

Amphastar Pharmaceuticals, Inc.
Form S-1/A
April 03, 2006

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As filed with the Securities and Exchange Commission on April 3, 2006

Registration No. 333-122725

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 7

TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AMPHASTAR PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

33-0702205
(I.R.S. Employer
Identification Number)

11570 Sixth Street
Rancho Cucamonga, California 91730
(909) 980-9484

(Address, Including Zip Code, and Telephone Number, Including
Area Code, of Registrant's Principal Executive Offices)

David W. Nassif
Chief Financial Officer
Amphastar Pharmaceuticals, Inc.
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(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

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**Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement becomes effective.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee(3)
Common Stock, par value \$.0001 per share	\$115,000,000	\$13,536

- (1) Includes shares which the underwriters have the option to purchase if they sell more than the number of shares they are required to purchase in the offering.
- (2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- (3) Fee previously paid in connection with the original filing of the Registration Statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective, on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated _____, 2006.

PROSPECTUS

Shares

Amphastar Pharmaceuticals, Inc.

Common Stock

We are offering _____ shares of our common stock. This is our initial public offering, and no public market currently exists for our shares.

We have applied to have our common stock approved for quotation on the NASDAQ National Market under the symbol "AMPR." We anticipate that the initial public offering price will be between \$ _____ and \$ _____ per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 8.

	<u>Per Share</u>	<u>Total</u>
Public Offering Price	\$ _____	\$ _____
Underwriting Discounts and Commissions	\$ _____	\$ _____
Proceeds, before expenses, to Amphastar	\$ _____	\$ _____

We have granted the underwriters a 30-day option to purchase up to an additional _____ shares from us on the same terms and conditions as set forth above if the underwriters sell more than _____ shares of our common stock in the offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about _____, 2006.

LEHMAN BROTHERS

UBS INVESTMENT BANK

CITIGROUP

_____, 2006

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	8
Forward-Looking Statements	25
Use of Proceeds	26
Dividend Policy	27
Capitalization	28
Dilution	29
Selected Consolidated Financial Data	30
Management's Discussion and Analysis of Financial Condition and Results of Operations	32
Business	43
Management	66
Principal Stockholders	78
Certain Relationships and Related Transactions	80
Description of Capital Stock	81
Shares Eligible for Future Sale	84
Material U.S. Federal Tax Considerations for Non-U.S. Holders	86
Underwriting	89
Legal Matters	93
Experts	93
Where You Can Find More Information	93
Index To Consolidated Financial Statements	F-1

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from the information contained in this prospectus. We are offering to sell shares of common stock, and seeking offers to buy common stock, only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of when this prospectus is delivered or when any sale of our common stock occurs.

For investors outside the U.S., neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the U.S. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Until _____, 2006, 25 days after the date of this offering, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in the shares. You should read the entire prospectus carefully, including "Risk Factors" and our financial statements and related notes.

Amphastar Pharmaceuticals, Inc.

We are a specialty pharmaceutical company that develops, manufactures, markets, and sells generic and proprietary injectable and inhalation products. We currently manufacture and sell 66 products and are continuing to develop a portfolio of generic and branded products that target large markets with high technical barriers to entry. We are capable of producing a broad range of dosage formulations, including solutions, emulsions, suspensions, jellies, lyophilized, or freeze-dried, products, as well as metered-dose inhalers and nasal sprays. We have long-standing relationships with all of the major group purchasing organizations and drug wholesalers in the U.S. that deliver products to our end markets, which we believe will enable us to rapidly introduce new products and quickly establish significant market share.

We began operations in February 1996 with a strategic focus on manufacturing and selling generic injectable products. To complement our internal growth, we acquired International Medication Systems, Limited in October 1998 and Armstrong Pharmaceuticals, Inc. in October 2003 as well as the new drug application, or NDA, for Cortrosyn®, an injectable diagnostic agent, in June 2003 and the abbreviated new drug application, or ANDA, for a generic version of Primatene® Mist in July 2004. As we expanded our infrastructure and developed our research and development expertise, our strategic focus has evolved into developing products for large markets with high technical barriers to entry. We believe these product candidates will generate higher margins for a longer period of time than products that face more substantial competition.

We are specifically focused on applying our technical expertise to develop products that:

require an active pharmaceutical ingredient that is difficult to source and/or manufacture;

involve complex manufacturing;

address deficiencies in the innovator's product formulation; and/or

improve upon an existing product through the use of drug delivery technology we have developed.

Our Competitive Advantages

We have built our company by integrating the capabilities that we believe are essential to compete effectively in the pharmaceutical industry, including:

Experienced product development team. Our product development team consists of 40 people, 11 of whom hold Ph.D.s, with expertise in areas such as pharmaceutical formulation, process development, *in vivo* study, analytical chemistry, drug delivery, and clinical research.

Comprehensive manufacturing capabilities. We manufacture pharmaceutical products in multiple dosage formulations, including solution, emulsion, suspension, jelly, lyophilized, or freeze-dried, as well as metered-dose inhalers and nasal spray products. During 2005 we produced approximately 16.0 million injectable units and five million metered-dose inhaler units.

Ability to develop and manufacture active pharmaceutical ingredients. One aspect of our development focus is on products that are difficult to manufacture because the active pharmaceutical

ingredient is not easily obtained. For example, we have leveraged our technical and manufacturing expertise to develop and manufacture the active pharmaceutical ingredient for enoxaparin, our injectable anticoagulant product candidate.

Proprietary drug delivery technology. Through our research and development efforts, we have developed a proprietary technology, or platform, focused on the improvement of drug delivery. Our sustained-release technology has enabled us to formulate injectable product candidates that are designed to allow single injections to be effective over an extended period.

Strong group purchasing organization and wholesaler relationships. We have long-standing relationships with all of the major group purchasing organizations and wholesalers in the U.S. Our relationships with group purchasing organizations and wholesalers give us access to most, if not all, of the injectable markets in the U.S.

We face significant competition for our marketed products from major, brand name pharmaceutical companies, who have greater research and development, financial, sales and marketing, manufacturing and other resources than we have. We also expect to face significant competition for our product candidates from the product innovator and any generic manufacturers of the product. Competitors may be able to devote greater resources to the development, manufacturing and marketing of their products as well as initiate or withstand substantial price competition, any of which could give them a significant advantage.

Our Product Candidates

The table below lists the significant product candidates that we are currently developing:

Product Candidate	Reference Drug⁽¹⁾	Therapeutic Classification	Regulatory Path⁽²⁾	FDA Filing/ Expected Filing Date
Enoxaparin	Lovenox®	Anticoagulant	ANDA	Q1 2003 ⁽³⁾
Medroxyprogesterone	DepoProvera®	Contraceptive	ANDA	Q3 2004 ⁽³⁾
Ampofol®	Diprivan®	General Anesthetic	505(b)(2) NDA	Q3 2005 ⁽³⁾
Fluticasone propionate	Flonase® (nasal) Flovent® (inhaler)	Anti-allergic; Anti-inflammatory	ANDA ANDA	Q2 2006 2007
Azithromycin	Zithromax® (azithromycin for injection)	Antibiotic	ANDA	Q2 2006
Albuterol HFA	Proventil®, Ventolin®	Bronchodilator	505(b)(2) NDA	2007
Amphacaine		Local Analgesic	NDA	2008
Epinephrine Mist HFA	Primatene® Mist	Bronchodilator	505(b)(2) NDA	2008

(1) Reference drug means the listed drug identified by the FDA as the drug product upon which an applicant relies in seeking approval of an abbreviated new drug application. Patents for Flovent, Lovenox, Proventil and Ventolin expire in 2017, 2012, 2015 and 2017, respectively. The patents relating to the reference drugs for our other product candidates have already expired.

(2) See "Business Regulatory Considerations" for information regarding the regulatory approval processes for the indicated submissions.

(3) Filed.

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According to IMS Health Incorporated ("IMS Health"), an independent provider of statistical information on the pharmaceutical industry, the combined sales in the U.S. in 2005 for the currently marketed versions of enoxaparin and Ampofol was in excess of \$2.4 billion.

We face challenges in the development of, and regulatory approval for, our product candidates. Prior to regulatory approval, we will need to demonstrate to the U.S. Food and Drug Administration, or FDA, that our generic product candidates are bioequivalent to the innovator drug and we may not be able to do so. The development of our product candidates requires significant investments and we may not realize any returns from these investments.

Enoxaparin

Enoxaparin is an injectable form of low molecular weight heparin, which is a class of medication used as an anticoagulant, or blood thinner, to prevent clotting of blood in the vein, commonly referred to as deep vein thrombosis, and acute coronary syndromes. Enoxaparin is currently marketed by Sanofi-Aventis ("Aventis") under the brand-name Lovenox. Enoxaparin is difficult to manufacture because the active pharmaceutical ingredient is not easily obtained. Our research and development team has developed a multi-step chemical process for converting raw material into the active pharmaceutical ingredient, which we believe overcomes technical barriers to producing the active pharmaceutical ingredient. Aventis' sales of Lovenox in the U.S. in 2005 were approximately \$1.8 billion, according to IMS Health.

In connection with the filing of our ANDA for enoxaparin sodium with the FDA in March 2003, we certified to the FDA that the existing patents in connection with Lovenox are invalid, unenforceable, or will not be infringed by our generic product candidate. Teva Pharmaceuticals USA, Inc. has also filed an ANDA with the FDA for enoxaparin. In August 2005, Momenta Pharmaceuticals, Inc. filed an ANDA with the FDA for enoxaparin. An ANDA is a pre-market application for approval for a generic drug that contains certain data and information, including product formulation, specifications and stability of the generic drug, to demonstrate that the product is bioequivalent to the innovator drug. Aventis brought a patent infringement lawsuit against both Amphastar and Teva in August 2003 with respect to enoxaparin. In June 2005, the U.S. District Court for the Central District of California granted summary judgment in our favor in the lawsuit. The final judgment was entered by the District Court in July 2005 and in September 2005, Aventis filed an appeal of the District Court's decision with the U.S. Court of Appeals for the Federal Circuit. The parties argued the appeal before the Federal Circuit in January 2006. In February 2003, Aventis filed a citizen petition with the FDA, to which it has filed several supplements. FDA regulations allow interested parties to file a "citizen petition" with the FDA to request that the FDA Commissioner take or refrain from taking certain regulatory or administrative actions such as requesting that approval of a drug be withheld or an approved product be removed from the market. Aventis' citizen petition requests, among other things, that the FDA refrain from approving any ANDA for a generic version of Lovenox unless certain conditions are satisfied. In connection with the FDA's review of our ANDA for enoxaparin sodium, the FDA has made several comments and requests to us for data in the areas of chemistry, bioequivalence and labeling. We have filed with the FDA data from an FDA-requested bioequivalence study in humans and additional information on our raw material, active pharmaceutical ingredient and finished product, as well as certain product characterization data.

On May 2, 2005, we entered into an agreement to grant certain exclusive marketing rights for our enoxaparin product candidate (the "Product") to Andrx Pharmaceuticals, Inc. ("Andrx"). Andrx's marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain such rights, Andrx made an up-front payment to us of \$4.5 million upon execution of the agreement. In addition, Andrx will make an additional \$5.5 million payment to us once certain milestones relating to the Product are achieved, including obtaining FDA marketing approval, should Andrx elect to participate in the commercial launch of the Product. Under the agreement, the parties will share the

gross profit from Andrx's sales of the Product in the Territory and we will receive 50% to 60% of the gross profit. In the event that we provide notice to Andrx of our intention to launch the Product at risk, and Andrx elects not to participate in such a launch, or we fail to provide Andrx with written notice of our intent to launch by June 30, 2006, then thereafter, Andrx will have the option to demand a refund of the \$4.5 million up-front payment to us.

Ampofol

Ampofol is the brand name for our injectable propofol product candidate, which is a general anesthetic compound formulated with soy bean oil and egg extract to form a stable emulsion which contains 1% propofol. Propofol is currently manufactured and sold by AstraZeneca PLC under the trade name Diprivan and as a generic product by (i) a joint venture between Baxter Healthcare Corporation and Gensia-Sicor Pharmaceuticals, a predecessor of Teva, and (ii) Bedford Laboratories. Combined sales in 2005 for these products was approximately \$522 million, according to IMS Health. Propofol is used for general anesthesia, monitored anesthesia care sedation, and sedation in the intensive care unit ("ICU") setting.

Our research and development team has developed and patented a third-generation propofol, which is formulated to retard microbial growth without any preservatives or additives and with half the amount of soybean oil and egg lecithin, a compound extracted from eggs that acts as an emulsifier, used in the second generation propofols. We have demonstrated in all of the clinical trials we have conducted, which have involved more than 800 patients and volunteers in three clinical settings, including a 200-patient multi-center trial based in the ICU, that Ampofol is bioequivalent to Diprivan. We believe Ampofol will have lower manufacturing and storage costs than second generation propofols because of the reduced lecithin amounts and the ability to store the product at room temperature.

We have established a production line and completed scale-up, validation, and stability batch filling for Ampofol. We filed a 505(b)(2) NDA for Ampofol with the FDA in July 2005. This type of FDA filing is an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA.

Our Existing Products and Services

We currently manufacture and sell 66 injectable and inhalation products. We recorded net revenues of \$61.2 million and \$84.3 million for the year ended December 31, 2004 and 2005, respectively. A significant portion of our revenues during these periods was derived from four products or product families: Cortrosyn, Lidocaine Jelly, Albuterol CFC, and our Critical Care Drug Portfolio. We have a history of net losses. For the years ended December 31, 2003, 2004 and 2005, we had net losses of \$3.9 million, \$6.6 million and \$1.7 million, respectively.

Our Strategy

Our goal is to be an industry leader in the development, manufacture and marketing of injectable and inhalation pharmaceutical products. The key elements of our strategy include:

- Focusing on high margin generic product opportunities;
- Developing proprietary products based on our technology platform;
- Enhancing our sales, marketing, and distribution capabilities; and
- Complementing internal growth with strategic acquisitions.

Corporate Information

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated in 1996 ("California Amphastar"). Amphastar Pharmaceuticals, Inc., a Delaware corporation ("Delaware Amphastar"), was incorporated in 2004 and California Amphastar merged with and into Delaware Amphastar in 2004. Our principal executive offices are located at 11570 Sixth Street, Rancho Cucamonga, California 91730, and our telephone number is (909) 980-9484. Our internet address is www.amphastar.com. Information contained on our web site does not constitute a part of this prospectus. References in this prospectus to "Amphastar," "our company," "we," "our," and "us" refer to Amphastar Pharmaceuticals, Inc., and its subsidiaries, unless the context indicates otherwise.

Our logos and Amphastar Pharmaceuticals are our trademarks. This prospectus contains product names, trademarks and trade names that are the property of other organizations.

The Offering

Issuer	Amphastar Pharmaceuticals, Inc.
Total common stock offered	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	To fund the development of all of our current, significant product candidates, upgrade, renovate and equip an additional building at our headquarters complex, repay indebtedness and for general corporate purposes and potential acquisitions of products or business.
Proposed NASDAQ National Market Symbol	AMPR

The number of shares outstanding after this offering is based on 36,928,816 shares outstanding on March 16, 2006 and excludes:

6,035,754 shares of common stock issuable upon exercise of options outstanding as of March 16, 2006, with a weighted average exercise price of \$8.54 per share; and

3,723,980 shares of common stock reserved for future grant under our stock incentive plans as of March 16, 2006.

Except as otherwise indicated, all share information in this prospectus assumes no exercise of the underwriters' option to purchase additional shares.

