

Amphastar Pharmaceuticals, Inc.  
Form S-1/A  
May 13, 2005

[QuickLinks](#) -- Click here to rapidly navigate through this document

As filed with the Securities and Exchange Commission on May 13, 2005

Registration No. 333-122725

---

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

## AMENDMENT NO. 1

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

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

---

Copies to:

**Cynthia A. Rotell, Esq.**  
**Latham & Watkins LLP**  
**633 West Fifth Street, Suite 4000**  
**Los Angeles, California 90071-2007**  
**(213) 485-1234**

**Alejandro E. Camacho, Esq.**  
**Andrew S. Epstein, Esq.**  
**Clifford Chance US LLP**  
**31 West 52nd Street**  
**New York, New York 10019-6131**

**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 \_\_\_\_\_, 2005.

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 \_\_\_\_\_, 2005.

**LEHMAN BROTHERS**

**UBS INVESTMENT BANK**

**DEUTSCHE BANK SECURITIES**

\_\_\_\_\_, 2005

## TABLE OF CONTENTS

	<b>Page</b>
Prospectus Summary	1
Risk Factors	8
Forward-Looking Statements	25
Use of Proceeds	26
Dividend Policy	26
Capitalization	27
Dilution	28
Selected Consolidated Financial Data	30
Management's Discussion and Analysis of Financial Condition and Results of Operations	32
Business	42
Management	65
Principal Stockholders	73
Certain Relationships and Related Transactions	75
Description of Capital Stock	77
Shares Eligible for Future Sale	80
Material U.S. Federal Tax Considerations for Non-U.S. Holders	82
Underwriting	85
Legal Matters	89
Experts	89
Where You Can Find More Information	89
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 \_\_\_\_\_, 2005, 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 43 people, 12 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. We currently produce approximately 12.5 million injectable units and five million metered-dose inhaler units per year.

*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:

<b>Product Candidate</b>	<b>Reference Drug<sup>(1)</sup></b>	<b>Therapeutic Classification</b>	<b>Regulatory Path<sup>(2)</sup></b>	<b>FDA Filing/ Expected Filing Date</b>
Enoxaparin	Lovenox®	Anticoagulant	ANDA	Q1 2003
Medroxyprogesterone	DepoProvera®	Contraceptive	ANDA	Q3 2004
Ampofol®	Diprivan®	General Anesthetic	505(b)(2) NDA	Q2 2005
Fluticasone propionate	Flonase® (nasal) Flovent® (inhaler)	Anti-allergic; Anti-inflammatory	ANDA ANDA	Q4 2005 2006
Azithromycin	Zithromax® (azithromycin for injection)	Antibiotic	ANDA	Q4 2005
Albuterol HFA	Proventil®, Ventolin®	Bronchodilator	505(b)(2) NDA	2006
Amphacaine		Local Analgesic	NDA	2007
Epinephrine Mist HFA	Primatene® Mist	Bronchodilator	505(b)(2) NDA	2007

(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 Lovenox, Proventil and Ventolin expire in 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.

We are currently focusing our research and development efforts on enoxaparin and Ampofol, both of which have technical barriers that we believe we have overcome. 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 2004 for the currently marketed versions of these products was in excess of \$2.1 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 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 active pharmaceutical ingredient, which we believe overcomes technical barriers to producing the active pharmaceutical ingredient. Aventis' sales of Lovenox in the U.S. in 2004 were approximately \$1.6 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. 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 that is currently pending. In February 2003, Aventis filed a citizen petition with the FDA, which Aventis supplemented in February 2004. 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 for data in the areas of chemistry, bioequivalence and labeling. Recently, the Company 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 its enoxaparin product candidate to Andrx Pharmaceuticals, Inc. Andrx Pharmaceuticals, Inc.'s marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain such rights, Andrx Pharmaceuticals, Inc. paid us \$4.5 million upon execution of the agreement and will make an additional \$5.5 million payment once certain milestones relating to the product are achieved, including obtaining FDA marketing approval and a favorable resolution of the pending patent litigation with Aventis. Under the agreement, the parties will share the net profits from Andrx Pharmaceuticals, Inc.'s sales of the product in the Territory with the Company receiving up to 60% of the net profits. Under certain specified conditions, Andrx Pharmaceuticals, Inc. will have the right to receive a refund of the amounts paid 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

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

trade name Diprivan and as a generic product by a joint venture between Baxter Healthcare Corporation and Gensia, a predecessor of Teva. Combined sales in 2004 for these products was approximately \$556 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 anticipate filing a 505(b)(2) NDA for Ampofol with the FDA in the second quarter of 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. For the year ended December 31, 2004, we recorded net revenues of \$61.2 million. A significant portion of our revenues during that period 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, 2002, 2003 and 2004, we had net losses of \$1.9 million, \$3.2 million and \$5.3 million, respectively.

