotics* (Nov. 2008) (November 2008 Guidance), Medicis submitted the 838 patent covering SOLODYN® to the FDA s Approved Drug Products with Therapeutic Equivalents (the Orange Book).

On December 8, 2008, we announced that we had received a Paragraph IV Patent Certification from Mylan Inc. (Mylan) advising that Mylan s majority owned subsidiary Matrix Laboratories Limited (Matrix) has filed an ANDA with the FDA for generic SOLODYN® in its current forms of 45mg, 90mg and 135mg strengths. Mylan has not advised us as to the timing or status of the FDA s review of Matrix s filing, or whether Matrix has complied with FDA requirements for proving bioequivalence. Mylan s Paragraph IV Certification alleges that our 838 Patent is invalid, unenforceable and/or will not be infringed by Matrix s manufacture, use, or sale of the product for which the ANDA

was submitted.

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On December 12, 2008, we announced that we had received a Paragraph IV Patent Certification from both Sandoz, Inc., a division of Novartis AG (Sandoz), and IMPAX, advising that they have each filed an ANDA with the FDA for generic SOLODYN® in its current forms of 45mg, 90mg and 135mg strengths. Sandoz has not advised us as to the timing or status of the FDA s review of their filing, or whether they have has complied with FDA requirements for proving bioequivalence. Sandoz s Paragraph IV Certification alleges that our 838 Patent is invalid, unenforceable and/or will not be infringed by either Sandoz s manufacture, use, or sale of the product for which the ANDA was submitted. IMPAX s certification alleges that the 838 Patent will not be infringed by IMPAX s manufacture, use or sale of the product for which the ANDA was submitted because it has been granted a patent license by us for the 838 Patent. As noted above, the FDA approved IMPAX s ANDA for generic SOLODYN® on February 3, 2009.

On December 29, 2008 we announced that we had received a Paragraph IV Patent Certification from Barr Laboratories, Inc. (Barr) advising that Barr has filed an ANDA with the FDA for generic SOLODYN® in its current forms of 45mg, 90mg and 135mg strengths. Barr has not advised us as to the timing or status of the FDA s review of its filing, or whether it has complied with FDA requirements for proving bioequivalence. Barr s Paragraph IV Certification alleges that our 838 Patent is invalid, unenforceable and/or will not be infringed by either Barr s manufacture, use, or sale of the product for which the ANDA was submitted.

On January 13, 2009, we filed suit against Mylan, Matrix, Matrix Laboratories Inc., Sandoz, and Barr (collectively Defendants) in the United States District Court for the District of Delaware seeking an adjudication that Defendants have infringed one or more claims of our 838 Patent by submitting to the FDA their respective ANDAs for generic versions of SOLODYN®. The relief we requested includes a request for a permanent injunction preventing Defendants from infringing the 838 patent by selling generic versions of SOLODYN®.

On February 13, 2009, we submitted a Citizen Petition to the FDA arguing that the Agency could not approve the Mylan, Sandoz and Barr ANDAs for generic versions of SOLODYN® for thirty (30) months pursuant to Section 505(j)(5)(B)(iii) of the FDCA because we sued the submitters of all three ANDAs for patent infringement within 45 days of receiving notice from them of the submission of a Paragraph IV Certification. In light of the recently enacted Antibiotic Act, we argued that neither FDAMA nor the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) stood as a barrier to SOLODYN® receiving a 30-month stay. The timing of the FDA s response to the Citizen Petition is uncertain. We believe the FDA should grant the Citizen Petition. However, there can be no guarantee as to the outcome.

In addition to SOLODYN®, our other primary prescription products, including VANOS®, may be subject to generic competition in the near future. For example, on May 1, 2008, we announced that Perrigo Israel Pharmaceuticals Ltd. (Perrigo) filed an ANDA with the FDA for a generic version of VANOS®. Perrigo has not advised us as to the timing or status of the FDA s review of its filing. Perrigo s certification letter sets forth allegations that our U.S. Patent No. 6,765,001 is invalid, unenforceable and/or will not be infringed by Perrigo s manufacture, use, or sale of the product for which the ANDA was submitted. 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.

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 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 to 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.

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On January 15, 2008, IMPAX filed a lawsuit against us in the United States District Court for the Northern District of California seeking a declaratory judgment that our 838 Patent related to SOLODYN® is invalid and is not infringed by IMPAX s filing of an ANDA for a generic version of SOLODYN®. On April 16, 2008, the Court granted Medicis motion to dismiss the IMPAX complaint for lack of jurisdiction. IMPAX appealed the Court s order dismissing the case to the United States Court of Appeals for the Federal Circuit. On November 26, 2008, we entered into a License and Settlement Agreement and a Joint Development Agreement with IMPAX. In connection with the License and Settlement Agreement, Medicis and IMPAX agreed to terminate all legal disputes between them relating to SOLODYN®. Additionally, under terms of the License and Settlement Agreement, IMPAX has confirmed that Medicis patents relating to SOLODYN® are valid and enforceable, and cover IMPAX s activities relating to its generic product under ANDA #90-024.