Summary Consolidated Financial Information

The table below sets forth summary consolidated financial information for the periods indicated. You should read this information together with the financial statements and the notes to those statements appearing elsewhere in this prospectus and the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,		
	2003 ⁽¹⁾	2004	2005
	(in thousands, except per share data)		
Consolidated Statements of Operations data:			
Net revenues	\$ 48,197	\$ 61,193	\$ 84,280
Cost of revenues	35,508	46,660	58,457
Gross profit	12,689	14,533	25,823
Operating expenses:			
Selling, distribution and marketing	3,194	3,561	3,898
General and administrative	5,537	9,212	10,812
Research and development	6,344	8,451	10,265
Impairment of long-lived assets	623	185	157
Management fees and rent expense related party	921	204	359
Total operating expenses	16,619	21,613	25,491
Income (loss) from operations	(3,930)	(7,080)	332
Non-operating income (expense):			
Interest income	174	53	71
Interest expense	(1,322)	(2,010)	(2,141)
Gain from settlement with Organon		2,215	
Other income (expense), net	(15)	250	56
	(1,163)	508	(2,014)
Loss before income taxes	(5,093)	(6,572)	(1,682)
Provision for income taxes	98		
Net loss before extraordinary gain	(5,191)	(6,572)	(1,682)
Extraordinary gain, net of taxes	1,341		
Net loss	(\$3,850)	(\$6,572)	(\$1,682)
Net loss per share before extraordinary gain ⁽²⁾ :			
Basic	(\$0.15)	(\$0.19)	(\$0.05)
Diluted	(\$0.15)	(\$0.19)	(\$0.05)
Net loss per share ⁽²⁾ :			
Basic	(\$0.11)	(\$0.19)	(\$0.05)
Diluted	(\$0.11)	(\$0.19)	(\$0.05)
Weighted-average shares outstanding			
Basic	33,520	34,597	36,104
Diluted	33,520	34,597	36,104

As of December 31, 2005

Actual	As Adjusted ⁽³⁾
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As of December 31, 2005

(unaudited)

(in thousands)

Consolidated Balance Sheet data:

Cash, cash equivalents and restricted short-term investments	\$ 8,347
Working capital	28,779
Total assets	176,698
Long-term debt and capital leases, including current portion	34,939
Accumulated deficit	(23,433)
Total stockholders' equity	101,154

- (1) Includes the results of operations of Armstrong since October 9, 2003.
- (2) See Note 2 of Notes to Consolidated Financial Statements for a description of the method used to compute basic and diluted net loss per share and the number of shares used in computing basic and diluted loss per share.
- (3) Reflects the sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, the mid-point of our anticipated price range, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

You should carefully consider the following risk factors and other information in this prospectus before deciding to invest in our common stock. If any of the following risks occur, our business, financial condition, results of operations, and prospects could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Business

Our ability to commercialize our current product candidates, particularly our enoxaparin and Ampofol product candidates, is critical to our success, and if we fail to do so, our business and financial condition will suffer.

We have made significant investments in the development of our product candidates including research and development expenses for the years ended December 31, 2004 and 2005 of \$8.5 million and \$10.3 million, respectively. These investments include our efforts to develop our enoxaparin and Ampofol product candidates, both of which are subject to regulatory approval. In addition, we expect to expend significant additional resources to continue to develop and commercialize our product candidates, some of which are dependent on the results of clinical trials. We may not obtain regulatory approval for our product candidates and if we obtain regulatory approval we may not be able to commercialize our product candidates or realize any return from these investments. In particular, the development of pharmaceutical products is risky because, even if we receive regulatory approval, other companies may be able to market similar products prior to the launch of our products, during which time their product may gain a significant marketing advantage. If we fail to successfully commercialize our enoxaparin or Ampofol product candidates, we would not earn any return on our investment in these product candidates, and we may be unable to generate sufficient revenue to attain or sustain profitability.

One of our product candidates, enoxaparin, is the subject of litigation and a citizen petition filed with the FDA which may prevent or delay regulatory approval of our enoxaparin product candidate.

In March 2003, we filed an ANDA with the FDA for enoxaparin sodium, seeking approval to engage in the commercial manufacture, sale, and distribution of enoxaparin in the U.S. Our ANDA for enoxaparin included a Paragraph IV certification to the FDA that the existing patents associated with Aventis's branded enoxaparin product, Lovenox, are invalid, unenforceable or will not be infringed by our generic product candidate. A Paragraph IV certification is a certification made under the Federal Food, Drug and Cosmetic Act, as amended, by the filer of an ANDA that a patent covering a marketed drug product is invalid, unenforceable or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. If the patent holder files a patent infringement action within 45 days of receiving notice of the Paragraph IV certification, the FDA places a 30 month stay of approval on the ANDA. As a result of the filing of ANDAs by us and another generic manufacturer, Aventis commenced litigation against us and the other generic manufacturer in August 2003 alleging infringement of one of the two patents covering their product. The litigation stayed the FDA from finally approving our ANDA until the earlier of a court decision in our favor or the expiration of 30 months from Aventis' receipt of our notice of the Paragraph IV certification. In August 2004, we filed a motion for summary judgment against Aventis seeking a judgment that the patent which is the subject of the litigation is unenforceable based on inequitable conduct. In June 2005, the U.S. District Court for the Central District of California granted summary judgment in our favor and the final judgment was entered by the District Court in July 2005. The entry of this decision in our favor terminated the 30 month stay of approval applicable to our ANDA. In September 2005, Aventis filed an appeal of the District Court's decision with the U.S. Court of Appeals for the Federal Circuit. The parties argued the appeal before the Federal Circuit in January 2006.

In May 2003, Aventis filed a patent application with the U.S. Patent and Trademark Office ("PTO") with respect to the patent in suit requesting reissuance of the patent in suit to address certain errors in the claims. Aventis announced in December 2004 that it was issued a notice of allowance by the PTO for the reissuance of the patent in suit. A notice of allowance is a notice from the PTO indicating the end of the prosecution of the pending patent application on the merits and the PTO's intent to reissue the patent with the claims then pending in the reissue application. In June 2005, the PTO reissued the patent in suit which Aventis then submitted to the FDA as covering their Lovenox product. The final judgment also determined that the reissued patent is unenforceable.

In February 2003, Aventis also filed a citizen petition with the FDA requesting, among other things, that the FDA refrain from approving any ANDA for a generic version of Lovenox unless the ANDA applicant demonstrates either that the manufacturing process used in producing the generic drug is equivalent to Aventis' manufacturing process or that the generic product is safe and effective through clinical trials. We have filed comments with the FDA in opposition to Aventis' citizen petition. The FDA has yet to rule on Aventis' citizen petition. See "Business Legal and Regulatory Proceedings Enoxaparin Paragraph IV Litigation" and " Enoxaparin Citizen Petition" and "Business Regulatory Considerations Generic Drug Approval." If the FDA grants Aventis' citizen petition in whole or in part, or if we do not ultimately prevail in the litigation with Aventis, the FDA may delay or refuse to grant approval of our ANDA to market enoxaparin, which could limit our ability to generate sufficient revenue to attain profitability.

We face significant competition from both brand-name and generic manufacturers that could adversely affect the success of our products and severely limit our growth.

Substantially all of our marketed products are generic versions of brand-name products. We face significant competition for our marketed products from major, brand-name pharmaceutical companies such as GlaxoSmithKline, Schering-Plough Corporation and Wyeth, and from companies focused on the generic injectable and inhalation markets such as American Pharmaceutical Partners, Inc., Novartis AG, Inc., Faulding, Inc., IVAX Corporation and Teva. Competition in the generic pharmaceutical industry has increased, as brand-name competitors have entered the business by creating generic subsidiaries, purchasing generic companies, or licensing their products to generic manufacturers prior to patent expiration or as their patents expire.

We face significant competition for our new products and product candidates from the respective product innovators and any generic manufacturer. Enoxaparin is currently marketed by Aventis under the brand-name Lovenox, and Teva and Momenta Pharmaceuticals, Inc. have filed ANDAs with the FDA for approval of their generic versions. Pfizer currently markets DepoProvera, its branded medroxyprogesterone product, and Teva received FDA approval for a generic version. Pfizer also currently markets azithromycin under the brand-name Zithromax, and Baxter Healthcare Corporation recently announced the launch of a generic azithromycin to be manufactured by Pfizer. AstraZeneca is the innovator of Diprivan, and generic versions of propofol are marketed by Baxter-Teva and Bedford Laboratories.

As patents for brand-name products expire and related exclusivity periods expire, the first company to market a generic product is generally able to achieve higher sales, profitability and market share with respect to that product because it is granted an exclusive right to market the product for 180 days. However, as competing generic manufacturers receive regulatory approval on similar products and the 180-day exclusivity period expires, market share, revenue, and gross profit typically decline.

The timeliness with which we can gain regulatory approval for our product candidates and launch them in the market will be a significant factor in their acceptance, and if competitors are able to launch their products first or delay the launch of our products, this may materially adversely affect our product candidates' success. In addition, our competitors may succeed in developing products and technologies that are more effective or less costly than any that we are developing, or that would render our product

candidates obsolete and noncompetitive. We anticipate that we will face increased competition in the future as new companies enter the market and advanced technologies emerge. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Many of our competitors have significantly greater research and development, financial, sales and marketing, manufacturing, and other resources than we have. Additionally, as evidenced by Teva's recent purchase of IVAX, we believe there is a trend towards consolidation among generic drug companies, increasing the relative size and power of companies in our market. As a result, they may be able to devote greater resources to the development, manufacture, marketing or sale of their products, initiate or withstand substantial price competition, or more readily take advantage of acquisitions or other opportunities.

If we are unable to obtain raw materials, active pharmaceutical ingredients, and other products from our suppliers that we depend on for our operations, our ability to deliver our products to market may be impeded.

We depend on suppliers for raw materials, active pharmaceutical ingredients and other components that are subject to stringent FDA requirements. The active pharmaceutical ingredient for Cortrosyn, our largest selling product, is only available from one source, Organon USA Inc. We have entered into a supply agreement with Organon to secure this active pharmaceutical ingredient. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, and environmental factors. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including transportation difficulties, political instability and labor unrest, export duties, fluctuation in currency exchange rates, and uncertainty regarding legal recourse.

If we are unable to secure on a timely basis sufficient quantities of the materials we depend on to market our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, the manufacture and/or sale of our products may be disrupted, which could increase our costs and significantly reduce our revenues from the sale of any approved products.

In connection with our acquisition of Cortrosyn from Organon USA Inc. in 2003, Organon agreed to continue to manufacture Cortrosyn finished product for us for a three year period. In February 2004, due to flooding in its manufacturing facility, Organon was forced to cease production of Cortrosyn finished product. We exhausted our inventory of Cortrosyn in June 2004. We transferred the manufacture of this product to our Rancho Cucamonga facility and began selling the product again in August 2004. As a result of the supply interruption, our revenues from the sale of Cortrosyn were adversely impacted in the second and third quarters of 2004. Cortrosyn sales were \$13.9 million and \$22.4 million for the years ended December 31, 2004 and 2005, respectively. Our costs to produce this product are higher than what we paid Organon to supply this product to us and therefore we do not expect our profit margin for Cortrosyn to equal our profit margin prior to the supply interruption.

The loss of any of the principal members of our scientific and management teams would impair our ability to successfully develop or commercialize our product candidates, which could materially adversely affect our ability to compete.

We are highly dependent on the principal members of our scientific and management teams, including Dr. Jack Zhang, our President and Chief Executive Officer, and Dr. Mary Luo, our Chief Operating Officer. We do not maintain key person life insurance for any of our key personnel. Because we focus on applying our technical expertise to develop products with high technical barriers to entry, we must continue to attract and retain qualified scientific and technical personnel. We do not have

employment agreements with our key personnel. Competition among pharmaceutical and biotechnology companies for qualified employees is intense, and the ability to attract and retain qualified individuals is critical to our success. The loss of the services of any one of our key personnel may significantly delay or prevent the achievement of our product development objectives and could have a material adverse effect on our business.

If clinical trials of any of our product candidates are delayed or are not successful, we may be unable to commercialize those product candidates in a timely manner, or at all.

For certain of our product candidates, we are required to conduct clinical trials to obtain FDA approval. Conducting clinical trials is a lengthy, time-consuming and expensive process, and the results of these trials are inherently uncertain. The commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including:

scheduling conflicts with participating clinicians and clinical institutions;

slower than anticipated patient enrollment; and

the occurrence of adverse events during the clinical trials.

The results from early clinical trials may not be predictive of results to be obtained in later clinical trials. Clinical trials may not demonstrate sufficient safety and efficacy to obtain the necessary regulatory approvals, or a commercially viable product.

If clinical trials for our product candidates are not completed or conducted as planned, or if any of these product candidates are not bioequivalent or do not prove to be safe and effective or do not receive required regulatory approvals, the commercialization of these products would be delayed or prevented, and our ability to generate revenues would be impaired, which could prevent us from achieving or maintaining profitability.

We depend on our wholesaler relationships and group purchasing organizations for the sale of our products, and if we are unable to maintain those relationships, our revenue will be harmed.

We sell our injectable pharmaceutical products to customers through arrangements with group purchasing organizations and wholesalers. The majority of hospitals contract with the group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from customers that have relationships with a small number of group purchasing organizations, in particular Novation and Premier, and wholesalers, specifically AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. These three wholesalers collectively accounted for over half of our net revenues in each of the last three fiscal years. AmerisourceBergen Corporation accounted for 20%, 17% and 18%, Cardinal Health, Inc. accounted for 21%, 18% and 21% and McKesson Corporation accounted for 14%, 18% and 17% of our net revenues in 2003, 2004 and 2005, respectively. In order to maintain these relationships, we believe we will need to offer a broad product line, remain price competitive, comply with FDA regulations, and provide high quality products. Most of our group purchasing organization agreements may be terminated on 60 or 90 days' notice. We have written terms and return policies with our major wholesalers, which are subject to renegotiation at any time. The group purchasing organizations and wholesalers with whom we have relationships may have relationships with manufacturers that sell competing products or combinations of competing products from which they earn higher margins or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization and wholesaler relationships, sales of our products and revenue will decline.

This network through which we sell our products has in the past undergone consolidation, marked by mergers and acquisitions among group purchasing organizations and drug wholesalers such as the merger of two of the largest wholesalers, AmeriSource Health Corporation and Bergen Brunswick Corporation, and may in the future undergo further consolidation. Also, the growth of national

pharmacy chains, and the increasing importance of mail order businesses may also adversely affect us. This consolidation trend may increase pricing and other competitive pressures on us and could have a material adverse effect on sales of our products.

We have a history of net losses, and we may not achieve profitability in the future.

We have a history of net losses. For the years ended December 31, 2003, 2004 and 2005, we had net losses of \$3.9 million, \$6.6 million and \$1.7 million, respectively. We had an accumulated deficit of \$23.4 million as of December 31, 2005. Our ability to generate revenue from existing products or to achieve or maintain profitability for any period is dependent on our ability to successfully and timely design, develop, obtain regulatory approval for, manufacture, and commercialize our product candidates. We expect to increase our operating expenses over the next several years, as we expand our research and development activities, acquire or license new technologies and product candidates, and scale up our manufacturing and quality operations and hire additional personnel. As a result, we may continue to incur operating losses. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable for any year, if at all.

We have recently made a number of improvements to our internal controls and accounting processes, and if these improvements are insufficient to permit us to maintain an effective system of internal controls, we may not detect in a timely manner misstatements that could occur in our financial statements in amounts that could be material. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

Our reporting obligations as a public company will require us to devote significant resources to our operational and financial systems for the foreseeable future. As a private company, we have had limited accounting personnel and other resources with which to address our internal controls, procedures and accounting. In anticipation of becoming a public company, we have taken a number of steps to improve our internal controls and accounting processes, including hiring additional accounting personnel, establishing monthly and quarterly financial closing procedures and establishing additional procedures with respect to account reconciliations and analyses. Upon completion of this offering, we will have had only limited operating experience with the improvements we have made to date. We will need to make continued efforts with respect to our internal controls in order to meet the requirements of being a public company, including the rules under Section 404 of the Sarbanes-Oxley Act of 2002, and the improvements we have made and the efforts with respect to our accounting processes that we will need to continue to make may not be sufficient to ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in misstatements in our financial statements in amounts that could be material. Insufficient internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will need an effective sales organization to market and sell our future branded products, and our failure to have an effective sales organization may harm our business.

We have only a small sales organization to market and sell any branded products that we may develop or acquire. Prior to the time that our products are available for commercial launch we may not be able to recruit or acquire additional sales and marketing personnel, license our products to pharmaceutical companies with sales organizations, or enter into a favorable co-promotion or contract sales arrangements. If we decide to market our products through third parties, these parties may not have the same interests as we do in marketing the products, and we may lose control over the sales of these products.

Our business may suffer if we are unable to identify, consummate, and integrate any future acquisitions successfully.