In November 2004, we launched Amphadase, our branded hyaluronidase (bovine) product, which is used to increase the absorption and dispersion of other agents injected into the eye, particularly anesthetics utilized in cataract and other ophthalmic surgeries. Also, in July 2004 we acquired the ANDA for Epinephrine Mist CFC, a generic version of Primatene Mist CFC from Alparma USPD which Alparma had ceased marketing in 2001. We reintroduced this generic product to the market in December 2004. Previous to that, epinephrine mist was only available from the innovator, Wyeth, who markets Primatene Mist. Epinephrine Mist CFC is a bronchodilator product used for fast-acting relief of bronchial asthma. In December 2004, we also entered into a multi-year agreement with Wyeth to manufacture Primatene Mist for them.

### **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](http://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 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 continued development of our product candidate portfolio, upgrade, renovate and equip an additional manufacturing and development building and for general corporate purposes and potential acquisitions.
Proposed NASDAQ National Market Symbol	AMPR

The number of shares outstanding after this offering is based on 35,245,740 shares outstanding on December 31, 2004 and excludes:

675,676 shares of common stock issued in February 2005 in a private placement at a price of \$14.80 per share;

5,074,154 shares of common stock issuable upon exercise of options outstanding as of December 31, 2004, with a weighted average exercise price of \$6.75 per share;

4,685,980 shares of common stock reserved for future grant under our stock incentive plan as of December 31, 2004.

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."

	Year Ended December 31,		
	2002	2003 <sup>(1)</sup>	2004
	(in thousands, except per share data)		
<b>Consolidated Statements of Operations data:</b>			
Net revenues	\$ 33,045	\$ 48,197	\$ 61,193
Cost of revenues	22,528	35,508	46,660
Gross profit	10,517	12,689	14,533
Operating expenses:			
Selling, distribution and marketing	2,289	3,194	3,561
General and administrative	6,954	5,537	9,212
Research and development	2,979	6,344	8,451
Impairment of long-lived assets		623	185
Management fees and rent expense related party	138	921	204
Total operating expenses	12,360	16,619	21,613
Loss from operations	(1,843)	(3,930)	(7,080)
Non-operating income (expense):			
Interest income	448	174	53
Interest expense	(59)	(767)	(774)
Gain from settlement with Organon			2,215
Other income (expense)	(448)	(15)	250
	(59)	(608)	1,744
Net loss before extraordinary gain	(1,902)	(4,538)	(5,336)
Extraordinary gain, net of taxes		1,341	
Net loss	(\$1,902)	(\$3,197)	(\$5,336)
Net loss per share before extraordinary gain <sup>(2)</sup>			
basic and diluted	(\$0.06)	(\$0.14)	(\$0.15)
Net loss per share <sup>(2)</sup>			
basic and diluted	(\$0.06)	(\$0.10)	(\$0.15)
Weighted-average shares outstanding:			
basic and diluted	31,592	33,520	34,597
	<b>As of December 31, 2004</b>		
	Actual	As Adjusted <sup>(3)</sup>	
	(in thousands)		
<b>Consolidated Balance Sheet data:</b>			

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

	<u>As of December 31, 2004</u>
Cash, cash equivalents and restricted short-term investments	\$ 6,007
Working capital	8,610
Total assets	139,449
Long-term debt and capital leases, including current portion	30,112
Accumulated deficit	(19,862)
Total stockholders' equity	86,175

- (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 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, 2003 and 2004 of \$6.3 million and \$8.5 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, and to expand our manufacturing, sales, and marketing capabilities. 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 profitability.

*One of our product candidates, enoxaparin, is the subject of a citizen petition filed with the U.S. Food and Drug Administration, or FDA, and a patent infringement lawsuit filed against us, either of 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 FDA is stayed 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 November 2004, we filed a second motion for summary judgment against Aventis seeking a judgment that the patent is invalid based on the indefiniteness of its claims following a claims construction hearing by the judge in the case. In March 2005, we filed a third motion for summary judgment against Aventis seeking a judgment that the patent is invalid based on prior art. The court has not yet ruled on these motions. The court may not rule in our favor with respect to our current motions for summary judgment or at all.

In May, 2003, Aventis filed a patent application with the 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 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 " 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 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., Eon Labs, Inc., Faulding, Inc., ISTA Pharmaceuticals, 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 has filed an ANDA with the FDA for approval of its generic version. Pfizer currently markets DepoProvera, its branded medroxyprogesterone product, and Teva recently received FDA approval for a generic version. AstraZeneca is the innovator of Diprivan, and the generic version of propofol is marketed by Baxter-Teva.