On August 18, 2008, we announced that the USPTO has granted a Request for Ex Parte Reexamination of our 838 Patent. During the reexamination process, the USPTO will review the 838 Patent and could determine that the patent claims, as written, were properly allowed. This determination would assist us in defending challenges to the validity of the 838 Patent. Alternatively, the USPTO could narrow or reject certain or all of the claims of the 838 Patent. Depending upon the specifics of what narrowing amendments are required and the claims rejected, these determinations of the USPTO could have a material adverse impact on our results of operations. The timing of the USPTO s completion of the reexamination is uncertain. We believe that the USPTO should reconfirm the validity of the 838 Patent. However, there can be no guarantee as to the outcome.

On January 13, 2009, we filed suit against Mylan, Matrix, Matrix Laboratories Inc., Sandoz, and Barr in the United States District Court for the District of Delaware seeking an adjudication that Defendants have infringed one or more claims of our 838 Patent by submitting to the FDA their respective ANDAs for generic versions of SOLODYN®. The relief we requested includes a request for a permanent injunction preventing Defendants from infringing the 838 patent by selling generic versions of SOLODYN®.

See Item 3 of Part I of this report, Legal Proceedings and Note 14, Commitments and Contingencies in the notes to the consolidated financial statements under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules, for information concerning our current intellectual property litigation.

We are pursuing several United States patent applications; although 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.

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.

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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. 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 know-how. In addition, others may independently develop similar or equivalent trade secrets or know-how.

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.

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 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 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. For example, the FDA recently stated it was reviewing the safety of two botulinum toxin products currently marketed in the U.S. due to adverse reactions

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associated with use of the products. 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;
- Risk Evaluation and Mitigation Strategies (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;
- 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 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, reimportation 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.

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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 manufacturers on one hand and prescribers, purchasers and formulary managers on the other. 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.

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 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 has 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)

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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 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 14, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and 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 Corporate Integrity Agreement we entered into with the Office of Inspector General of the Department of Health and Human Services. If we fail to comply with the Corporate Integrity Agreement 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, 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 recently entered into distribution services agreements with McKesson and Cardinal. During 2008, McKesson and Cardinal accounted for 45.8% and 21.2%, respectively, of our net revenues. During 2007, McKesson and Cardinal accounted for 52.2% and 16.9%, respectively, of our net revenues. During 2006, McKesson and Cardinal accounted for 56.8% and 19.3%, 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® products in the United States and Canada.

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.

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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® and ZIANA®, and sales of our dermal aesthetic products, RESTYLANE® 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.

We are experiencing intense competition in the dermal filler market. Other dermal filler products, such as Juvéderm®, Evolence®, Prevelle® Silk, Radiesse®, Sculptra® and Elevess® have also recently been approved by the FDA. Patients may differentiate these products from RESTYLANE® and PERLANE® 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.

Each of IMPAX, Mylan, Sandoz and Barr have filed with the FDA to obtain approval to introduce a generic form of SOLODYN®. On January 13, 2009, we filed suit against Mylan, Matrix, Matrix Laboratories Inc., Sandoz, and Barr (collectively Defendants) in the United States District Court for the District of Delaware seeking an adjudication that Defendants have infringed one or more claims of our 838 Patent by submitting to the FDA their respective ANDAs for generic versions of SOLODYN®. The relief we requested includes a request for a permanent injunction preventing Defendants from infringing the 838 patent by selling generic versions of SOLODYN®. On February 3, 2009, the FDA approved IMPAX s ANDA for generic SOLODYN®. IMPAX has not yet launched a generic formulation of SOLODYN®. 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.

On May 1, 2008, we announced that Perrigo filed an ANDA with the FDA for a generic version of VANOS®. Perrigo has not advised us as to the timing or status of the FDA s review of its filing. Perrigo s certification letter sets forth allegations that our U.S. Patent No. 6,765,001 is invalid, unenforceable and/or will not be infringed by Perrigo s manufacture, use, or sale of the product for which the ANDA was submitted.

Sales related to our primary prescription products, including SOLODYN®, VANOS® and ZIANA®, and sales of our dermal restorative products, 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, plastic surgeons and/or podiatrists;
- 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, plastic surgeons and/or podiatrists; and

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

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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. For example, on January 7, 2009, Ipsen announced that the FDA provided notification to Ipsen that the Prescription Drug User Fee Act (PDUFA) action date for the BLA for RELOXIN®, in aesthetics has been extended to April 13, 2009.