In the past, we have grown our operations in part through acquisitions of companies and products. Since we began operations in 1996, we have acquired two companies, International Medication Systems, Limited in 1998 and Armstrong in 2003, and two products, Cortrosyn in 2003 and Epinephrine Mist in 2004. As part of our business strategy, we plan to continue to acquire businesses, products, and technologies that we believe complement our business. We are not currently a party to any agreements, commitments or understandings with respect to any potential acquisitions. Future acquisitions, however, may entail many risks and may result in unforeseen difficulties in integrating the operations and personnel of companies that we acquire and the products and technologies that we acquire. Potential acquisitions may require significant management attention that would otherwise be available for ongoing development of our existing portfolio of products and product candidates. In addition, we may not be able to maintain the levels of operating efficiency or product sales that any acquired company or product achieved in the past or might have achieved separately. For example, since we began manufacturing Cortrosyn, our costs to manufacture this product have been higher than the costs we paid to purchase the product from Organon. Successful integration of the companies we acquire will depend on our ability to, among other things, eliminate redundancies and excess costs. As a result of difficulties associated with combining operations, we may not be able to achieve cost savings and other benefits that we might hope to achieve with acquisitions. Future acquisitions could result in potentially dilutive issuances of equity securities, result in the incurrence of debt and contingent liabilities, or have a negative impact on our consolidated financial statements.

We expect that we will need significant cash resources for our research and development and commercialization efforts. We may need to raise additional capital, and if we are unable to raise additional capital when needed, we may be forced to curtail or delay these activities.

We expect that we will require substantial funds to continue our research and development activities and commercialization activities and plan to use part of the proceeds from this offering for this purpose. We estimate that our research and development costs for our current, significant product candidates identified in "Prospectus Summary Our Product Candidates" may require up to \$20.0 million which we anticipate funding from the proceeds from this offering. However, because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize these product candidates or other product candidates we may develop in the future. Because our business requires us to continually develop new products, we may need to raise additional capital to expand our business in the future through public or private equity offerings, debt financings or licensing arrangements which may not be available on terms favorable to us, or at all. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. If we cannot raise capital when needed on favorable terms, or at all, it may delay our development and commercialization of product candidates we develop in the future, which could harm our business.

If a natural or man-made disaster strikes one or more of our facilities, we may be unable to manufacture certain products for a substantial amount of time and our revenue could decline.

Our facilities may be affected by natural or man-made disasters. Our thirteen manufacturing facilities are located in four locations: Rancho Cucamonga and South El Monte, California, and Canton and West Roxbury, Massachusetts. These facilities and the manufacturing equipment that we use to produce our products would be difficult to replace and could require substantial lead time to repair or replace. Certain of our manufacturing facilities produce more than one product. In the event that one of our manufacturing facilities was affected by a disaster, we would be forced to shift production to our other manufacturing facilities or rely on third-party manufacturers, and our other facilities or a third-party manufacturer may not have the capability to effectively supply all of the affected products. In particular, a natural disaster, such as an earthquake, could seriously impair our manufacturing

capabilities in California. If we were to shift production from one facility to another, we would need to secure FDA approval to manufacture the product in the new facility. Depending on the value of our product, this could take between six months and three years and we may not be able to outsource the manufacture during that time. We currently carry business interruption insurance with a \$15 million policy limit and our subsidiaries, International Medication Systems, Limited and Armstrong, have separate policies with policy limits of \$18 million and \$6 million, respectively. Our insurance coverage may not be sufficient in scope or amount to cover potential losses.

Other Risks Related to Intellectual Property Rights

Third parties may claim that we infringe their proprietary rights and may delay or prevent us from manufacturing and selling our products, which could limit our ability to generate sufficient revenue to attain or maintain profitability.

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use, and sale of new generic products and the validity and infringement of patents or proprietary rights. When seeking regulatory approval for our product candidates, we may be required to certify to the FDA that these products do not infringe third-party patents, or that such patents are invalid. Filing such a certification against a patent, commonly known as a Paragraph IV certification, gives the patent holder the right to bring a patent infringement lawsuit against us. Brand-name pharmaceutical companies regularly institute these suits, and we expect them to continue to use these tactics because it is a cost-effective way to delay or prevent generic competition. A lawsuit stays the FDA's approval decision until the earlier of a court decision or 30 months from the patent holder's receipt of notice of certification. A claim of infringement and the resulting delay results in additional expenses and could even prevent us from manufacturing and selling certain products. In this regard, we were recently a defendant in a Paragraph IV patent infringement litigation initiated in 2003 by Aventis concerning one of our product candidates, enoxaparin, a generic version of Lovenox. The U.S. District Court for the Central District of California granted summary judgment in our favor in June 2005 and the final judgment was entered by the District Court in July 2005. The entry of this decision in our favor terminated the 30 month stay of approval applicable to our ANDA. In September 2005, Aventis filed an appeal of the District Court's decision with the U.S. Court of Appeals for the Federal Circuit. The parties argued the appeal before the Federal Circuit in January 2006. See "Business Legal and Regulatory Proceedings Enoxaparin Paragraph IV Litigation."

We are subject to other patent infringement claims from time to time in the ordinary course of our business, and third parties could assert patent infringement claims against us in the future with respect to our current products, products we may develop, or products we may license. Litigation could force us to:

delay or prevent selling, manufacturing, or using products that incorporate or are made using the challenged intellectual property;

incur significant expenses or pay damages, including attorneys fees; or

enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any patent litigation, regardless of its outcome, would delay the regulatory approval process, be costly, and require significant time and attention of our key management and technical personnel.

Commercialization of our enoxaparin product or any other generic product, prior to the final resolution of a patent infringement litigation with respect to such product, could expose us to significant damages if the outcome of such litigation is unfavorable and could impair our reputation.

If we receive FDA approval of our ANDA for enoxaparin or any other product, we may consider commercializing the product prior to the final resolution of any related patent infringement litigation. The risk involved in marketing enoxaparin prior to the final resolution of the appeal of the decision in the recent Paragraph IV patent infringement lawsuit may be substantial because the remedies available to Aventis could include, among other things, damages measured by the profits lost by Aventis and not by the profits earned by us. Aventis may also recover damages caused by the erosion of prices for its patented drug as a result of the introduction of our generic drug in the marketplace. Further, in the case of a willful infringement, which requires a complex analysis of the totality of the circumstances, such damages may be trebled. Moreover, because the discount pricing typically involved with generic products, patented branded products generally realize a substantially higher profit margin than generic products. Typically a patent owner's profit margin is reduced when a generic product is introduced on the market. This profit reduction can act as a disincentive to the patent owner to settle patent litigation on terms that could allow our products to be marketed upon the settlement of such litigation. However, in order to realize the economic benefits of some of our products, including enoxaparin, we may decide to risk an amount that may exceed the profit we anticipate making on our product. There are a number of factors we would need to consider in order to decide whether to launch our product prior to final resolution, including assessing the probability of an adverse court decision and the magnitude of the monetary damages we would face and our ability to pay damages. An adverse court decision in a case such as this, or in other similar litigation, could require us to pay a significant amount in damages which could harm our business and reputation and could cause the market value of our common stock to decline. If the revenues from our products or our access to our lines of credit are insufficient to satisfy any damages we would be required to pay, we may be forced to use a portion of the proceeds of this offering to pay such damages.

We depend on our ability to protect our intellectual property and proprietary rights, and we cannot be certain of their confidentiality and protection.

Our inability to protect our intellectual property rights could adversely affect our ability to manufacture or sell our products. We primarily rely on trade secrets, unpatented proprietary know-how, and continuing technological innovation to protect our products and technology, especially where we do not believe patent protection is appropriate or obtainable. Although, in some cases, we seek patent protection to preserve our competitive position, our current patent portfolio is relatively insignificant with respect to the majority of our existing products and product candidates. We own 12 patents issued by the PTO covering formulations, processes and equipment used in the manufacture of our products. The expiration dates of these patents range from 2006 to 2022. We may not be able to obtain patent or other forms of protection for inventions or other intellectual property developed by our officers or employees, or consultants because we might not have been the first to invent the patentable technology or others may have independently developed similar or alternative technologies.

Despite our efforts to protect our proprietary information through the use of confidentiality and non-disclosure agreements, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary. Other parties may independently develop know-how or obtain access to our technologies. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

Intellectual property protection is highly uncertain and involves complex legal and technical questions. Our patents and any patent for which we have licensed or may license rights, may be challenged, narrowed, invalidated, or circumvented. Our issued patents may not contain claims

sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

We rely on the ability of our licensors to obtain, maintain and enforce patent protection for intellectual property we license. Our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

The PTO and the courts have not established a consistent policy regarding the breadth of claims allowed related to pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

Risks Related to Our Industry

The sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we do not obtain these approvals or comply with these requirements, it could delay or prevent us from selling our products.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, export, marketing, and distribution of our products are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable governmental authorities in foreign markets. We are dependent on obtaining timely regulatory approvals before our products can be sold. The FDA approval process for a particular product candidate can take several years and requires us to dedicate substantial resources to securing approvals, and we may not be able to obtain regulatory approval for our product candidates in a timely manner, or at all. In order to receive approval from the FDA for each product candidate, we must demonstrate that the new drug product is safe and effective for its intended use, and that our manufacturing processes for that product candidate comply with the FDA's Current Good Manufacturing Practices, or cGMPs. The FDA may require substantial additional clinical testing or find our drug product does not satisfy the standards for approval. In addition, in order to obtain approval for our generic product candidates, we must demonstrate that our drug product is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator drug. Bioequivalency may be demonstrated by comparing the generic product candidate to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. The FDA may not agree that the bioequivalence studies we submit in ANDA applications for our generic drug products are adequate to support approval. If it determines that an ANDA application is not adequate to support approval, the FDA could deny our application or request additional information, including clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product. For instance, in connection with the FDA's review of our ANDA for enoxaparin sodium, the FDA has made several comments and requests for data in the areas of chemistry, bioequivalence and labeling to which we have responded by filing amendments to our ANDA. Amendments may extend the review period applicable to our application, and the FDA may not agree that our amendments to our ANDA are adequate to support approval on a timely basis, or at all. The FDA also has the authority to revoke drug approvals previously granted and remove these products from the market for a variety of reasons, including a failure to comply with applicable regulations, the discovery of previously unknown problems with the product, or because the ingredients in the drug are no longer approved by the FDA.

As a manufacturer of pharmaceutical and medical device products, we and our suppliers must comply with cGMPs, which include requirements related to production processes, quality control and assurance, and recordkeeping. Our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. In May 2000 and

September 2003, we received warning letters from the FDA alleging violations of the FDA's drug and medical device cGMP regulations. Both warning letters pertained to the facilities of our subsidiary, International Medication Systems, Limited in South El Monte, California. The May 2000 letter related to an inspection that year concerning pharmaceutical manufacturing deficiencies that had predated our acquisition of International Medication Systems, Limited in 1998. All issues raised in the warning letter were addressed in the response to the original observations submitted to FDA in March 2000 and verified to be adequate during a meeting held with the FDA in March 2000. There were no product removals or recalls as a result of this warning letter.

The September 2003 letter related to an inspection that year concerning International Medication Systems, Limited's device manufacturing deficiencies with respect to packaging equipment qualification and certain documentation failing to meet all requirements of the quality system regulation. We held a meeting with the FDA in September 2003 to present a corrective action plan and clarify specific issues. International Medication Systems, Limited sent a complete response to the letter to the FDA in October 2003 and the FDA responded later that month with a letter stating that all issues seemed to be adequately resolved. During a February 2004 inspection of the facility the FDA verified the corrective actions. There were no product removals or recalls as a result of this warning letter.

Any additional violations may result in enforcement actions, including delaying or preventing new product approvals, a delay or suspension in manufacturing operations, consent decrees, or civil or criminal penalties.

In addition, the U.S. Drug Enforcement Administration ("DEA") and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, record keeping, and distribution of drugs that are considered controlled substances. Some of the pain management products we manufacture contain morphine sulfate as the active pharmaceutical ingredient and are considered controlled substances. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us.

Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and criminal prosecution. Any of these or other regulatory actions could materially adversely affect our business and our financial condition.

Changes in the regulatory environment may prevent us from exploiting exclusivity periods that are critical to the success of our generic products.

The FDA's policy regarding the award of a 180-day marketing exclusivity period to generic manufacturers who successfully challenge patents relating to branded products continues to be the subject of much litigation and legislative reform in the U.S. Pursuant to the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act), the FDA currently awards 180 days of marketing exclusivity to the first generic manufacturer who submits to the FDA a substantially complete ANDA with a Paragraph IV certification under the Hatch-Waxman Act challenging the patent of the branded product if the ANDA is approved by the FDA. We may not be able to secure the benefit of this exclusivity period, which depends on a variety of factors, some of which are beyond our control, such as whether we are the first generic applicant to submit a substantially complete ANDA for a product, whether other ANDA applicants share that exclusivity, and whether the branded product will also be marketed as a generic (sometimes referred to as an authorized generic).

New court decisions, FDA interpretations, and legislative changes have modified the rules governing eligibility for and the timing of 180-day marketing exclusivity periods. For example, the FDA

had previously taken the position that it could award "shared" 180-day marketing exclusivity if different ANDA applicants were first-to-file Paragraph IV certifications to different patents listed in the Orange Book, for the same product. The "Orange Book" is a listing compiled and maintained by the FDA which contains approved drug products with corresponding therapeutic equivalence evaluations and any patent and/or applicable exclusivity for such approved drug products. The Orange Book is used by formularies to determine for which name brand drug products one or more interchangeable generic versions are available. This interpretation was recently challenged in two cases in the United States district court, which resulted in differing conclusions regarding the reasonableness of the FDA's interpretation. On appeal both decisions were vacated on other grounds in December 2004. Despite the questionable legality of the FDA's shared exclusivity approach, the FDA has announced that it will continue to rely on this interpretation of shared exclusivity for ANDAs filed before December 8, 2003, when the Medicare Prescription Drug Improvement and Modernization Act of 2003, also known as the Medicare Act, amended the Hatch-Waxman Act to prospectively eliminate this type of shared exclusivity. Until this issue is resolved, it is unclear how the 180-day marketing exclusivity period will apply to certain of our pending ANDAs. For ANDAs that are filed on or after December 8, 2003, the 180-day marketing exclusivity period will only be awarded to the first ANDA applicant(s) to assert a Paragraph IV certification as to any patent listed in the Orange Book for that product (including multiple ANDA applicants who file the first Paragraph IV certification on the same day) that receives approval from the FDA.

The Medicare Act also modified the rules governing when the 180-day marketing exclusivity period is triggered or forfeited. Prior to this legislation, the 180-day marketing exclusivity period was triggered upon the first commercial marketing of the ANDA or a final and non-appealable court decision holding the patent invalid, unenforceable or not infringed. In response to two court cases, the FDA changed its policy in March 2000 so that the 180-day marketing exclusivity period began running immediately upon a decision holding the patent as invalid, unenforceable, or not infringed at the district court rather than the appellate court level, regardless of whether the ANDA had been approved and the generic product had been marketed. In codifying the FDA's original policy, the Medicare Act retroactively applies a final and non-appealable court decision trigger for all ANDAs filed before December 8, 2003, leaving intact the first commercial marketing trigger. For ANDAs filed after December 8, 2003, the marketing exclusivity period is only triggered upon the first commercial marketing of the ANDA product, but that exclusivity may be forfeited under certain circumstances, including if the ANDA is not marketed within a certain timeframe after a final and non-appealable court decision in favor of the first-to-file or another ANDA applicant, or if the FDA does not tentatively approve the first-to-file applicant's ANDA within 30 months. The ANDA for our enoxaparin product was filed before December 8, 2003, and thus, its exclusivity period, if any, will not be triggered under the Medicare Act until the first commercial marketing of the product or a final, non-appealable court decision in our favor in the litigation with Aventis.

It is difficult to predict if or how the FDA will change the procedures for granting 180-day marketing exclusivity in response to court decisions and legislative reforms and the effects such changes may have on our business. Any changes in FDA regulations, procedures, or interpretations may make ANDA approvals more difficult or otherwise limit the benefits available to us through the granting of 180-day marketing exclusivity. If we are not able to exploit the 180-day marketing exclusivity period for any of our generic product candidates for any reason, our product may not gain market share, which could materially adversely affect our results of operations.