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. 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. Certain of these materials may only be available from one or a limited number of sources such as the raw material used in our enoxaparin product candidate, and the hyaluronidase active pharmaceutical ingredient extracted from cow tissue used in our Amphadase product. We have entered into exclusive supply agreements to secure these materials from third parties. 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. Prior to the supply interruption, our revenues from Cortrosyn for the first quarter of 2004 were \$4.99 million. In the two quarterly periods following the supply interruption, our revenues from sales of Cortrosyn were \$1.35 million and \$2.54 million, respectively. In the fourth quarter of 2004 revenues from sales of Cortrosyn were \$5.04 million. 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, 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%, 20% and 17%, Cardinal Health, Inc. accounted for 17%, 21% and 18% and McKesson Corporation accounted for 15%, 14% and 18% of our net revenues in 2002, 2003 and 2004, 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 Brunswig 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, 2002, 2003 and 2004, we had net losses of \$1.9 million, \$3.2 million, and \$5.3 million respectively. We had an accumulated deficit of \$19.9 million as of December 31, 2004. Our ability to generate revenue from existing products or to achieve profitability 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, 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 recent 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, however, 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 Primatene 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 an undesirable 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 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. 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 our product candidates. 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 new products, 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 are currently 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. 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 pending 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 pending 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 11 patents issued by the U.S. Patent and Trademark Office 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.

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.

The U.S. Patent and Trademark Office, or 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 complies 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. 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.

***Recent 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 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 at issue 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, nonappealable 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 Food and Drugs 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.

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

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. International Medication Systems, Limited is also one of approximately 39 defendants in six lawsuits brought by approximately 128 plaintiffs under a variety of claims relating to alleged exposure to contaminated drinking water. These cases have been consolidated and are being handled in a special forum for complex litigation and are currently in the discovery stage. 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, will go into effect in 2006. We cannot predict the full impact of the new payment methodologies and the new prescription 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"). At the federal level, the Anti-Kickback Statute prohibits any person 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. Violations of the Anti-Kickback Statute may result in 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. If there is a change 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. If these investigations 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.***

Our Chief Executive Officer and Chief Operating Officer and their affiliates currently beneficially own approximately 27% 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;

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;

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.

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 new 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 new 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 new 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 our product candidate portfolio;

upgrade, renovate, and equip a manufacturing and development building at our headquarters complex; and

fund general corporate purposes, including working capital, other capital expenditures, debt reduction, the anticipated growth of our sales, marketing, and customer service capabilities 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 to continue the development of all of our current product candidates and to upgrade, renovate and equip an additional manufacturing and development building at our headquarters complex. 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 anticipate that the net proceeds from this offering will be sufficient to fund the development of our current product candidate portfolio and the proposed building renovation. For a description of our portfolio, see "Business-Our Product Candidates."

We anticipate using the remaining net proceeds from this offering for general corporate purposes, including working capital, other capital expenditures, debt reduction, the anticipated growth of our sales, marketing and customer service capabilities and potential acquisitions of products or businesses that expand or complement our current business. We currently do not have 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, 2004:

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.

	<b>As of December 31, 2004</b>	
	<b>Actual</b>	<b>As Adjusted</b>
	<b>(dollars in thousands)</b>	
Cash, cash equivalents, and short-term investments restricted <sup>(1)</sup>	\$ 6,007	\$
Long-term debt and capital leases, including current portion		30,112
Stockholders' equity:		
Common stock, par value \$.0001 per share; 100,000,000 shares authorized, 35,245,740 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	106,033	
Accumulated deficit	(19,862)	
Total stockholders' equity	86,175	
Total capitalization	\$ 116,287	\$

(1) Excludes proceeds received from a \$10.0 million private placement of our common stock in February 2005.

The share information in the table above excludes, as of December 31, 2004:

675,676 shares of common stock issued in February 2005 in a private placement at a price of \$14.80 per share;

5,074,154 shares of common stock issuable upon exercise of options outstanding as of December 31, 2004, with a weighted average exercise price of \$6.75 per share;

4,685,980 shares of common stock reserved for future grant under our stock incentive plans as of December 31, 2004.

**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, 2004, was \$1.69 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, 2004 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	\$
<hr/>	
Net tangible book value per common share as of December 31, 2004	\$
Increase per share attributable to new investors	\$
<hr/>	
Pro forma net tangible book value per share after this offering	\$
<hr/>	
Dilution per share to new investors	\$
<hr/>	

The following table shows, as of December 31, 2004, 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	35,245,740	%	\$ 106,033,000	%	\$ 3.01
New investors					
<hr/>					
Total		%	\$	%	
<hr/>					

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

675,676 shares of common stock issued in February 2005 in a private placement at a price of \$14.80 per share;

5,074,154 shares of common stock issuable upon exercise of options outstanding as of September 30, 2004, with a weighted average exercise price of \$6.75 per share;

4,685,980 shares of common stock reserved for future grant under our stock incentive plans as of December 31, 2004.