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. For example, on March 20, 2005, we entered into an agreement and plan of merger with Inamed, pursuant to which we agreed to acquire Inamed. On December 13, 2005, we entered into a merger termination agreement with Inamed following Allergan Inc. s exchange offer for all outstanding shares of Inamed, which was commenced on November 21, 2005.

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.

Our operating results and financial condition may fluctuate.

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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;
- 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 the possible mutation of the avian form of influenza from birds or other animal species to humans, current human morbidity, and mortality levels persist following such potential mutation;
- 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;

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 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

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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 dermal 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, 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 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® and if approved, the companies producing such products could charge less to doctors for their products.

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

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We have made substantial investments in, and entered into significant collaborations 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 or collaborations, 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 and collaborations are unsuccessful, our results of operations could materially suffer.

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

In order for our products to receive reimbursement by state Medicaid programs, we must participate in the Medicaid drug rebate program. Participation in the program requires us to provide a rebate for each unit of our products that is reimbursed by Medicaid. 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 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. We are required to report AMP and best price for each of our covered outpatient drugs to the government on a regular basis. In July 2007, the Centers for Medicare and Medicaid Services (CMS), the federal agency that is responsible for administering the Medicaid drug rebate program, issued a final rule that, among other things, clarifies how manufacturers must calculate both AMP and best price and implements new requirements under the Deficit Reduction Act of 2005 on the use of AMP to calculate federal upper limits on pharmacy reimbursement amounts under the Medicaid program. These upper limits are used to determine ceilings placed on the amounts that state Medicaid programs can pay for certain prescription drugs using federal dollars. We cannot predict the full impact of these changes, which became effective in part on January 1, 2007 and in part on October 1, 2007, on our business, nor can we predict whether there will be additional federal legislative or regulatory proposals to modify current Medicaid rebate rules.

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 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, 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 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 VHCA formula; 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 all to other FSS purchasers. 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.

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. To the extent that the statutory and regulatory definitions of AMP and the Medicaid rebate amount change as a result of the Deficit Reduction Act and final rule discussed above, these changes also could impact the discounted purchase prices that we are obligated to provide under this program. We cannot predict the full impact of these changes, which became effective in part on January 1, 2007 and in part on October 1, 2007, 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.

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Our profitability may be impacted by our ongoing review of our prior reports 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 Veterans Health Care Act of 1992, 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 Department of Veterans Affairs, 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 are undertaking a review and recalculation of our Non-Federal Average Manufacturer Prices (Non-FAMPs) and related Federal Ceiling Prices, Average Manufacturer Prices (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 will generally review 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. It is unclear whether any issue that may be identified during this review may result in any changes to our Medicaid rebate liability and/or Public Health Service Drug Pricing Program prices for prior quarters, or any penalties, or whether any such changes or penalties would have a material impact on our business, financial condition, results of operations or cash flows.

In addition, we conducted a review and recalculation of our Non-Federal Average Manufacturer Prices (Non-FAMPs) and Federal Ceiling Prices (FCPs) for a period spanning the duration of our current 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, 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 our current 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 submission, which, based on certain issues uncovered subsequent to the September 15, 2008 submission, showed an additional $61,459 in overcharges. The VA has informed us that our submission is currently under review. Upon VA approval of our submissions, we will calculate the impact, if any, associated with August December 2008.

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.

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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;
- government or regulatory delays. For example, on January 7, 2009, Ipsen announced that the FDA provided notification to Ipsen that the PDUFA action date for the BLA for RELOXIN®, in aesthetics has been extended to April 13, 2009; 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.

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

Our business, and in particular our dermal restorative 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 2009. 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. In the second half of 2008, added concerns fueled by the U.S. government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government financial assistance to American International Group Inc., Citibank, Bank of America and other federal government interventions in the U.S. financial system lead to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

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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 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 complimentary 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 recent subprime loan losses and write-downs, as well as other economic trends in the credit market industry, 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. In addition, while we believe existing cash and short-term investments, together with funds generated from operations, should be sufficient to meet operating requirements for the foreseeable future, our cash balances decreased materially during 2008 due to the repurchase of $283.7 million of our 1.5% Contingent Convertible Senior Notes Due 2033 and the $150.0 million payment of the initial purchase price for our acquisition of LipoSonix, which could adversely affect our ability to obtain financing.