If branded pharmaceutical companies are successful in limiting the use of brand equivalent products through their legislative and regulatory efforts, our sales of brand equivalent products may suffer.

Many brand-name manufacturers have increasingly used state and federal legislative and regulatory means to delay or prevent generic competition. These manufacturers' efforts have included:

pursuing new patents or extensions of existing patents for an existing brand product that could extend patent protection for the brand product and delay the launch of generic products;

pursuing pediatric exclusivity for their brand products;

submitting citizen petitions to request that the Commissioner of the FDA take administrative action with respect to an ANDA approval;

seeking changes to the United States Pharmacopeia, an industry-recognized compendia of drug standards;

attaching special patent extension amendments to unrelated federal legislation; and

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some brand-name drugs with generic drugs.

We have been subject to certain of these actions. Aventis filed a citizen petition with the FDA asking the agency to take or refrain from taking certain actions that would impact our ANDA for our enoxaparin product candidate. See " Legal and Regulatory Proceedings Enoxaparin Citizen Petition." Aventis has also sought and received a reissuance of the patent related to its Lovenox product to address certain errors in its claims.

If these efforts to delay generic competition are successful, we may be unable to sell our products that are subject to these efforts, which could have a material adverse effect on our future results of operations.

Our business involves the use of hazardous materials and has subjected us to environmental liability, and any future environmental liability could seriously harm our financial condition.

Our research and development and manufacturing activities involve the use and disposal of various materials commonly used in conducting these activities in the pharmaceutical industry, such as hydrochloric acid, alcohol and methanol. These materials are considered hazardous because they may be toxic, corrosive or flammable under certain conditions. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these materials. Some of our facilities are located in areas that may experience environmental contamination due to the activities of third parties. In 2002 our subsidiary, International Medication Systems, Limited, and several other unrelated entities settled claims with the Environmental Protection Agency ("EPA") related to a groundwater contamination problem from a number of chemicals in a portion of the San Gabriel Basin. The settlement included payment of remediation costs for which International Medication Systems, Limited was responsible for approximately \$365,000. In 2003, International Medication Systems, Limited and other parties were notified that another chemical was detected in the groundwater and that it would have to be treated immediately. International Medication Systems, Limited and other potentially responsible parties are in conversations with the EPA to discuss a settlement of this liability. International Medication Systems, Limited has also been named as a third-party defendant in litigation matters between the water purveyors and other non-settling industrial defendants. In March 2006, IMS settled a litigation matter in which it was one of approximately 39 defendants brought by plaintiffs alleging exposure to contaminated drinking water. See "Business Legal and Regulatory Proceedings Environmental Litigation and EPA Proceedings" for more information.

We cannot eliminate the risk of accidental injury or contamination from the manufacture, storage, handling, and disposal of materials we use. In the event of an accident or contamination, we could be liable for damages or be penalized with fines, and this liability could be substantial and exceed our resources, which could materially adversely affect our financial condition. We may have to incur significant costs to comply with future environmental laws and regulations.

We may incur significant costs from any product liability claims if our insurance for those claims is inadequate.

If any of our products cause or merely appear to cause injury, we may become subject to liability claims. We also face the risk of product liability exposure related to the testing of our product candidates in human clinical trials. We face liability risks even with respect to products that have received, or may in the future receive, regulatory approval for commercial use.

Our product liability insurance may not be adequate and, at any time, insurance coverage may not be available on commercially reasonable terms or at all. Each of Amphastar, International Medication Systems, Limited and Armstrong currently have their own product liability insurance policy with a limit of \$5 million. A product liability claim could result in liability to us greater than our insurance coverage or assets. Even if we have adequate insurance coverage, product liability claims could result in the decreased demand for our products, injury to our reputation, and/or the withdrawal of clinical trial participants as well as have a negative impact on our results of operations, financial position, or cash flows.

We face uncertainty related to pricing, reimbursement, and health care reform.

Sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations, and other health care-related organizations. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation, rules, and regulations affecting third-party payors' coverage and reimbursement policies, which are designed to contain or reduce the cost of health care. There may be future changes that result in reductions in current coverage and reimbursement levels for our products, and we cannot predict the full scope of the changes or the impact that those changes would have on our operations.

Current cost control initiatives may decrease coverage and payment levels for existing and future products and, in turn, the price that we receive for any existing product or those that we develop or market in the future. For example, the Medicare Act revised the Medicare payment methodology for many drugs covered under Medicare Part B. In addition, the new Medicare prescription drug benefit (Medicare Part D), mandated by the Medicare Act, went into effect in 2006. We cannot predict the full impact of the new payment methodologies and the new prescription drug benefit on our business.

In addition, because third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, significant uncertainty exists as to the coverage and reimbursement status of newly approved pharmaceutical products, including injectable products. Our new products may not be considered reasonable and necessary, cost effective, or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments.

We are also impacted by efforts by private payors to control costs. If there are continued pricing pressures from efforts by private payors, this could negatively impact our results of operations and financial condition.

We may need to change our business practices to comply with changes to fraud and abuse laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including the federal fraud and abuse law (sometimes referred to as the "Anti-Kickback Statute") which apply to our sales and marketing practices and our relationships with physicians. At the federal level, the Anti-Kickback Statute prohibits any person or entity from knowingly and willfully soliciting, receiving, offering, or providing any remuneration, including a bribe, kickback, or rebate, directly or indirectly, in return for or to induce the referral of patients for items or services covered by federal health care programs, or the furnishing, recommending, or arranging for products or services covered by federal health care programs. Federal health care programs have been defined to include plans and programs that provide health benefits funded by the federal government, including Medicare and

Medicaid, among others. The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose on an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal healthcare programs, the statute has been violated. The federal government has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will assure parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement will be illegal or that prosecution under the federal Anti-Kickback Statute will be pursued, but such transactions or arrangements face an increased risk of scrutiny by government enforcement authorities and an ongoing risk of prosecution. If our sales and marketing practices or our relationships with physicians (such as physicians serving on our Scientific Advisory Board) are considered by federal or state enforcement authorities to be knowingly and willfully soliciting, receiving, offering or providing any remuneration in exchange for arranging for or recommending our products and services, and such activities do not fit within a safe harbor, then these arrangements could be challenged under the Anti-Kickback Statute. If our operations are found to be in violation of the federal Anti-Kickback Statute we may be subject to civil and criminal penalties including fines of up to \$25,000 per violation, civil monetary penalties of up to \$50,000 per violation, assessments of up to three times the amount of the prohibited remuneration, imprisonment, and exclusion from participating in the federal health care programs. In addition, a number of states have anti-fraud and anti-kickback laws similar to the Anti-Kickback Statute that prohibit certain direct or indirect payments if such arrangements are designed to induce or encourage the referral of patients or the furnishing of goods or services. Some states' anti-fraud and anti-kickback laws apply only to goods and services covered by Medicaid. Other states' anti-fraud and anti-kickback laws apply to all health care goods and services, regardless of whether the source of payment is governmental or private. Due to the breadth of these laws and the potential for changes in laws, regulations, or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could materially adversely affect our business.

Certain federal and state governmental agencies, including the U.S. Department of Justice and the U.S. Department of Health and Human Services, have been investigating issues surrounding pricing information reported by drug manufacturers and used in the calculation of reimbursements as well as sales and marketing practices. For example, many government and third party payors, including Medicare and Medicaid, reimburse doctors and others for the purchase of certain pharmaceutical products based on the product's average wholesale price, or AWP, reported by pharmaceutical companies. The federal government, certain state agencies and private payors are investigating and have begun to file actions related to pharmaceutical companies' reporting practices with respect to AWP, alleging that the practice of reporting prices for pharmaceutical products has resulted in a false and overstated AWP, which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and others to health care providers who prescribed and administered those products. In addition, some of these same payors are also alleging that companies are not reporting their "best price" to the states under the Medicaid program. We are not currently subject to any such investigations or actions, but if we do or if these investigations and actions were to result in changes to our operations, it could materially adversely affect our results of operations.

We may become subject to federal and state false claims litigation brought by private individuals and the government.

We are subject to state and federal laws that govern the submission of claims for reimbursement. The federal False Claims Act imposes civil liability on individuals or entities that submit false or fraudulent claims for payment to the government. Violations of the False Claims Act and other similar

laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The False Claims Act also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the False Claims Act. These suits, known as qui tam actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the False Claims Act allows an individual to share in any amounts paid to the federal government in fines or settlement as a result of a successful qui tam action.

Risks Related to This Offering

Future sales of our common stock by our stockholders could depress our stock price.

Approximately % of our outstanding common stock upon completion of this offering will be available for sale in the public market 180 days after the date of the final prospectus relating to this offering, subject in some cases to volume and other limitations, while the remaining % of our outstanding common stock will not be subject to such restrictions. Lehman Brothers Inc. and UBS Securities LLC may waive the 180-day restrictions prior to the expiration of the lock-up period without prior notice. If our stockholders sell substantial amounts of our common stock in the public market, or the market perceives that these sales may occur, the market price of our common stock could fall.

Our Chief Executive Officer and Chief Operating Officer and their affiliates will beneficially own approximately % of our outstanding common stock upon completion of this offering, and will have the ability to exercise significant control over our company and of any matter presented to our stockholders, which may result in conflicts of interest that could cause our stock price to decline.

As of March 16, 2006, our Chief Executive Officer and Chief Operating Officer and their affiliates beneficially owned in the aggregate approximately 32% of the outstanding shares of our common stock and will beneficially own or control approximately % of the outstanding shares of our common stock upon completion of this offering. Accordingly, they will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets, or any other significant corporate transactions, and may also delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. See "Management" and "Principal Stockholders" for details on our capital stock ownership.

A public market for our securities may not develop or be sustained, which could cause our stock price to fall below the initial public offering price.

Prior to this offering, you could not buy or sell our common stock publicly. The initial public offering price may bear no relationship to the price at which our common stock will trade upon completion of this offering. Although we have applied to have our common stock quoted on the Nasdaq National Market, an active trading market for our common stock may not develop or be sustained following this offering, and the market price of our common stock might fall below the initial public offering price. The initial public offering price will be determined based on negotiations between us and the representatives of the underwriters, based on factors that may or may not be indicative of future market performance.

Our common stock may experience price and volume fluctuations.

The market price of our common stock may fluctuate substantially due to a variety of factors, many of which are beyond our control, including:

announcements of technological innovations or new products by us or our competitors;

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media reports and publications about pharmaceutical products;

announcements concerning our competitors or the pharmaceutical industry in general;

new regulatory pronouncements and changes in regulatory guidelines;

announcements concerning results of clinical trials for our product candidates;

general and industry-specific economic conditions; or

changes in financial estimates or recommendations by securities analysts.

The market prices of the securities of pharmaceutical and biotechnology companies have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. Moreover, market prices for securities of pharmaceutical and biotechnology companies, particularly following an initial public offering, frequently reach levels that bear no relationship to the operating performance of these companies. These market prices may not be sustainable and are subject to wide variation. In the past, securities class action litigation has been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs, divert management's attention and resources and harm our business.

This offering will cause immediate and substantial dilution in net tangible book value of your shares.

We expect the initial public offering price of our common stock to be substantially higher than the net tangible book value per share of our outstanding common stock. Accordingly, investors purchasing shares of common stock in this offering will:

pay a price per share that substantially exceeds the net book value of our common stock determined by the value of our net assets after subtracting liabilities; and

contribute % of the total amount invested to date to fund us but will own only % of the shares of common stock outstanding.

Additional dilution may be incurred if holders of stock options, whether currently outstanding or subsequently granted, exercise their options. See "Dilution."

Provisions in our certificate of incorporation and bylaws or Delaware law might discourage, delay or prevent a change of control of our company, which could negatively affect your investment.

Our certificate of incorporation and bylaws contain provisions that could discourage, delay, or prevent a change of control of our company or changes in our management that our stockholders may deem advantageous. These provisions include:

authorizing the issuance of preferred stock that can be created and issued by our board of directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of our common stock;

limiting the persons who can call special stockholder meetings;

providing that a supermajority vote of our stockholders is required to amend some provisions of our certificate of incorporation or bylaws;

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establishing advance notice requirements to nominate persons for election to our board of directors or to propose matters that can be acted on by stockholders at stockholder meetings;

no provision for cumulative voting in the election of directors; and

filling vacancies on our board of directors by action of a majority of the directors and not by the stockholders.

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These and other provisions in our organizational documents could allow our board of directors to affect your rights as a stockholder in a number of ways, including making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing members of our management team, these provisions could in turn affect any attempt to replace the current management team. These provisions could also limit the price that investors would be willing to pay in the future for shares of our common stock.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay, or prevent a change of control of our company. See "Description of Capital Stock."

We will incur increased costs as a result of being a public company.

As a public company, we will annually incur significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission (the "SEC") and the NASDAQ National Market, have required changes in corporate governance practices of public companies. We expect these new rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, as a result of becoming a public company, we will be implementing policies regarding internal controls and disclosure controls and procedures. In addition, we will incur additional costs associated with our public company reporting requirements. We also expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

We do not intend to pay dividends, which may limit the return on your investment.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. You should not rely on an investment in our company if you require dividend income from your investment. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value after this offering or even maintain the price at which you purchased your shares.

We may allocate the net proceeds from this offering in ways that may not enhance the value of our common stock.

We intend to use the net proceeds from this offering to:

- fund the development of all of our current, significant product candidates;
- upgrade, renovate and equip an additional building at our headquarters complex;
- repay indebtedness; and
- fund general corporate purposes and potential acquisitions of products or businesses.

Our management will, however, have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.

FORWARD-LOOKING STATEMENTS

This prospectus, including particularly the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. These risks and other factors include those listed under "Risk Factors" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as "anticipates," "believes," "continue," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. You should be aware that the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, or the Securities Act, do not exempt from liability any forward-looking statements that we make in connection with this offering.

USE OF PROCEEDS

We estimate that the net proceeds from this offering to us will be approximately \$ million, based upon an estimated initial public offering price of \$ per share, the mid-point of the range on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds to us will be approximately \$ million.

We intend to use a majority of the net proceeds from this offering for the development of all of our current, significant product candidates and to upgrade, renovate and equip an additional building at our headquarters complex. We estimate that research and development costs for our eight significant product candidates, identified in "Prospectus Summary - Our Product Candidates," may require a total of up to \$20.0 million of the proceeds, which amount we currently believe should be sufficient to complete development of all of these product candidates. We expect that the building renovation will include the addition of a 110,000 square foot second floor and, when finished, that the building will provide four additional manufacturing lines, 32,000 square feet for research and development activities, and more than 100,000 square feet of space for administrative and general use. We estimate that the costs to upgrade, renovate and equip the building will aggregate up to \$45.0 million, comprised of approximately \$20.0 million for construction, \$10.0 million for laboratory equipment and \$15.0 million for manufacturing and utility equipment. If possible, we may finance up to \$20.0 million of these costs under equipment financing facilities. We do not currently have any commitments with respect to the proposed building renovation but anticipate that following the offering we will move forward with the project, which could take 18 months or more to complete.

We may also use up to \$4.0 million of the proceeds from this offering to make a portion of the \$6.0 million in final payments due in 2006 to Organon in connection with our purchase of certain rights to the product Cortosyn. We may also use a portion of the proceeds to make payments under our loan agreement with General Electric Capital Corporation ("GECC") in the aggregate principal amount of \$20.0 million and our loan agreements in the aggregate principal amount of \$19.0 million with East West Bank (of which only \$8.2 million has been borrowed), however we may use cash from operations for such payments. The GECC loan agreement bears interest at a variable rate equal to the three month London Interbank Offered Rate ("LIBOR") plus 5.52% per annum and the loans mature in November 2009. We used the proceeds to purchase new equipment and to pay all outstanding amounts with Cathay Bank and the remainder was used for working capital. The loan agreement between us and East West Bank bears interest at a variable rate equal to the three month LIBOR plus 2.5% per annum and matures in October 2010. The loan agreements between International Medication Systems, Limited ("IMS") and East West Bank bear interest at a variable rate equal to the daily Wall Street Journal Prime Rate. Two loan agreements mature in September 2006 and the other matures in September 2009. The proceeds of the IMS loan agreements that have been drawn to date were used to pay all outstanding amounts owed to Bank of the West and the remainder was added to working capital.