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

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, 2003 and 2004, and for each of the three years in the period ended December 31, 2004 from the audited consolidated financial statements included in this prospectus. We derived the selected consolidated financial data at December 31, 2000, 2001, 2002 and for the years ended December 31, 2000 and 2001 from our audited consolidated financial statements that are not included in this prospectus. Our historical results are not necessarily indicative of future results.

	Year Ended December 31,				
	2000	2001	2002	2003 <sup>(1)</sup>	2004
(in thousands, except per share data)					
<b>Consolidated Statement of Operations data:</b>					
Net revenues	\$ 27,272	\$ 32,373	\$ 33,045	\$ 48,197	\$ 61,193
Cost of revenues	22,062	22,969	22,528	35,508	46,660
Gross profit	5,210	9,404	10,517	12,689	14,533
Operating expenses:					
Selling, distribution and marketing	2,262	2,332	2,289	3,194	3,561
General and administrative	5,815	6,132	6,954	5,537	9,212
Research and development	2,072	2,629	2,979	6,344	8,451
Impairment of long-lived assets				623	185
Management fees and rent expense related party		125	138	921	204
Total operating expenses	10,149	11,218	12,360	16,619	21,613
Loss from operations	(4,939)	(1,814)	(1,843)	(3,930)	(7,080)
Non-operating income (expense):					
Interest income	307	400	448	174	53
Interest expense	(240)	(104)	(59)	(767)	(774)
Gain from settlement with Organon					2,215
Other income (expense)	135	(135)	(448)	(15)	250
	202	161	(59)	(608)	1,744
Net loss before extraordinary gain	(4,737)	(1,653)	(1,902)	(4,538)	(5,336)
Extraordinary gain, net of taxes				1,341	
Net loss	(\$4,737)	(\$1,653)	(\$1,902)	(\$3,197)	(\$5,336)
Net loss per share before extraordinary gain <sup>(2)</sup> :					
basic and diluted	(\$0.19)	(\$0.06)	(\$0.06)	(\$0.14)	(\$0.15)
Net loss per common share <sup>(2)</sup> :					
basic and diluted	(\$0.19)	(\$0.06)	(\$0.06)	(\$0.10)	(\$0.15)
Weighted-average shares outstanding:					
basic and diluted	24,945	26,741	31,592	33,520	34,597

(1) Includes the results of operations of Armstrong since October 9, 2003.

(2)

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

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

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

As of December 31,

	2000	2001	2002	2003	2004
--	------	------	------	------	------

(in thousands)

**Consolidated Balance Sheet data:**

Cash, cash equivalents and restricted short-term investments	\$ 7,656	\$ 18,228	\$ 21,216	\$ 8,723	\$ 6,007
Working capital	12,124	18,002	29,453	7,575	8,610
Total assets	53,838	72,553	86,433	113,271	139,449
Long-term debt and capital leases, including current portion	5,636	15,843	4,097	21,604	30,112
Accumulated deficit	(7,776)	(9,427)	(11,329)	(14,526)	(19,862)
Total stockholders' equity	41,538	49,659	75,823	73,876	86,175

31

**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 our products are used in hospital or urgent care clinical settings and are primarily sold through group purchasing organizations and drug wholesalers. We currently have a portfolio of 66 products that we sell through wholesalers and group purchasing organizations. 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 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. 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, revenues from sales of Cortrosyn were \$5.04 million. 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, 2002, 2003, and 2004, and had an accumulated deficit of \$19.9 million as of December 31, 2004.

**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.

**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. The Company expenses 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, 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 the current year increased by \$1.8 million, while our gross profit margin decreased from 26% to 24%. Increases in sales volume in the current year 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 was \$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 \$0.8 million and \$0.8 million for the years ended December 31, 2003 and 2004, respectively. The Company incurred higher levels of interest expense in 2004 that were 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 \$0.026 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.

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

#### **Years Ended December 31, 2002 and 2003**

*Net revenues.* Net revenues were \$33.0 million and \$48.2 million in 2002 and 2003 respectively, representing an increase of \$15.2 million, or 46%. Product revenues increased principally due to sales of Cortrosyn, which we acquired mid-year 2003, and which contributed \$7.9 million in revenues in 2003. Armstrong, which we acquired in the fourth quarter of 2003, contributed \$2.9 million in domestic product revenues from Albuterol sales in 2003. Additionally, we recorded increased revenues across most of our product lines totaling \$3.0 million in 2003. Revenues from contract manufacturing services also increased from \$0.5 million in 2002 to \$1.9 million in 2003, due to increased efforts to expand contract relationships with other pharmaceutical, biopharmaceutical, and biotechnology companies.