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, 2008, our investments included $38.2 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 recent negative conditions in the credit markets have prevented some investors from liquidating their holdings, including their holdings of auction rate floating securities. During the three months ended March 31, 2008, we were informed that there was insufficient demand at auction for the 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. As a result of the lack of liquidity of these investments, we recorded an other-than-temporary impairment loss of $6.4 million during 2008, based on our estimate of the fair value of these investments. We could be required to record further impairment losses in the future, depending on market conditions.

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

RESTYLANE®, PERLANE®, RESTYLANE FINE LINES™ and RESTYLANE SUBQ™ currently have patent protection in the United States until 2015, and the exclusivity period of the license granted to us by Q-Med will terminate on the later of (i) the expiration of the last patent covering the products or (ii) upon the licensed know-how becoming publicly known. If the validity or enforceability of these 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 may not be able to collect all scheduled license payments from BioMarin.

As part of our asset purchase agreement, license agreement and securities purchase agreement with BioMarin Pharmaceutical Inc. (BioMarin) discussed in Note 9 to our consolidated financial statements, BioMarin will make license payments to us of $1.5 million per quarter for the two quarters beginning in January 2009. While we did receive all scheduled quarterly license payments during 2008, 2007 and 2006, we cannot give any assurances as to BioMarin s continuing ability to make these payments to us. Currently, our revenue recognition of these payments is on a cash basis. In addition, while we expect BioMarin to make the final payment of $70.6 million to us during the third quarter of 2009 for the purchase of all of the outstanding shares of Ascent Pediatrics, we cannot give any assurances as to BioMarin s ability to make this payment. If BioMarin defaults on its obligations to make the required payments, we may be forced to incur indebtedness or otherwise reallocate our financial resources to cover the loss of these expected cash payments.

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 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.

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. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies, products and companies acquired, and 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, 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.

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We may not be able to successfully integrate the operations of LipoSonix.

We are currently integrating the operations of LipoSonix into our own. There are inherent challenges in integrating the operations that could result in a delay or the failure to achieve the anticipated synergies and, therefore, any potential cost savings and increases in earnings. Issues that must be addressed in integrating the operations of LipoSonix into our own include, among other things:

- conforming standards, controls, procedures and policies, business cultures and compensation structures between the companies;
- conforming information technology and accounting systems;
- consolidating corporate and administrative infrastructures;
- consolidating sales and marketing operations;
- retaining existing customers and attracting new customers;
- retaining key employees;
- identifying and eliminating redundant and underperforming operations and assets;
- minimizing the diversion of management s attention from ongoing business concerns;
- coordinating geographically dispersed organizations;
- managing tax costs or inefficiencies associated with integrating the operations of the combined company; and
- making any necessary modifications to operating control standards to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.

If we are not able to adequately address these challenges, we may not realize the anticipated benefits of the integration of the companies. Actual cost and synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate.

We may not realize all of the anticipated benefits of our acquisition of LipoSonix.

Our ability to realize the anticipated benefits of our acquisition of LipoSonix could be affected by a number of factors, including:

- our ability to attain regulatory approvals of LipoSonix s product both in the United States and worldwide, and the timing of such approvals;
- the efficacy of LipoSonix s technology;
- market acceptance of LipoSonix s technology;
- increases or decreases in the expected costs to be incurred in connection with the research and development, clinical trials, regulatory approvals, commercialization and marketing of the LipoSonix technology;
- the anticipated size of the markets and demand of the LipoSonix technology;
- our ability to integrate the operations of LipoSonix with our operations;
- our ability to retain key personnel of LipoSonix; and

our ability to effectively compete in the liposuction marketplace.

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 U.S. Foreign Corrupt Practices Act 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 also provide training to relevant employees and agents regarding compliance with anti-bribery laws. We cannot guarantee that our policies and procedures, contractual obligations, 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

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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 human 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 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 Medicis and potentially subject us to sanctions, including:

- delays, warning letters, and fines;
- product recalls or seizures;
- injunctions on sales;
- refusal of 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, and we may be subject to claims, fines or other penalties. We are pursuing an indemnification claim against the manufacturer, but no

assurance can be given that we will ultimately recoup our losses.

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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 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® , PERLANE®, RESTYLANE FINE LINES™ and RESTYLANE SUBQ™.

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

We depend exclusively on Q-Med for our supply of RESTYLANE®, PERLANE®, RESTYLANE FINE LINES™ and RESTYLANE SUBQ™ 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®, PERLANE®, RESTYLANE FINE LINES™ and RESTYLANE SUBQ™ 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.

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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.

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 inadequate supply of our products in channels of distribution.

We sell our products primarily to major wholesalers and retail pharmacy chains. Approximately 65-75% of our gross revenues are typically derived from two major drug wholesale concerns. We have recently entered into 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.

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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.

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. The former Secretary of Health and Human Services did not make 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 recently 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 yet 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 bro