We anticipate using the remaining net proceeds of \$ for other general corporate purposes and potential acquisitions of products or businesses that expand or complement our current business. We currently do not have any agreements or commitments relating to any potential acquisition for which we would use any of the net proceeds and we may not complete any such future acquisitions.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amount of proceeds expended for any particular purpose also may vary based on a number of factors, including the developmental progress of our product candidates, including regulatory approval, litigation and clinical trials, and our other operational needs. We reserve the right to reallocate the proceeds of this offering in response to these and other contingencies. Accordingly, our management will have broad discretion in the

application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

The amount and timing of our expenditures will depend on several factors, including the developmental progress of our product candidates and the amount of cash used in or provided by our operations. Pending their uses, we plan to invest the net proceeds of this offering in short- and medium-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to support our operations and to finance the growth and development of our business. Therefore, we do not expect to pay any dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2005:

on an actual basis; and

on an as adjusted basis to give effect to the completion of this offering, including the application of the estimated net proceeds from this offering as described under "Use of Proceeds."

You should read the following table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of Capital Stock" and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	As of December 31, 2005	
	Actual	As Adjusted
	(unaudited)	
	(dollars in thousands)	
Cash, cash equivalents, and short-term investments restricted	\$ 8,347	\$
Long-term debt and capital leases, including current portion	\$ 34,939	\$
Stockholders' equity:		
Common stock, par value \$.0001 per share; 300,000,000 shares authorized, 36,428,816 shares issued and outstanding-actual, shares issued and outstanding, as adjusted		4
Preferred stock, par value \$.0001 per share; 20,000,000 shares authorized, no shares outstanding		
Additional paid-in capital	124,583	
Accumulated deficit	(23,433)	
Total stockholders' equity	101,154	
Total capitalization	\$ 136,093	\$

The share information in the table above excludes, as of March 16, 2006:

6,035,754 shares of common stock issuable upon exercise of options outstanding as of March 16, 2006, with a weighted average exercise price of \$8.54 per share;

3,723,980 shares of common stock reserved for future grant under our stock incentive plans as of March 16, 2006.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock upon completion of this offering.

Investors participating in this offering will incur immediate and substantial dilution. The net tangible book value per share of our common stock as of December 31, 2005, was \$2.11 per share. Net tangible book value per share represents the amount of our total tangible assets (total assets less intangible assets) less total liabilities, divided by the number of shares of our common stock outstanding.

After giving effect to our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the mid-point of the range as indicated on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2005 would have been approximately \$ _____, or approximately \$ _____ per share. This represents an immediate increase in pro forma net tangible book value of \$ _____ per share to existing stockholders before this offering and an immediate dilution of \$ _____ per share to new investors participating in this offering. The following table illustrates this dilution:

Assumed initial public offering price per share	\$ _____
Net tangible book value per common share as of December 31, 2005	\$ 2.11
Increase per share attributable to new investors	\$ _____
Pro forma net tangible book value per share after this offering	\$ _____
Dilution per share to new investors	\$ _____

The following table shows, as of March 16, 2006, the total number of shares of common stock purchased from us, the total consideration paid for these shares and the average price per share paid by existing stockholders and new investors at an assumed initial public offering price of \$ _____ per share, which is the mid-point of the range as indicated on the cover page of this prospectus.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	36,928,816	%	\$ 134,587,000	%	\$ 3.64
New investors					
Total		%		%	

The foregoing discussion and tables assume no exercise of the underwriters' option to purchase additional shares and excludes:

6,035,754 shares of common stock issuable upon exercise of options outstanding as of March 16, 2006, with a weighted average exercise price of \$8.54 per share;

3,723,980 shares of common stock reserved for future grant under our stock incentive plans as of March 16, 2006.

There will be further dilution to new investors with respect to the shares issued pursuant to the warrant and to the extent any of these options or the underwriters' option to purchase additional shares is exercised. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of common stock held by existing stockholders before this offering will be reduced to _____% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to _____ shares or _____% of the total number of shares of common stock to be outstanding after this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and accompanying footnotes. We derived the selected consolidated financial data at December 31, 2004 and 2005, and for each of the three years in the period ended December 31, 2005 from the audited consolidated financial statements included in this prospectus. We derived the selected consolidated financial data at December 31, 2001, 2002, 2003 and for the years ended December 31, 2001 and 2002 from our audited consolidated financial statements that are not included in this prospectus. Our historical results are not necessarily indicative of future results.

	Years Ended December 31,				
	2001	2002	2003 ⁽¹⁾	2004	2005
	(in thousands, except per share data)				
Consolidated Statement of Operations data:					
Net revenues	\$ 32,373	\$ 33,045	\$ 48,197	\$ 61,193	\$ 84,280
Cost of revenues	22,969	22,528	35,508	46,660	58,457
Gross profit	9,404	10,517	12,689	14,533	25,823
Operating expenses:					
Selling, distribution and marketing	2,332	2,289	3,194	3,561	3,898
General and administrative	6,132	6,954	5,537	9,212	10,812
Research and development	2,629	2,979	6,344	8,451	10,265
Impairment of long-lived assets			623	185	157
Management fees and rent expense related party	125	138	921	204	359
Total operating expenses	11,218	12,360	16,619	21,613	25,491
Income (loss) from operations	(1,814)	(1,843)	(3,930)	(7,080)	332
Non-operating income (expense):					
Interest income	400	448	174	53	71
Interest expense	(104)	(59)	(1,322)	(2,010)	(2,141)
Gain from settlement with Organon				2,215	
Other income (expense), net	(135)	(448)	(15)	250	56
	161	(59)	(1,163)	508	(2,014)
Loss before income taxes	(1,653)	(1,902)	(5,093)	(6,572)	(1,682)
Provision for income taxes			98		
Net loss before extraordinary gain	(1,653)	(1,902)	(5,191)	(6,572)	(1,682)
Extraordinary gain, net of taxes			1,341		
Net loss	(\$1,653)	(\$1,902)	(\$3,850)	(\$6,572)	(\$1,682)
Net loss per share before extraordinary gain ⁽²⁾					
Basic	(\$0.06)	(\$0.06)	(\$0.15)	(\$0.19)	(\$0.05)
Diluted	(\$0.06)	(\$0.06)	(\$0.15)	(\$0.19)	(\$0.05)
Net loss per share ⁽²⁾					
Basic	(\$0.06)	(\$0.06)	(\$0.11)	(\$0.19)	(\$0.05)
Diluted	(\$0.06)	(\$0.06)	(\$0.11)	(\$0.19)	(\$0.05)
Weighted average shares outstanding					
Basic	26,741	31,592	33,520	34,597	36,104

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Years Ended December 31,

Diluted	26,741	31,592	33,520	34,597	36,104
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(1) Includes the results of operations of Armstrong since October 9, 2003.

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(2)

See Note 2 of Notes to Consolidated Financial Statements for a description of the method used to compute basic and diluted net income (loss) per share and the number of shares used in computing basic and diluted loss per share.

As of December 31,					
	2001	2002	2003	2004	2005
(in thousands)					
Consolidated Balance Sheet data:					
Cash, cash equivalents and restricted short-term investments	\$ 18,228	\$ 21,216	\$ 8,723	\$ 6,007	\$ 8,347
Working capital	18,002	29,453	9,266	9,468	28,779
Total assets	72,553	86,433	113,271	139,449	176,698
Long-term debt and capital leases, including current portion	15,843	4,097	21,604	30,112	34,939
Accumulated deficit	(9,427)	(11,329)	(15,179)	(21,751)	(23,433)
Total stockholders' equity	49,659	75,823	73,223	84,286	101,154

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

You should read this discussion together with our consolidated financial statements, the notes to such statements and the other financial information included in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the Section entitled "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company that is engaged in developing, manufacturing, acquiring, marketing, and selling generic and proprietary injectable and inhalation pharmaceutical products. Most of the 66 products we currently sell are used in hospital or urgent care clinical settings and are primarily sold through group purchasing organizations and drug wholesalers. We are also currently engaged in the development of our own branded product candidates that build on our scientific expertise in developing generic products.

In October 1998, we acquired International Medication Systems, Limited ("IMS") from Medeva PLC UK and in October 2003, we acquired Armstrong Pharmaceuticals, Inc. ("Armstrong") from Andrx Pharmaceuticals, Inc. The Armstrong acquisition gave us the rights to Albuterol CFC and included a one-year distribution agreement for that product with Andrx. In 2003, we also acquired the NDA to and trademark for Cortrosyn from Organon USA Inc. ("Organon") for a purchase price of \$28.0 million, originally payable as follows: \$16.0 million at closing, \$6.0 million in June 2004 and the remaining \$6.0 million in June 2005. In December 2004, the due dates of the two remaining payments were extended to June 2005 and February 2006 and the June 2005 payment was decreased to \$4.3 million as a result of Organon ceasing to manufacture the finished product for us pursuant to our contract during 2004. The \$4.3 million payment was made on June 24, 2005. In February 2006, we and Organon agreed to revise the payment terms for the remaining \$6 million payment. As a result, payments of \$1.0 million, \$1.0 million, \$1.0 million and \$3.0 million are due in March, April, May and June 2006, respectively. We also sold a royalty interest in the U.S. sales of Cortrosyn for \$8.0 million to Drug Royalty USA, Inc. in 2003. The Cortrosyn supply interruption in the second and third quarters of 2004 adversely impacted our sales, margins, profitability, and cash flow for that period. Prior to the supply interruption, our revenues from Cortrosyn for the first quarter of 2004 were \$4.99 million. In the two quarterly periods impacted by the supply interruption, our revenues from sales of Cortrosyn were \$1.35 million and \$2.54 million, respectively. In the fourth quarter of 2004, first quarter of 2005, second quarter of 2005, third quarter of 2005 and fourth quarter of 2005, revenues from sales of Cortrosyn were \$5.04 million, \$8.7 million, \$4.4 million, \$4.3 million and \$4.9 million, respectively. Our costs to produce this product are higher than what we paid Organon to supply this product to us, and therefore, we do not expect our profit margin for Cortrosyn to equal our profit margin prior to the supply interruption.

We generated net losses for the years ended December 31, 2003, 2004 and 2005, and had an accumulated deficit of \$23.4 million as of December 31, 2005. For the year ended December 31, 2005, we recorded a net loss of \$1.7 million.

Financial Overview

Net revenues and cost of sales. Our net revenues consist principally of revenue generated from the sale of our products. Included in net revenues are adjustments for estimated product returns and wholesaler chargebacks. Our cost of revenues consists of labor, raw materials, components, packaging, quality assurance and control, manufacturing overhead costs and cost of finished products purchased from third parties.

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Research and development. We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. Research and development costs consist primarily of salaries and other personnel-related expenses for employees involved with research and development activities, clinical trials and other related expenses. We expense research and development costs as incurred.

General and administrative expenses. General and administrative expenses consist primarily of salaries and benefits, professional services fees, facilities, stock compensation, and other corporate overhead costs. After this offering, we anticipate increases in general and administrative expenses as we add personnel, become subject to reporting obligations applicable to publicly-held companies and continue to develop and prepare for commercialization of our product candidates. The timing and the extent of legal fees related to product development and costs associated with public company compliance requirements could result in fluctuations of total general and administrative expense from period to period.

Selling, distribution and marketing expenses. Selling, distribution and marketing expenses consist primarily of shipping costs, salaries, other personnel-related expenses, as well as costs for travel, trade shows, conventions, promotional materials, catalogs, advertising, and promotion. We believe that our selling, distribution and marketing expenses will continue to increase as we grow our business and will increase due to expenses associated with product introductions.

Results of Operations

Year Ended December 31, 2004 and 2005

Net revenues. Net revenues were \$61.2 million and \$84.3 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$23.1 million, or 38%. The increase was primarily due to increased Cortrosyn sales of \$8.5 million and increased sales of inhalant products of \$6.7 million. Cortrosyn sales were higher in 2005 due primarily to our resolution of a supply interruption that we experienced in 2004.

Cost of revenues. Cost of revenues were \$46.7 million and \$58.5 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$11.8 million, or 25%. The increase was due to higher sales levels in the year ended December 31, 2005 compared to the prior year.

The gross profit margin was 24% and 31% for the years ended December 31, 2004, and 2005, respectively. The improvement in gross profit margin in 2005 primarily resulted from increased sales of Cortrosyn, our highest-margin product.

Selling, distribution and marketing. Selling, distribution and marketing expenses were \$3.6 million and \$3.9 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$0.3 million, or 9%. The increase was primarily due to higher distribution costs related to higher levels of sales in the year ended December 31, 2005.

General and administrative. General and administrative expenses were \$9.2 million and \$10.8 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$1.6 million, or 17%. This increase was primarily due to higher personnel costs resulting from increased staffing levels and increases in litigation expenses.

Research and development. Research and development costs were \$8.5 million and \$10.3 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$1.8 million, or 21%. The increase is primarily due to the payment of a \$0.7 million fee to the FDA at the time of filing the NDA for Ampofol and to increased clinical trial expenses.

Impairment of long-lived assets. Impairment of long-lived assets was \$0.185 million and \$0.157 million for the years ended December 31, 2004 and 2005, respectively, representing a decrease of \$0.028 million.

Management Fees and Rent Expense Related Party. Management fees and rent expense was \$0.20 million and \$0.36 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$0.16 million.

Interest Expense. Interest expense was \$2.0 million and \$2.1 million for the years ended December 31, 2004 and 2005, respectively, representing an increase of \$0.1 million.

Other income (expense). Other income was \$2.5 million and \$0.06 million for the years ended December 31, 2004 and 2005, respectively, representing a decrease of \$2.44 million.

Year Ended December 31, 2003 and 2004

Net Revenues. Net revenues were \$48.2 million and \$61.2 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$13.0 million, or 27%. This increase was principally due to Cortrosyn revenues and Albuterol revenues that were \$6.1 million higher and \$3.9 million higher, respectively, than in the prior period, and Amphadase revenues of \$1.6 million, which we introduced in the fourth quarter of 2004. Cortrosyn revenues for the year ended December 31, 2004 included a full year of revenues compared to six months of Cortrosyn revenues in fiscal 2003. Revenues from Albuterol commenced with our acquisition of Armstrong Pharmaceuticals in October 2003. The majority of Albuterol sales during 2004 were made to Andrx under a one-year distribution agreement that expired in 2004. We renewed the agreement in the fourth quarter of 2004 for one year with a subsidiary of Andrx. That subsidiary has a substantially lower purchase commitment than Andrx's commitment under the expired agreement. Revenues from contract manufacturing services were \$1.9 million in each of the years ended December 31, 2003 and 2004, respectively.

Cost of revenues. Cost of revenues was \$35.5 million and \$46.7 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$11.2 million, or 32%. Our gross profit in 2004 increased by \$1.8 million, while our gross profit margin decreased from 26% to 24%. Increases in sales volume in 2004 accounted for \$4.6 million or 41% of the increase in cost of revenues. \$6.6 million or 59% of the increase in cost of revenues was due to increases in manufacturing variances resulting from underutilization of plant capacity and a decrease in capitalized labor and overhead from capital projects in 2004.

Selling, distribution and marketing. Selling, distribution and marketing expenses were \$3.2 million and \$3.6 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$0.4 million or 13%. The increase was principally due to higher product distribution costs resulting from increased levels of product shipments.

General and administrative. General and administrative expenses were \$5.5 million and \$9.2 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$3.7 million, or 67%. This increase was primarily due to increases in patent infringement litigation expenses and higher personnel costs resulting from increased staffing levels.

Research and development. Research and development costs were \$6.3 million and \$8.5 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$2.2 million, or 35%. This increase was primarily the result of increased personnel costs from a higher headcount and clinical trial expenses.

Impairment of long-lived assets. Charges related to the impairment of long-lived assets were \$0.6 million and \$0.2 million for the years ended December 31, 2003 and 2004, respectively,

representing a decrease of \$0.4 million, or 67%. This decrease was primarily attributable to fewer discontinued capitalized projects in 2004.

Management fees and rent expense related party. Management fees and rent expense were \$0.9 million and \$0.2 million for the years ended December 31, 2003 and 2004, respectively, representing a decrease of \$0.7 million, or 78%. The decrease was due to the fact that an obligation to pay a management fee to APCL expired at the end of the 2003 fiscal year.