*Cost of revenues.* Cost of revenues was \$22.5 million and \$35.5 million in 2002 and 2003, respectively, representing an increase of \$13.0 million, or 58%. For these same periods, our gross profit margins were 32% and 26%, respectively. The increase in cost of revenues in 2003 was principally due to the introduction of new product lines, which contributed \$8.7 million to cost of revenues, including amortization expense of \$0.9 million relating to the intangible asset booked for the acquisition of Cortrosyn, with the balance of the increase related to costs associated with increased contract manufacturing and higher manufacturing expenses.

*Selling, distribution and marketing.* Selling, distribution and marketing expenses were \$2.3 million and \$3.2 million in 2002 and 2003, respectively, representing an increase of \$0.9 million, or 39%. This increase was principally due to an increase in commissions and product distribution costs resulting from higher levels of product shipments.

*General and administrative.* General and administrative expenses were \$7.0 million and \$5.5 million in 2002 and 2003, respectively, representing a decrease of \$1.5 million, or 23%. The decrease was principally due to the recording of wages, overhead and pre-production expenses of the manufacturing plant in Rancho Cucamonga as general and administrative expenses in fiscal 2002. Once the FDA approved this facility and production commenced in 2003, these expenses were recorded in cost of revenues.

*Research and development.* Research and development expenses were \$3.0 million and \$6.3 million in 2002 and 2003, respectively, representing an increase of \$3.3 million, or 110%. The increase was mainly due to significantly higher clinical trial expenses (principally related to our Ampofol product), as well as increased expenses related to manufacturing sufficient quantities of products to be used in research and development activities.

*Impairment of long-lived assets.* During 2003, we wrote off \$0.6 million in real estate development costs and equipment, which was no longer being used, and for which there was no further use. There was no impairment of long-lived assets in 2002.

*Management fees and rent expense related party.* Management fees and rent expenses were \$0.1 million and \$0.9 million in 2002 and 2003. The increase of \$0.8 million resulted from an amendment to the agreement between the Company and APCL, clarifying the terms of a fee paid by us to APCL for managing the leasing arrangements and paying all of the costs related to the purchase or lease of equipment for us.

*Interest income.* Interest income was \$0.4 million and \$0.2 million in 2002 and 2003, respectively, representing a decrease of \$0.2 million, or 50%, principally due to the investment of proceeds from a private placement closed in 2002.

*Interest expense.* Interest expense was \$0.1 million and \$0.8 million in 2002 and 2003, respectively, representing an increase of \$0.7 million. The increase in 2003 was due to a significant increase in the amount of debt outstanding. Interest expense is composed of interest on debt outstanding and the accretion of the difference between the net present value of the two remaining installment payments owed by us to Organon to complete the purchase of Cortrosyn, and the contractual obligation of \$12.0 million. The implicit interest rate for the two payments to Organon is 7.5% per annum.

*Extraordinary gain.* We recorded an extraordinary gain in the fourth quarter of 2003 from the acquisition of Armstrong in the amount of \$1.3 million, net of tax expense of \$0.04 million. There was no extraordinary gain in 2002.

## **Liquidity and Capital Resources**

Through December 31, 2004, we financed our operations since inception primarily through sales of our products, private placements of equity securities totaling \$88.3 million, borrowings under various credit and leasing facilities, a product royalty sale and capital contributions from a related party, APCL.

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 \$4.0 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 on self-constructed assets, \$2.0 million for the purchase of product rights to Epinephrine Mist CFC and \$1.1 million for the 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 \$21.0 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.

As of December 31, 2003, we had \$8.1 million in cash and cash equivalents as compared to \$15.5 million at December 31, 2002. The decrease was principally the result of the \$16.0 million payment to Organon in June 2003 for purchase of product rights for Cortrosyn offset by our sale of the royalties related to Cortrosyn to Drug Royalty, USA, Inc. for \$8.0 million. Net cash provided by

operating activities was \$1.2 million for the year ended December 31, 2003 compared to net cash used in operating activities of \$4.0 million for the year ended December 31, 2002. The positive cash flow from operating activities was principally the result of the sales of Cortrosyn since June 2003. Net cash used in investing activities was \$21.5 million for the year ended December 31, 2003 compared to \$8.1 million for the year ended December 31, 2002. The increase in 2003 was principally the result of the \$16.0 million payment to Organon. Net cash provided by financing activities was \$12.9 million for the year ended December 31, 2003 compared to \$14.6 million for the year ended December 31, 2002. In 2002, we raised \$25.0 million in a private placement of common stock, which we used to pay down \$12.3 million in long-term debt. In 2003, we borrowed \$6.2 million under our credit facility with Cathay Bank and received \$8.0 million in the form of a royalty purchase from Drug Royalty, USA, Inc.

The Company and its subsidiary, International Medication Systems, Limited ("IMS"), have three principal credit facilities. The Company entered into an agreement with Cathay Bank (the "CB Credit Facility"), dated as of February 8, 2001, as amended, providing for borrowings under a \$6.2 million revolving line of credit. Borrowings under the CB Credit Facility bear interest at the Wall Street Journal prime rate and mature in November 2005. The CB Credit Facility borrowings are secured by certain accounts receivable, inventory and leasehold improvements. The CB Credit Facility requires the Company to meet certain financial covenants including a minimum annual profitability test, a minimum current ratio and a maximum debt to tangible net worth ratio of 0.75 to 1.00. At December 31, 2004, the Company was not in compliance with two of these tests as follows: the Company had a net loss of \$5.3 million, and had a debt to tangible net worth ratio of .89 to 1.0. The Company received a waiver from Cathay Bank for these defaults through December 31, 2004. As of March 31, 2005, the CB Credit Facility was fully drawn. In November 2004, Cathay Bank exercised its warrant to purchase 124,000 shares of the Company's common stock at an exercise price of \$7.50 per share, resulting in \$0.9 million in cash proceeds.

IMS has a \$5.0 million equipment purchase facility with Bank of the West dated October 10, 2002, as amended. Borrowings under this facility bear interest at the Bank of the West prime rate and mature on various dates through 2008. IMS also entered into a \$3.0 million line of credit facility with Bank of the West dated as of February 25, 2004 as amended. Borrowings under the line of credit bear interest at the Bank of the West prime rate and mature in April 2006. The Bank of the West facility borrowings are secured by certain accounts receivable, inventory, equipment and leasehold improvements of IMS. The Company has guaranteed the obligations of IMS under the Bank of the West facilities. The Bank of the West facilities contain certain financial covenants, including a requirement that IMS maintain a minimum quick ratio (liquid assets plus net trade receivables divided by total liabilities) of 1.0 to 1.0, an effective tangible net worth of \$20 million, a maximum debt/effective tangible net worth ratio of 0.75 to 1.0 and impose limitations on the amount of funds that can be advanced from IMS to the Company. IMS was not in compliance with these covenants at December 31, 2004 and at such date had a quick ratio of 0.72 to 1.0, an effective tangible net worth of \$17 million, and a debt/effective tangible net worth ratio of 1.05 to 1.0. Bank of the West waived these defaults through April 12, 2005 and amended the covenants to require IMS to comply with the following: a minimum effective tangible net worth of \$16.0 million, a maximum debt/effective tangible net worth of 1.10 to 1.0 and a quick ratio of no less than 0.70 to 1.0. In addition, upon completion of this offering, the Company will be required to advance to IMS the sum of \$5.0 million. In March 2005, we reduced our line of credit borrowings with Bank of the West to zero. At March 31, 2005, the line of credit facility was fully available and the equipment facility was fully utilized.

The Company anticipates that it will be able to meet its covenant and financial ratio requirements in the future.

In November 2004, the Company borrowed \$5 million from the Bank of the West pursuant to a 5-year note with a variable interest rate linked to the London Interbank Offered Rate. The loan is secured by a deed of trust on the Company's recently acquired building in Rancho Cucamonga. The

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

Company netted \$1.9 million from the loan after paying off the \$2.6 million existing loan due to Manufacturers Life on the property and a prepayment penalty of \$458,000, which is included in nonoperating income in the statement of operations.

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.

In February 2005, we obtained \$3.4 million in equipment lease financing. The terms of the financing will require us to secure the loan with a line of credit of \$1.7 million, which will require setting aside \$1.7 million in restricted investments.