Interest expense. Interest expense was \$1.3 million and \$2.0 million for the years ended December 31, 2003 and 2004, respectively representing an increase of \$0.7, or 52%. We incurred higher levels of interest expense in 2004 that were partially offset by increased capitalization of interest expense resulting from higher levels of self-constructed assets that qualify for capitalization of interest.

Other income (expense). Other income (expense) was (\$0.015) million and \$0.25 million for the years ended December 31, 2003 and 2004, respectively, representing an increase of \$0.265 million. This increase was primarily due to the receipt of a \$0.5 million early termination fee from the tenant in one of our buildings in 2004. These gains were partially offset by a prepayment fee of \$0.5 million related to the refinancing of the mortgage debt on one of our buildings.

Provision for income taxes. Provision for income taxes decreased \$0.098 million in the year ended December 31, 2004 compared to the year ended December 31, 2003. In the year ended December 31, 2003, we recorded alternative minimum tax expense related to the utilization of net operating loss carryforwards.

Gain from settlement with Organon. We recorded a gain of \$2.2 million from a settlement with Organon related to a supply interruption.

Liquidity and Capital Resources

Through December 31, 2005, we financed our operations since inception primarily through sales of our products, private placements of equity securities totaling \$106.6 million, borrowings under various credit and leasing facilities, a product royalty sale and capital contributions from a related party, APCL.

As of December 31, 2005, we had \$6.8 million in cash and cash equivalents compared to \$4.3 million at December 31, 2004. Net cash provided by operating activities was \$0.05 million, which includes a net loss for the year of \$1.7 million and \$6.8 million of depreciation and amortization. During the year ended December 31, 2005, inventory increased \$17.4 million principally related to an increase in inventory awaiting regulatory approval. The increase in unearned payment from corporate partner is a \$4.5 million up-front payment related to a distribution agreement with Andrx Pharmaceuticals, Inc. The increase in accounts receivable of \$5.3 million from the beginning of the year is primarily due to higher sales levels in fiscal 2005. The increase in accounts payable, accrued expenses and deferred revenues of \$12.5 million is primarily related to accruals for the purchase of inventory and increased levels of deferred revenue and charge back accruals.

Net cash used in investing activities of \$16.4 million in 2005 is principally related to the purchase of machinery and equipment.

Net cash provided by financing activities of \$18.8 million in 2005 is primarily due to private placements of common stock totaling \$18.3 million and borrowings of \$28.4 million under financing arrangements with General Electric Capital Corporation ("GECC") and East West Bank, which were partially offset by a \$3.0 million payoff of outstanding debt under the Bank of the West line of credit, a \$6.2 million payoff of the outstanding debt under the Cathay Bank line of credit, principal payments on long-term debt of \$15.1 million, payments of deferred royalties of \$1.5 million and \$2.1 million of costs associated with our initial public offering.

As of December 31, 2004, we had \$4.3 million in cash and cash equivalents compared to \$8.1 million at December 31, 2003. Net cash used in operating activities was \$5.2 million for the year ended December 31, 2004, principally due to a loss for the year and includes the adverse effects of lost sales of Cortrosyn resulting from a supply interruption. Purchases of components for products awaiting regulatory approval were offset by increases in accounts payable and accrued liabilities. Net cash used in investing activities in the year ended December 31, 2004 was \$20.8 million due to \$17.0 million in purchases of property, plant, and equipment, \$2.2 million in capitalized labor, interest and overhead on self-constructed assets, \$2.0 million for the purchase of product rights to Epinephrine Mist CFC and \$1.1 million for purchases of marketable securities and short-term investments, offset by \$1.4 million in proceeds from sales of a building and a parcel of land. Cash flow received from financing activities of \$22.2 million in the year ended December 31, 2004 was principally the result of a \$15.6 million private placement in the first half of fiscal 2004 and increased borrowings.

In August and September 2005, we borrowed an aggregate of \$20.0 million under a loan agreement with GECC. We used \$5.0 million of the proceeds to purchase new equipment and \$2.2 million to pay all outstanding borrowings under the prior credit facility with Cathay Bank and the remainder was added to working capital. The loans are secured by the a building and equipment at our Rancho Cucamonga facility and certain other equipment at our other facilities. The loans are payable in 48 equal monthly installments with one final payment of all outstanding interest and principal. The initial interest rate is a variable per annum interest rate equal to the three month London Interbank Offered Rate ("LIBOR") plus 5.52% per annum. The interest rate may be reduced to LIBOR plus 3.50% if we attain certain debt service coverage ratios beginning in the fourth quarter of 2005. Our loan agreement requires us to maintain a debt service coverage ratio of at least 1.40 to 1.0. As of December 31, 2005, we were not in compliance with the GECC covenant requiring a debt service coverage ratio of 1.40 to 1.0, or greater. Subsequent to December 31, 2005 we obtained a waiver of the debt service coverage ratio covenant for the period ending December 31, 2005, and a modification of the March 31, 2006 debt service coverage ratio covenant to 1.0 to 1.0.

In September 2005 the Company and IMS entered into loan facilities with East West Bank to repay all borrowings outstanding under our prior Bank of the West facilities and to provide additional loan availability. We entered into a secured term loan with East West Bank in the principal amount of \$5.0 million which matures in October 2010. The loan is payable in monthly installments with a final payment of the majority of the principal at maturity. The loan is guaranteed by IMS and is secured by one of the buildings at our Rancho Cucamonga headquarters complex. The variable interest rate is equal to the three month LIBOR plus 2.5%. Additionally, the entire amount becomes due if any of IMS's credit facilities with East West Bank are repaid in full.

In September 2005, IMS also entered into a secured term loan facility in the amount of \$4.0 million secured by equipment held by IMS, a revolving credit facility in the amount of \$5.0 million secured by inventory, accounts receivables and general intangibles of IMS, and an equipment line of credit in the amount of \$5.0 million to be secured by new equipment purchased with such proceeds. The term loan matures in September 2009 and the revolving credit facility and equipment line of credit mature in September 2006. Each of the loans are guaranteed by the Company. IMS has not drawn any funds under the revolving credit facility or the equipment line of credit. All three loans contain financial covenants requiring IMS to maintain an effective tangible net worth of at least \$20.0 million, a debt to effective tangible net worth of at least 1.3 to 1 and a debt coverage ratio of at least 1.45 to 1. Interest on all three is variable and equal to the daily Wall Street Journal Prime Rate.

In January 2006, we completed a private placement pursuant to Regulation S promulgated under the Securities Act of 1933 issuing 500,000 shares of our common stock at a price of \$20.00 per share for gross cash proceeds of \$10.0 million.

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In June 2005, we entered into a subscription agreement with an institutional investor whereby the investor agreed to purchase up to 633,000 shares of our common stock. Pursuant to this Regulation S private placement, in June 2005, we sold 417,000 shares of our common stock at a purchase price of \$15.80 per share for aggregate gross cash proceeds of \$6.6 million, and in July 2005, we sold 90,000 shares of our common stock at a purchase price of \$20.00 per share for gross proceeds of \$1.8 million.

In December 2004, we signed a supply agreement with Wyeth in which we will provide technology transfer and development services to the customer prior to manufacturing a bronchodilator product for it. The agreement provides for non-refundable aggregate payments to us of up to \$1.2 million for technology transfer to be received in December 2004, January 2005 and upon shipment of the first lot of product to the customer. As of December 31, 2005, we had received \$1.0 million in payments pursuant to the agreement.

On May 2, 2005, we entered into an agreement to grant certain exclusive marketing rights for our enoxaparin product candidate (the "Product") to Andrx Pharmaceuticals, Inc. ("Andrx"). Andrx's marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain these rights, Andrx made an up-front payment to us of \$4.5 million upon execution of the agreement. In addition, in the event Andrx elects to participate in the commercial launch of the Product, Andrx will make an additional \$5.5 million payment to us once certain milestones relating to the Product are achieved, including obtaining FDA marketing approval. Under the agreement, we will receive 50% to 60% of the gross profit from Andrx's sales of the Product in the Territory. In the event that we provide notice to Andrx of our intention to launch the Product at risk, and Andrx elects not to participate in such a launch, or we fail to provide Andrx with written notice of our intent to launch by June 30, 2006, then thereafter, Andrx will have the option to demand a refund of the \$4.5 million up-front payment to us. In this case, we may elect to refund the up-front payment in one lump sum or in installments over the course of a year.

In February 2005, we completed a private placement of 675,676 shares of our common stock at a purchase price of \$14.80 per share for aggregate gross proceeds of \$10.0 million.

Set forth below are our contractual payment obligations (including interest obligations but excluding intercompany obligations) as of December 31, 2005 (in thousands):

Contractual Obligations	Total	2006	2007	2008	2009	2010	Beyond 2010
Long-term Debt ⁽¹⁾	\$ 41,148	\$ 13,533	\$ 7,549	\$ 9,025	\$ 6,234	\$ 4,807	\$
Operating Leases	15,493	4,466	2,839	2,684	2,303	2,063	1,138
Capital Leases	134	38	38	26	26	6	
Purchase Obligations ⁽²⁾	3,537	3,537					
Deferred Royalty Payments ⁽³⁾	7,301	2,578	2,576	2,147			
Total	\$ 67,613	\$ 24,152	\$ 13,002	\$ 13,882	\$ 8,563	\$ 6,876	\$ 1,138

(1) Long-term Debt includes the remaining payments owed by us to Organon relating to the purchase of Cortrosyn.

(2) The purchase obligations principally relate to pharmaceutical manufacturing and laboratory equipment. We anticipate meeting these purchase obligations through a combination of cash on hand, future cash flows from operations and debt and lease facilities. We have made deposits on these obligations totaling \$2,602 as of December 31, 2005.

(3) We have recorded the \$8.0 million in consideration received from Drug Royalty, USA, Inc. as debt and have classified the liability as deferred royalties on the accompanying consolidated balance sheets. The debt is amortized using the effective interest method. Payments are contingent on sales and the payments due by period under this obligation are based on estimates of future sales.

We intend to use a portion of the net proceeds from this offering to upgrade, renovate and equip an additional building at our headquarters complex. We expect that the building renovation will include the addition of a 110,000 square foot second floor and, when finished, that the building will provide

four additional manufacturing lines, 32,000 square feet for research and development activities, and more than 100,000 square feet of space for administrative and general use. We estimate that the costs to upgrade, renovate and equip the building will aggregate up to \$45.0 million, comprised of approximately \$20.0 million for construction, \$10.0 million for laboratory equipment and \$15.0 million for manufacturing and utility equipment. If possible, we may finance up to \$20.0 million of these costs under equipment financing facilities. We do not currently have any commitments with respect to the proposed building renovation, but anticipate that following the offering we will move forward with the project, which could take 18 months or more to complete.

We expect our cash requirements to increase significantly in the foreseeable future as we move forward with our product candidates, and to sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our development-stage current product candidates.

We expect that the proceeds from the offering, the proceeds from our private placements in 2005 and 2006, our 2005 loans from GECC and East West Bank, the \$4.5 million up-front payment from Andrx relating to the enoxaparin distribution agreement and cash flows from our existing products will enable us to meet our obligations as they become due for the foreseeable future, including scheduled debt and lease payments. We expect additional cash flows to be generated from future contract manufacturing agreements and potential strategic alliances such as the Wyeth supply agreement and the Andrx distribution agreement.

If our cash flow from operations is not sufficient to meet our obligations as they come due, then we may seek to reschedule debt payments and/or seek additional equity and debt financing. Alternative sources of sufficient financing may not be available to us on acceptable terms, or at all. If we are not able to reschedule debt payments and/or obtain funding from these financing activities, we will consider postponing research and development expenditures and postponing the acquisition of property, plant and equipment. A lack of sufficient cash flow could result in fewer funds for the development of our early-stage product candidates, which are described in the "Business" section. We expect that we will be able to meet our cash flow requirements for the next twelve months.

As of December 31, 2003, 2004 and 2005, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk is interest rate sensitive investments and credit facilities, which are affected by changes in the general level of U.S. interest rates. Due to the nature of our short-term investments (i.e., certificates of deposit), we believe that we are not subject to any material interest rate risk.

As of December 31, 2005, we had \$34.9 million in long-term debt and capital leases outstanding. Of this amount, \$28.9 million had variable interest rates with a weighted average interest rate of 9% at December 31, 2005. A 1% (100 basis points) increase in the index underlying these rates would increase our annual interest expense on the variable-rate debt by approximately \$289,000 per year.

Most foreign sales are negotiated with payment terms in U.S. dollars. Therefore, we have limited exposure to foreign currency price fluctuation. Further, we have has no derivative financial instruments.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles. The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. In some cases changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. We refer to accounting estimates of this type as critical accounting policies, which we discuss further below. Our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included in this prospectus.

Revenue Recognition

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products. Net revenues reflect adjustments to gross revenues for estimated product returns and wholesaler chargebacks, which are recorded in the same period that the related revenues are recorded. Generally, we recognize revenues at the time of product delivery for domestic customers and the time of product shipment for foreign customers.

Contract manufacturing service revenues are recognized when development and other services are provided and/or products are shipped to customers. In accordance with SEC Staff Accounting Bulletin, or SAB, No. 101, Revenue Recognition in Financial Statements, as well as recently issued SAB No. 104, Revenue Recognition, we recognize revenues when persuasive evidence of an arrangement exists, transfer of title has occurred, the price to the customer is fixed or determinable and collection of the resulting receivable is reasonably assured. In addition, we do not recognize revenues until all customer acceptance requirements have been met.

In accordance with EITF Issue No. 00-21, our accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenue is recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. In connection with our underlying supply agreement with Wyeth, we will recognize revenue from non-refundable, up-front fees over the four year term of the agreement. As of December 31, 2005, we had received \$1.0 million in non-refundable payments from Wyeth, the recognition of which has been deferred. Revenue recognition will commence with the first product delivery under the agreement and will be recognized over the remaining term of the supply agreement.

Deferred Royalty Payments

We have recorded the proceeds from DRC that were received in exchange for a five-year royalty on the future U.S. net sales of Cortrosyn as interest bearing debt pursuant to EITF 88-18 "Sales of Future Revenues." We recognize interest expense on this debt using the effective interest method over the course of the five-year royalty. The amount of interest expense is calculated using an imputed interest rate equivalent to the projected internal rate of return that DRC would receive based on total estimated future royalty payments. We review our estimates of future royalty payments on a regular basis. Changes in estimated future royalties and differences between actual future payments and expected payments will result in a change to that interest rate, which will be applied prospectively.

The imputed interest rate calculated for this obligation during the period from the loan origination date through December 31, 2004, was 16.77%. The weighted average imputed interest rate calculated

for this obligation for the year ended December 31, 2005, was 18%. The current imputed interest rate for this obligation at December 31, 2005 is 19.5%. A 5% increase in future royalty payments would result in an imputed interest rate of 23.10% and would increase interest expense \$345,000 over the remaining term of the royalty agreement.

Impairment of Long-Lived Assets

We review long-lived assets and certain identifiable assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount exceeds the fair value of the assets (assets to be held and used) or fair value less cost to sell (assets to be disposed of).

Accrual for Wholesaler Chargebacks

The provision for chargebacks is a significant estimate used in the recognition of revenue. As part of our sales terms to wholesale customers, we agree to reimburse wholesalers for differences between the gross sales price of products we sell to wholesalers and expected retail prices of such products under contractual arrangements with third parties such as hospitals and group purchasing organizations. We estimate wholesaler chargebacks at the time of sale based on the terms of agreements with customers, our chargeback processing experience, external information on wholesaler inventory stocking levels, historic charge-back rates and current contract pricing.

The following table is an analysis of chargebacks:

	Years ended December 31,	
	2004	2005
	(amounts in thousands)	
Beginning balance	\$ 3,982	\$ 3,673
Provision related to sales made in the current period	28,741	40,249
Provision related to sales made in prior periods		68
Payments related to sales made in the current period	(25,068)	(33,694)
Payments related to sales made in prior periods	(3,982)	(3,741)
Ending balance	\$ 3,673	\$ 6,555

Changes in chargeback accruals from period to period are primarily dependent on the level of inventory held at the wholesalers and variations in the estimate can occur as a result of changes in the wholesaler customer mix. The approach that we use to estimate chargebacks has been consistently applied for all periods presented. We have found that our procedures for estimating charge backs have provided accurate estimates of this liability in the past; variations have been historically low. We believe that our approach will continue to provide accurate estimates in the future. We continually monitor the provision for chargebacks and make adjustments when we believe that the actual chargebacks may differ from estimates. Settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

Accrual for Product Returns

We offer customers the right to return qualified excess or expired stock ("qualified returns") for credit. We estimate amounts that may be incurred under our product return policies and record an accrual in the amount of such costs at the time product revenue is recognized. The accrual for estimated product returns is based, in part, upon the historical relationship of product returns to sales,

but we also consider amended contract terms. We classify a portion of the accrual as a long-term obligation to reflect qualified sales, which do not become eligible for return credit under the policy until one year after the balance sheet date. The approach that we use to estimate product returns has been consistently applied for all periods presented. We have found that our procedures for estimating product returns have provided materially accurate estimates of this liability in the past and believe that our approach will continue to provide materially accurate estimates in the future.

The following table is an analysis of product returns:

	Years ended December 31,	
	2004	2005
	(amounts in thousands)	
Beginning balance	\$ 876	\$ 778
Provision related to sales made in the current period	360	810
Provision related to sales made in prior periods	54	124
Returns related to sales made in the current period		
Returns related to sales made in prior periods	(512)	(470)
Ending balance	\$ 778	\$ 1,242

Actual returns principally relate to the return of expired product from sales made in prior periods.

During the year ended December 31, 2005, we recorded a provision for returns using a rate of 0.6% of qualified sales. If the returns provision percentage were to increase by 0.1% of qualified sales, then an additional provision of \$0.25 million would result.

Stock-based compensation

As permitted by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), and as amended by SFAS 148, "Accounting for Stock-Based Compensation Transition and Disclosure," we account for stock options granted to our employees and nonemployee members of the board of directors in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations. Under APB 25, no compensation expense is recorded if the exercise price of the stock options is equal to or greater than the market price of the underlying stock on the date of grant. Options granted to nonemployees have been accounted for at deemed fair market value in accordance with SFAS 123.

The Board of Directors, in determining the fair market value of our common stock, considers numerous factors, including recent cash sales of common stock to independent third party investors and new business and economic developments affecting us. No valuation specialist was used to determine fair value, for purposes of establishing exercise prices of our options.

The exercise prices of stock option grants to our employees are typically set at the last independent third party cash sale of our common stock. If there have been new business or economic developments affecting us since the last third party cash sale that the Board has determined changes the fair market value of our common stock, the stock option exercise price is typically set at such changed fair market value at the time of grant. Management believes that this approach provides the best evidence of fair value, and thus, is the required valuation method under generally accepted accounting principles. The determination of the fair market value of our common stock is performed on a contemporaneous basis at the time of the granting of equity instruments.

Deferred Taxes

We recognize deferred tax assets and liabilities based on the differences between the financial statement carrying values and the tax bases of assets and liabilities. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical taxable income, projected future taxable income, and the expected timing of the reversals of existing temporary differences. We have a history of losses from our operations, which generated significant federal and state net operating loss carryforwards. We record a valuation allowance against deferred tax assets if we believe that we are not likely to realize future tax benefits. A change in trend to recurring quarterly profits would be a basis for concluding that we would be able to realize a portion of the deferred tax assets, and therefore, reverse a portion of the valuation allowance. Subsequent adjustments to our estimates of our ability to recover the deferred tax assets or other changes in circumstances or estimates could cause our provision for income taxes to vary from period to period.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (the "FASB") issued Statement No. 151, "Inventory Costs - an amendment of ARB No. 43." This Statement clarifies the accounting for abnormal amounts of certain inventory cost components and requires the allocation of fixed production overheads to the costs of conversion to be based on the normal capacity of the production facilities. This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. However, we have early adopted Statement No. 151 as of December 31, 2005. The adoption of this statement did not have a material impact on the Company's consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment," which requires companies to measure and recognize compensation expense for all equity-based payments at fair value. In April 2005, the Securities and Exchange Commission amended the effective date of SFAS No. 123(R) to the first interim period of the first fiscal year beginning after June 15, 2005. We intend to adopt the new standard during the first quarter of 2006, as required, under the modified-prospective method.

Under the modified-prospective method, our equity-based compensation expense will include expense amortization related to grants that were issued prior to the implementation of SFAS No. 123(R). This expense is expected to be comparable to pro-forma levels reported in the past and is considered significant in relation to our historic results of operations.

We are currently evaluating our policy regarding the use of options as employee compensation. The financial significance of equity-based compensation expense related to potential future grants issued after implementation of SFAS No. 123(R) will depend on a number of factors, including the amount of awards granted and the fair value of those awards at the time of grant.

In November 2005, the FASB issued FASB Staff Position ("FSP") No. FAS 123(R)-3, "Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards." This FSP provides a practical transition election related to accounting for the tax effects of share-based payment awards to employees as an alternative to the transition guidance for the APIC pool in paragraph 81 of Statement 123(R). The guidance in this FSP is effective after November 10, 2005 as posted to the FASB website. We may take up to one year from the later of adoption of SFAS 123(R) or the effective date of this FSP to evaluate its available transition alternatives and make its one-time election. We will evaluate this guidance, but do not expect a material impact on our results of operations or financial position.

BUSINESS

Overview

We are a specialty pharmaceutical company that develops, manufactures, markets, and sells generic and proprietary injectable and inhalation products. We currently manufacture and sell 66 products and are continuing to develop a portfolio of generic and branded products that targets large markets with high technical barriers to entry. Our manufacturing sites are capable of producing a broad range of dosage formulations including solutions, emulsions, suspensions, jellies, lyophilized, or freeze-dried, products, as well as metered-dose inhalers and nasal sprays. We have long-standing relationships with all of the major group purchasing organizations and drug wholesalers in the U.S. that deliver products to our end markets, which we believe will enable us to rapidly introduce new products and quickly establish significant market share.

We began our operations in February 1996 with a strategic of focusing on manufacturing and selling generic injectable products. To complement our internal growth, we acquired International Medication Systems, Limited ("IMS") in October 1998 and Armstrong Pharmaceuticals, Inc. ("Armstrong") in October 2003 as well as the NDA to Cortrosyn in June 2003 and the ANDA for a generic version of Primatene Mist in July 2004. As we expanded our infrastructure and developed our research and development expertise, our strategic focus has evolved into developing products for large markets with high technical barriers to entry. We believe these product candidates will generate higher margins for a longer period of time than products that face more substantial competition.

We are specifically focused on applying our technical expertise to develop products that:

require an active pharmaceutical ingredient, that is difficult to source and/or manufacture;

involve complex manufacturing;

address deficiencies in the innovator's product formulation; and/or

improve upon an existing product through the use of drug delivery technology we have developed.

Our portfolio of product candidates that we are developing includes enoxaparin, a generic formulation of the anti-coagulant, Lovenox, and Ampofol, a proprietary formulation of the general anesthetic, Diprivan. According to IMS Health Incorporated ("IMS Health"), an independent provider of statistical information on the pharmaceutical industry, the currently marketed versions of these products generated combined sales in the U.S. in 2005 in excess of \$2.4 billion. We are also developing product candidates based on our proprietary sustained-release technology platform.

Our Competitive Advantages

We have built our company by integrating the capabilities we believe are essential to compete effectively in the pharmaceutical industry, including:

Experienced product development team. Our product development team consists of 40 people, 11 of whom have Ph.D.s, with expertise in areas such as pharmaceutical formulation, process development, *in vivo* study, analytical chemistry, drug delivery, and clinical research. This expertise has enabled us to focus on product candidates that are difficult to develop and/or manufacture. Our substantial research and development resources have allowed us to accelerate product development timelines and build a portfolio of technically sophisticated product candidates.

Comprehensive manufacturing capabilities. We manufacture pharmaceutical products in multiple dosage formulations, including solutions, emulsions, suspensions, jellies, and lyophilized products, as well as metered-dose inhalers and nasal sprays. We own seven aseptic filling lines and four

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metered-dose inhalers/nasal spray filling lines. In addition, we are currently planning to upgrade, renovate and equip an additional manufacturing and development building at our headquarters complex. During 2005 we produced approximately 16.0 million injectable units and five million metered-dose inhaler units. We believe our manufacturing capabilities enable us to compete effectively in our markets.

Ability to develop and manufacture active pharmaceutical ingredients. One aspect of our development strategy is to focus on products that are difficult to manufacture because the active pharmaceutical ingredient is not easily obtained. For example, our research and development team has developed a multi-step chemical process for converting raw material into the active pharmaceutical ingredient for enoxaparin. This expertise enables us to pursue the development of other products we identify with active pharmaceutical ingredients that are difficult to source and/or manufacture.

Proprietary drug delivery technology. Through our research and development efforts we have developed a proprietary technology or platform focused on the improvement of drug delivery. Our sustained-release technology has enabled us to formulate injectable product candidates that are designed to allow single injections to be effective over an extended period. We have multiple product candidates in early stages of development that utilize our proprietary platform. In addition, our prefilled disposable pipette technology is a new unit-dose drug delivery system designed to allow for solutions, lotions, creams, jellies, or syrups with a variety of potential applications.

Strong group purchasing organization and wholesaler relationships. We have long-standing relationships with all of the major group purchasing organizations and wholesalers in the U.S. Group purchasing organizations and wholesalers are essential members of the distribution channel to hospitals, long-term care facilities, alternate care sites, clinics, and doctors' offices where our products are used. We believe the breadth and composition of our product portfolio, which is comprised of 66 products, enhances our relationships with these group purchasing organizations and wholesalers. Our relationships with these group purchasing organizations and wholesalers give us access to most, if not all, of the injectable markets in the U.S.

Our Strategy

Our goal is to be an industry leader in the development, manufacture, and marketing of injectable and inhalation pharmaceutical products. To achieve this goal, we are pursuing the following key strategies:

Focus on high margin generic product opportunities. We believe we have significant opportunities for growth driven by our technical expertise in the development of product candidates with high technical barriers to entry. We expect these product candidates are likely to face more limited competition, if commercialized, than other generic products, which should enable us to earn higher margins for a longer period of time. Generic competition for these products is likely to be limited because of complexities in product development, including the need for specialized research and development skill sets and manufacturing capabilities. Two of our generic product candidates with high barriers to entry are enoxaparin and medroxyprogesterone.

Develop proprietary products utilizing our technical expertise. We are applying our expertise in drug formulation to develop proprietary versions of existing products that address deficiencies in those products. We are also developing proprietary products that utilize our sustained-release technology. We believe applying this expertise and these technologies will enable us to develop proprietary products with differentiated characteristics. Examples of our proprietary product candidates that capitalize on our technological capabilities are Ampofol and Amphacaine, a sustained-release analgesic product candidate.

Enhance our sales, marketing, and distribution capabilities. We intend to continue to maintain our strong relationships with the leading group purchasing organizations and wholesalers in the U.S. We also expect to expand our internal sales and marketing capabilities, and in some cases, enter into strategic alliances to license our products to other pharmaceutical companies, in order to ensure maximum market penetration for our product candidates.

Complement internal growth with strategic acquisitions. In addition to making significant investments in internal product development, we have enhanced and may continue to enhance our competitive position by acquiring products or companies with complementary products and technologies. For example, in 2003 and 2004, we expanded our product portfolio through the acquisition of Armstrong, the purchase of the rights to Cortrosyn, an injectable diagnostic agent, from Organon USA Inc. ("Organon") and its affiliates, and the purchase of the rights to Epinephrine Mist from Alpharma USPD ("Alpharma"). In addition to acquisitions, we may seek to in-license rights to pharmaceutical products that leverage our existing infrastructure.

Our Existing Products and Services

The following table lists the net revenues attributable to each of our significant products or product categories for each of the last three fiscal years (in thousands):

Product	2003	2004	2005
Cortrosyn	\$ 7,863	\$ 13,924	\$ 22,374
Lidocaine Jelly	10,890	11,031	11,505
Epinephrine Mist CFC		415	6,954
Albuterol CFC	2,877	6,807	6,819
Critical Care Drug Portfolio	15,424	16,051	18,876

We currently manufacture and sell 66 generic injectable and inhalation products. For the year ended December 31, 2005, we recorded net revenues of \$84.3 million, including \$4.4 million in contract development and manufacturing services. The following is a description of significant products or product families in our existing portfolio.

Cortrosyn

Cortrosyn (cosyntropin for injection) is a sterile lyophilized powder that is currently the only FDA-approved product indicated for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency. Symptoms of this condition include impaired renal function, weight loss, fatigue, and hypoglycemia. We acquired the U.S. and Canadian product rights to Cortrosyn from Organon and its affiliates in June 2003 and August 2003, respectively. As part of the transaction, Organon agreed to manufacture finished product for us for three years following the date of closing. In February 2004, we were notified that Organon's facility was flooded and in April 2004, Organon informed us it would have to cease production. We transferred the manufacturing from Organon's facility to one of our facilities and began manufacturing and selling this product in August 2004. Initially, we were approved to sell the product with a label indicating six months of expiration dating. In December 2004, the FDA allowed us to extend the expiration dating to 24 months, which was the dating on the product when it was being manufactured by Organon.

In August 2003, we entered into a Royalty Purchase Agreement with Drug Royalty USA, Inc. ("DRC"), whereby DRC provided \$8 million in cash to us in exchange for a royalty on the future U.S. net sales of Cortrosyn. We have recorded the consideration received from DRC as debt, which is classified as deferred royalties on the accompanying consolidated balance sheets. We amortize the obligation using the effective interest method and utilize an imputed interest rate equivalent to the projected internal rate of return that DRC would receive based on total estimated future royalty

payments. DRC has a secured interest in Cortrosyn intellectual property that is subordinate to Organon's, in addition to a secured interest in Cortrosyn inventory and accounts receivables resulting from the sale of Cortrosyn. Pursuant to the royalty agreement, royalties are due quarterly through 2008. Royalties to be paid to DRC are calculated based upon net sales. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and " Manufacturing" for further information about the acquisition and manufacturing of Cortrosyn.

Lidocaine Jelly

Lidocaine jelly is a local anesthetic product used primarily for urological procedures. We manufacture lidocaine jelly in a prefilled syringe with a specially designed proprietary applicator called the Uro-Jet®. Our Uro-Jet delivery system offers the only method for the administration of lidocaine jelly prior to urologic procedures, which reduces patient discomfort. Our product is a single-use system that eliminates the need to add preservatives to prevent microbial growth. Competing lidocaine jelly products are manufactured in an aluminum tube containing preservatives, and must be applied during (not prior to) the urological procedure.

Epinephrine Mist CFC

Epinephrine Mist CFC is a bronchodilator product used for fast-acting relief of bronchial asthma. We acquired the ANDA for a generic version of Primatene Mist from Alpharma in July 2004. Alpharma had ceased marketing Primatene Mist in 2001 and until we reintroduced this product to the market in December 2004, Epinephrine Mist CFC was only available from the innovator, Wyeth. We have entered into a four-year supply agreement with Wyeth to provide technology transfer and development and manufacturing services for Primatene Mist.

Albuterol CFC

Albuterol CFC is a bronchodilator product used for the prevention and relief of bronchospasm associated with asthma and other respiratory conditions. This metered-dose inhaler product contains the propellant chlorofluorocarbon, or CFC, a substance that has been shown to deplete the ozone layer in the atmosphere. As a result, the FDA has issued a final rule that albuterol metered-dose inhalers using CFC propellants may not be marketed or sold in the U.S. after December 31, 2008. We are currently working on an Albuterol HFA product that is formulated with hydrofluoroalkane, or HFA, a non-ozone depleting chemical propellant. We began clinical trials on our Albuterol HFA product candidate in February 2005 and we expect to file a 505(b)(2) NDA with the FDA in 2007. We do not expect the phaseout of our CFC product to have any effect on our operations or financial condition as we plan to have the HFA product on the market on or before the phaseout date.

Critical Care Drug Portfolio

We market more than 20 drugs in prefilled syringes, such as atropine, epinephrine, lidocaine, naloxone, and sodium bicarbonate, which are designed for use in emergency room and other critical care settings. We believe we are one of only two companies in the U.S. that offer a full portfolio of critical care drug products in syringe form. We also market and sell critical care drug products in the United Kingdom and Australia through a distributor.