Set forth below are our contractual payment obligations as of December 31, 2004 (in thousands):

Contractual Obligations	Payments due by Period						
	Total	2005	2006	2007	2008	2009	Beyond 2009
Long-term Debt <sup>(1)</sup>	\$ 30,548	\$ 15,146	\$ 7,403	\$ 1,307	\$ 2,150	\$ 4,542	\$
Operating Leases	11,642	3,579	2,495	1,761	1,522	1,344	941
Capital Leases	241	186	50	5			
Purchase Obligations <sup>(2)</sup>	8,245	8,245					
Deferred Royalty Payments <sup>(3)</sup>	5,368	2,478	2,890				
<b>Total</b>	<b>\$ 56,044</b>	<b>\$ 29,634</b>	<b>\$ 12,838</b>	<b>\$ 3,073</b>	<b>\$ 3,672</b>	<b>\$ 5,886</b>	<b>\$ 941</b>

(1) Long-term Debt includes the net present value of the two remaining payments owed by the Company to Organon relating to the purchase of Cortrosyn. In the first quarter of 2004, Organon ceased manufacturing Cortrosyn and in June 2004 closed its manufacturing facility, despite a contractual obligation to manufacture Cortrosyn for us through June 2006. This supply interruption adversely impacted sales during the second and third quarters of 2004. We transferred the manufacturing process from Organon to our Rancho Cucamonga facility and re-launched the product in August 2004.

(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 \$2,929 as of December 31, 2004.

(3) We have recorded the \$8.0 million in consideration received from Drug Royalty, USA, Inc. as deferred royalties on the accompanying consolidated balance sheets and is reducing the liability as royalty payments are made. The payments due by period under this obligation are based on estimates of future sales.

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 February 2005 private placement and February 2005 equipment lease line, 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. The Company expects additional cash flows to be generated from future contract manufacturing agreements and potential strategic alliances such as our four-year agreement with Wyeth to supply Primatene Mist.

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. 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, 2002, 2003 and 2004, 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, 2004, we had \$30.1 million in long-term debt and capital leases outstanding. Of this amount, \$20.1 million had variable interest rates with a weighted average interest rate of 5.2% at December 31, 2004. 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 \$200,000 per year.

Most foreign sales are negotiated with payment terms in U.S. dollars. Therefore, the Company has limited exposure to foreign currency price fluctuation. Further, the Company 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, upfront fees over the four year term of the agreement. At December 31, 2004, we had received a \$0.5 million non-refundable payment, 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.

#### ***Impairment of Long-Lived Assets***

The Company reviews 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. Changes in chargeback accruals from period to period are primarily dependent on the level of inventory held at the wholesalers. We continually monitor the provision for chargebacks and make adjustments when we believe that the actual chargebacks may differ from estimates. At December 31, 2003 and 2004, chargebacks of \$4.0 million and \$3.7 million, respectively, were recorded as current liabilities. Settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

#### ***Accrual for Product Returns***

The Company offers certain distributors the right to return qualified excess or expired stock ("qualified returns") for credit. During 2002 and until June 2003, qualified returns were accepted up to six months from the date of shipment and three months before and after the expiration date for credits ranging from 50% to 75% of the original selling price. Beginning effective as early as July 1, 2003, pursuant to revised terms with the Company's distributors, qualified returns were expanded to include new product lines and will be accepted in certain instances up to 12 months from the date of shipment and six months before and after the expiration date for credits ranging from 80% to 90% of the current list price. The Company estimates amounts that may be incurred under its product return policies and records 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. The Company classifies 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. During 2002, the Company reduced the sales return percentage from approximately 0.9% of qualified sales in 2001 to 0.4% of qualified sales in 2002 based upon experience rates, resulting in a reduction in the accrual of approximately \$400, which was recorded as an increase in revenues. During 2003, the Company increased its sales

return percentage from 0.4% to 0.7% of qualified sales as a result of changes in wholesaler contract terms, resulting in an increase in the accrual of approximately \$457,000, which was recorded as a decrease in revenues. During 2004, the Company decreased its sales return percentage from 0.7% to 0.4% of qualified sales as a result of changes in wholesaler contract terms resulting in a decrease in the accrual of approximately \$482,000, which was recorded as an increase in revenue.

#### ***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.

#### **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 January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. (FIN) 46, "Consolidation of Variable Interest Entities" an interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements." The primary objectives of FIN 46 are to provide guidance on the identification of entities which the Company may control through means other than through voting rights ("variable interest entities") and to determine when and which business enterprise ("primary beneficiary") should consolidate the variable interest entity. FIN 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among the parties involved. Variable interest entities that effectively disperse risks will not be consolidated unless a single party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003. In December 2003, FASB revised FIN 46 (FIN 46R) to address certain FIN 46 implementation issues. The revised provisions are applicable no later than the first reporting period ending after March 15, 2004. The Company adopted FIN 46 and FIN 46R and determined that it does not have any variable interest entities that require consolidation or disclosure.