Contract Services

We manufacture products for pharmaceutical and biotechnology companies pursuant to contractual arrangements and also provide formulation and other product development services to these companies. In December 2004, we signed a supply agreement with Wyeth to provide technology transfer and development services and to manufacture Primatene Mist for Wyeth over a period of four years. The agreement provides for aggregate payments to us of up to \$1.2 million for technology transfer. To date, we have received \$1.0 million of such payments.

Our Product Candidates

The table below lists the significant product candidates that we are currently developing:

Product Candidate	Reference Drug(1)	Therapeutic Classification	Regulatory Path(2)	FDA Filing/ Expected Filing Date
Enoxaparin	Lovenox	Anticoagulant	ANDA	Q1 2003 ⁽³⁾
Medroxyprogesterone	DepoProvera	Contraceptive	ANDA	Q3 2004 ⁽³⁾
Ampofol	Diprivan	General Anesthetic	505(b)(2) NDA	Q3 2005 ⁽³⁾
Fluticasone propionate	Flonase (nasal) Flovent (inhaler)	Anti-allergic; Anti-inflammatory	ANDA ANDA	Q2 2006 2007
Azithromycin	Zithromax (azithromycin for injection)	Antibiotic	ANDA	Q2 2006
Albuterol HFA	Proventil, Ventolin	Bronchodilator	505(b)(2) NDA	2007
Amphacaine		Local Analgesic	NDA	2008
Epinephrine Mist HFA	Epinephrine CFC	Bronchodilator	505(b)(2) NDA	2008

- (1) Reference drug means the listed drug identified by the FDA as the drug product upon which an applicant relies in seeking approval of an ANDA. Patents for Flovent, Lovenox, Proventil and Ventolin expire in 2017, 2012, 2015 and 2017, respectively. The patents relating to the reference drugs for our other product candidates have already expired.
- (2) See " Regulatory Considerations" for information regarding the regulatory approval processes for the indicated submissions.
- (3) Filed.

Set forth below are descriptions of the product candidates listed in the above table.

Enoxaparin

Enoxaparin is an injectable, low molecular weight heparin, a class of medication used as a blood thinner, or anticoagulant, to prevent clotting of blood in the vein, commonly referred to as deep vein thrombosis, and acute coronary syndromes. Enoxaparin is currently sold by Sanofi-Aventis ("Aventis") under the brand-name Lovenox. Aventis' sales of Lovenox in the U.S. in 2005 totalled approximately \$1.8 billion, according to IMS Health.

We filed an ANDA for enoxaparin sodium with the FDA in March 2003, which was accepted by the FDA in April 2003. At the time we filed our ANDA with the FDA, Aventis had two listed patents for Lovenox in the FDA's Orange Book, which is the FDA's listing of approved drug products. In connection with our filing, we certified to the FDA that the existing patents in connection with Lovenox were invalid, unenforceable or will not be infringed by our generic product candidate. Teva, Inc. has also filed an ANDA for enoxaparin. Aventis brought a patent infringement lawsuit against both us and Teva in August 2003. In June 2005, the U.S. District Court for the Central District of California granted summary judgment in our favor in the lawsuit. The final judgment was entered by the District Court on July 25, 2005 and in September 2005, Aventis filed an appeal of the District Court's decision with the U.S. Court of Appeals for the Federal Circuit. The parties argued the appeal before the Federal Circuit in January 2006. In addition, in February 2003, Aventis filed a citizen petition with the

FDA requesting, among other things, that the FDA refrain from approving any ANDA for a generic version of Lovenox unless certain conditions are satisfied. See "Business Legal and Regulatory Proceedings Enoxaparin Paragraph IV Litigation" and " Enoxaparin Citizen Petition" and "Business Regulatory Considerations Generic Drug Approval" for additional information. In connection with the FDA's review of our ANDA for enoxaparin sodium, the FDA has made several comments and requests for data in the areas of chemistry, bioequivalence and labeling. We have filed with the FDA data from an FDA-requested bioequivalence study in humans and additional information on our raw material, active pharmaceutical ingredient and finished product, as well as certain product characterization data. In August 2005, Momenta Pharmaceuticals, Inc. filed an ANDA with the FDA for enoxaparin.

Enoxaparin is difficult to manufacture because the active pharmaceutical ingredient is not easily obtained. Our research and development team has developed a multi-step chemical process for converting raw heparin, the starting material, to the active pharmaceutical ingredient, which we believe overcomes technical barriers to producing the active pharmaceutical ingredient.

On May 2, 2005, we entered into an agreement to grant certain exclusive marketing rights for our enoxaparin product candidate (the "Product") to Andrx Pharmaceuticals, Inc. ("Andrx"). Andrx's marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain these rights, Andrx made an up-front payment to us of \$4.5 million upon execution of the agreement. In addition, in the event Andrx elects to participate in the commercial launch of the Product, Andrx will make an additional \$5.5 million payment to us once certain milestones relating to the Product are achieved, including obtaining FDA marketing approval. Under the agreement, we will receive 50% to 60% of the gross profit from Andrx's sales of the Product in the Territory. In the event that we provide notice to Andrx of our intention to launch the Product at risk, and Andrx elects not to participate in such a launch, or we fail to provide Andrx with written notice of our intent to launch by June 30, 2006, then thereafter, Andrx will have the option to demand a refund of the \$4.5 million up-front payment to us. In this case, we may elect to refund the up-front payment in one lump sum or in installments over the course of a year.

Medroxyprogesterone

Medroxyprogesterone acetate, or MPA, a progesterone derivative, is an injectable sustained-release contraceptive product candidate with a duration of greater than three months. Pfizer Inc. markets the product under the brand-name DepoProvera. Patents covering DepoProvera expired in 1994. Until July 2004, when Teva Pharmaceutical USA, Inc. announced FDA approval of its generic version of DepoProvera, there had been no generic competition for this product because of its sustained-release complexities. According to IMS Health, U.S. sales of DepoProvera and its generic equivalent were approximately \$217 million in 2005. Our research and development team utilized its expertise in formulation of sustained-release products to overcome the technical difficulties presented by MPA. We filed the ANDA for this product in the third quarter of 2004. In November 2004, a Black Box Warning was added to the labeling of DepoProvera that cautions of the potential for significant bone loss with increasing duration of use of MPA. We would be required to include this warning if we market our MPA product candidate, which could deter long-term use of the product.

Ampofol

Ampofol is our proprietary 1% propofol injectable emulsion product candidate. Propofol is currently manufactured and sold by AstraZeneca PLC under the trade name Diprivan and as a generic by a (i) joint venture of Baxter Healthcare Corporation ("Baxter") and Gensia Sicor Pharmaceuticals ("Gensia"), a predecessor of Teva and (ii) Bedford Laboratories. Combined sales in the U.S. in 2005 for these products was approximately \$522 million, according to IMS Health. Propofol is used for general anesthesia, monitored anesthesia care sedation, and sedation in the intensive care unit, or ICU, setting.

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AstraZeneca launched Diprivan in the U.S. in 1990 as the first generation of propofol. This formulation was easily contaminated by bacteria during administration. AstraZeneca developed a second generation of Diprivan, which was launched in 1997 with the additive ethylene diamine tetra-acetic acid, a microbial retardant. In 1999, Gensia developed a generic version of second generation propofol by adding sodium metabisulfite to achieve a similar microbial retardation.

Both second generation propofols are manufactured with preservatives or additives that have two deficiencies that are most commonly manifested during long-term administration in the ICU. First, the bacterial retardants may deplete a patient's heavy metals, such as zinc, which are necessary for normal functioning of the body. Second, the second generation propofols contain high amounts of soybean oil and egg lecithin, which can cause fat overload syndrome including hypertriglyceridemia and hyperlipidemia. In addition, Baxter-Teva's product labeling and advertising state that its propofol with sulfite may cause life-threatening or less severe allergic-type reactions in certain susceptible people.

In August 2005, Bedford Laboratories obtained approval of its ANDA for propofol. This product uses benzyl alcohol to retard microbial growth. The product's label contains a precaution which states that in high doses such as in long-term ICU sedation, the product may cause toxicity.

Our research and development team has developed Ampofol, a third generation propofol, which is formulated without any preservatives or additives and half the amount of soybean oil and egg lecithin used in the second generation propofols. We have demonstrated in five completed clinical trials that Ampofol is bioequivalent to Diprivan and that it maintains microbial growth retardation without the use of preservatives. We have a U.S. patent for this novel formulation. We believe Ampofol will have lower manufacturing and storage costs than the second generation propofols because of the reduced lecithin amounts and the ability to store the product at room temperature.

We have established a production line and have completed scale-up, validation, and stability batch filling for Ampofol. We have completed five clinical studies, involving more than 800 patients and volunteers. These studies included two dose-ranging and three bioequivalence clinical trials conducted in the three clinical settings. An ICU-based, multi-center study involved 200 patients. We filed a 505(b)(2) NDA for Ampofol with the FDA in July 2005.

Fluticasone Propionate

Fluticasone propionate is a synthetic, trifluorinated corticosteroid with anti-inflammatory activity. It is marketed in inhalable aerosol form for the management of asthma and in a nasal spray form for the symptoms of seasonal and perennial allergic and nonallergic rhinitis. GlaxoSmithKline PLC is the innovator for both the metered-dose inhaler form, Flovent, for asthma, and the nasal spray form, Flonase, for symptoms of rhinitis. The patents covering Flovent and Flonase have both expired. The U.S. sales for Flonase and Flovent in 2005 were approximately \$1.2 billion and \$600 million, respectively, according to IMS Health. We intend to file ANDAs with the FDA for our formulation of Flonase in the second quarter of 2006 and for our formulation of Flovent in 2007.

Azithromycin

Azithromycin is an antibiotic used to treat mild to moderate bacterial infections. Pfizer Inc. owns the branded product Zithromax®, which according to IMS Health had U.S. sales of \$1.9 billion in 2005 in its oral suspension, tablet, and injectable formulations. According to IMS Health, the injectable form of Zithromax had U.S. sales of \$97.7 million in 2005. We expect to file an ANDA with the FDA covering the injectable form of the product in the second quarter of 2006.

Albuterol HFA

Albuterol HFA is a bronchodilator product candidate used for the prevention and relief of bronchospasm. Albuterol HFA is being developed to replace our Albuterol CFC in accordance with the FDA's required phaseout of Albuterol CFC by December 31, 2008. HFA is a non-ozone depleting chemical propellant. We have exclusively licensed three patents from Virginia Commonwealth University covering the HFA technology. We began clinical trials on this product in February 2005 and we expect to file a 505(b)(2) NDA with the FDA for Albuterol HFA in 2007.

Amphacaine

Amphacaine is our sustained-release formulation of an anesthetic agent designed to provide ultralong-acting (10-48 hours) local analgesia, pain control and postoperative analgesia. Initially, we intend to pursue approval of the product for administration by infiltration. We are utilizing our sustained-release technology to develop this drug and have submitted preclinical results to the FDA. We currently anticipate filing an investigational new drug application, or IND, and commencing clinical trials in 2006. We expect to file an NDA in 2008.

Epinephrine Mist HFA

Epinephrine Mist HFA is being developed to replace our existing Epinephrine Mist CFC product. We anticipate that in the future the FDA will require the CFC version of the epinephrine mist product to be phased out because of the environmental advantages of HFA over CFC propellant. We are utilizing our formulation expertise and the HFA technology patents that we licensed to develop Epinephrine Mist HFA. We plan to file a 505(b)(2) NDA with the FDA for Epinephrine Mist HFA in 2008. We do not expect a phaseout of our CFC product will have an adverse effect on our operations or financial condition as we plan to have the HFA product on the market on or before any required phaseout date.

Developing Proprietary Drug Delivery Platforms

We have developed two proprietary platforms aimed at improving drug delivery: sustained-release and prefilled disposable pipettes.

Sustained-release. We believe injectable, sustained-release products offer several benefits over oral dosage forms. Although oral dosage forms are generally more convenient to administer, in many cases the effectiveness of oral medications is limited. For example, an orally administered drug may not be absorbed without loss of activity, or it may have poor bioavailability due to insolubility in water or low permeability through biological membranes. We believe our injectable, sustained-release drug delivery systems will:

minimize system toxicity and maximize effectiveness by direct injection into the desired region;

reduce dosing frequency without compromising effectiveness; and

increase dosing compliance when treatment requires multiple doses.

We have developed several innovative injectable sustained-release systems that enable consistent delivery of a drug over a longer period of time than currently available systems. We are developing a new local anesthetic drug candidate, Amphacaine, using this technology and have submitted preclinical results to the FDA.

Prefilled Disposable Pipette Technology. Prefilled disposable pipette is a new external drug delivery system utilizing disposable plastic dispensers, or pipettes, that can be filled with a variety of liquid products, including solutions, creams, lotions, jellies, or syrups. It is a single dose system that can be combined with specialized applicators (for example, cotton swab, dropper, plastic applicator) that are

attached to the prefilled disposable pipette tips and provide clean and convenient medications for consumers.

Prefilled disposable pipette has many potential applications including:

dermatologic medications;

dental products;

cough and cold products for both adults and children;

oral products for ICU patients; and

veterinary products.

We own four issued U.S. patents related to our prefilled disposable pipette technology that include the prefilled disposable pipette concept, prefilled disposable pipette applications, high efficiency filling technology, and liquid barriers. We also have pending patent applications in 33 countries related to this technology. We intend to launch several products utilizing the prefilled disposable pipette delivery system, we may perform third-party contract manufacturing using this technology and/or market turnkey equipment systems and license this technology to third parties.

Research and Development

We have 29 employees dedicated to research and development, 11 of whom have Ph.D.s, with expertise in areas such as pharmaceutical formulation, process development, *in vivo* study, analytical chemistry, drug delivery, and clinical research. Our focus on developing products with high barriers to entry requires a significant investment in research and development, including clinical development. In particular, developing proprietary products that are reformulations of existing branded compounds often requires clinical trials to gain regulatory approval. We have a team dedicated to designing and managing clinical trials. We have successfully completed several clinical trials including a 200-patient clinical trial for Ampofol at 12 ICU sites. We are in the process of planning clinical trials for other products under development.

We have made, and will continue to make, substantial investments in research and development. Research and development costs for the year ending December 31, 2005 were approximately \$10.3 million or 12% of our net revenues for that period.

Manufacturing

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California, and Canton and West Roxbury, Massachusetts. We have in total more than 734,000 square feet of manufacturing, research and development, distribution, packaging, laboratory, office, and warehouse space. Our facilities are regularly inspected by the FDA in connection with product approvals and we believe that all of our facilities are being operated in material compliance with the FDA's current Good Manufacturing Practices, or cGMP regulations. These facilities include active pharmaceutical ingredient, prefilled syringe filling, cold-filling, and pressure filling, as well as oncolytic manufacturing suites. We believe we currently have sufficient capacity to meet our manufacturing demands for the foreseeable future. We are currently planning the renovation of another manufacturing building in our headquarters complex that will add an additional 110,000 square feet, which we expect to be available by late 2008 to accommodate future capacity needs.

We can produce a broad range of dosage formulations, including solutions, emulsions, suspensions, jellies, lyophilized products, both aseptically filled and terminally sterilized, and inhalation products. We currently produce approximately 17.5 million units per year. We have leveraged our manufacturing expertise to develop production capabilities for the active pharmaceutical ingredient for enoxaparin. In

addition to manufacturing, we have fully integrated manufacturing support systems, including quality assurance, quality control, regulatory affairs, validation, and inventory control. These support systems enable us to maintain high standards of quality for our products and simultaneously deliver reliable services and goods to our customers on a timely basis.

Raw Material and Other Suppliers

We depend on suppliers for raw materials, active pharmaceutical ingredients and other components that are subject to stringent FDA requirements. The active pharmaceutical ingredient for Cortrosyn, our largest selling product, is only available from one source, Organon USA Inc. We have entered into a supply agreement with Organon to secure this active pharmaceutical ingredient. Further, we obtain a significant portion of raw materials from foreign sources. Establishing additional or replacement suppliers for these or other materials may take a substantial period of time, as suppliers must be approved by the FDA.

Sales and Marketing

Our products are primarily marketed and sold to hospitals, long-t