In September 2004, the Emerging Issues Task Force of FASB reached a final consensus on EITF Issue No. 04-10, "Determining Whether to Aggregate Operating Segments That Do Not Meet the

Quantitative Thresholds." Under EITF Issue No. 04-10, operating segments that do not meet the quantitative thresholds can be aggregated into a reportable segment if aggregation is consistent with the objective and basic principles of FASB Statement No. 131, the segments have similar economic characteristics, and the segments share a majority of the other aggregation criteria as defined by FASB Statement No. 131, paragraph 17. EITF Issue No. 04-10 is effective for fiscal years ending after October 13, 2004. The corresponding information for earlier periods, including interim periods, shall be restated unless it is impractical to do so. Restatement of previously issued financial statements is required. The adoption of EITF Issue No. 04-10 did not impact our financial statements and related disclosures.

In November 2004, FASB issued Statement No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4." 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. We are currently assessing the impact of Statement No. 151 on our financial statements and related disclosures.

On December 16, 2004, FASB issued Statement No. 123 (revised 2004), "Share-Based Payment" ("Statement 123(R)"). Statement 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values (i.e., pro forma disclosure is no longer an alternative to financial statement recognition). We will need to comply with Statement 123R in the interim financial statements for the first quarter ended March 31, 2006. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified retrospective option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the modified retrospective method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.



## 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, and lyophilized (freeze-dried) products, as well as metered-dose inhalers and nasal sprays. We have long-standing relationships with the leading group purchasing organizations and wholesalers that deliver products to our end markets.

We began our operations in February 1996 with a strategy of focusing 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. ("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 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 our proprietary drug delivery technology.

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 sales in the U.S. in 2004 in excess of \$2.1 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 43 people, 12 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 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. We currently produce approximately 12.5 million injectable units and five million

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

metered-dose inhaler units per year. 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 platforms.* Through our research and development efforts we have developed a proprietary 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. In the future, we believe these relationships will enable us to rapidly introduce new products and quickly establish market share leadership.

### **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	2002	2003	2004
Cortrosyn	-0-	7,863	13,924
Lidocaine Jelly	11,631	10,890	11,031
Albuterol CFC	-0-	2,877	6,807
Critical Care Drug Portfolio	12,552	15,424	16,051

We currently manufacture and sell 66 generic injectable and inhalation products. For the year ended December 31, 2004, we recorded net revenues of \$61.2 million, including \$1.9 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 deferred royalties on the accompanying consolidated balance sheets and are reducing the liability as royalty payments are made. 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 and may exceed the consideration received, at which time royalties will be expensed as incurred. 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.

#### *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 2006. 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 be received in December 2004, January 2005 and upon shipment of the first lot of product to Wyeth.

### **2004 Product Approvals and Launches**

#### *Amphadase*

Amphadase is our branded hyaluronidase (bovine) product, which is used to increase the absorption and dispersion of other agents injected into the eye, particularly anesthetics utilized in cataract and other ophthalmic surgeries. In January 2001, Wyeth, the innovator of bovine, or cow-derived, hyaluronidase discontinued manufacturing its product Wydase. Although the active

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

pharmaceutical ingredient for hyaluronidase, which is derived from bovine tissue extracts, is difficult to obtain, we have secured an exclusive long-term supply agreement with a biochemical company in China. The agreement has a term of seven years from the date of the FDA's approval of Amphadase and provides that the biochemical company will be the exclusive supplier of the active pharmaceutical ingredient for cow-derived hyaluronidase. We launched this product in November 2004, following receipt of FDA approval of our new drug application, or NDA. ISTA Pharmaceuticals, Inc. has received regulatory approval for its hyaluronidase product, Vitrase (and a five-year exclusivity for ovine, or sheep-derived, hyaluronidase), which launched in early 2005.

### *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.

### **Our Product Candidates**

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

<b>Product Candidate</b>	<b>Reference Drug(1)</b>	<b>Therapeutic Classification</b>	<b>Regulatory Path(2)</b>	<b>FDA Filing/ Expected Filing Date</b>
Enoxaparin	Lovenox	Anticoagulant	ANDA	Q1 2003
Medroxyprogesterone	DepoProvera	Contraceptive	ANDA	Q3 2004
Ampofol	Diprivan	General Anesthetic	505(b)(2) NDA	Q2 2005
Fluticasone propionate	Flonase (nasal) Flovent (inhaler)	Anti-allergic; Anti-inflammatory	ANDA ANDA	Q4 2005 2006
Azithromycin	Zithromax (azithromycin for injection)	Antibiotic	ANDA	Q4 2005
Albuterol HFA	Proventil, Ventolin	Bronchodilator	505(b)(2) NDA	2006
Amphacaine		Local Analgesic	NDA	2007
Epinephrine Mist HFA	Epinephrine CFC	Bronchodilator	505(b)(2) NDA	2007

(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 Lovenox, Proventil and Ventolin expire in 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.

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 Aventis under the brand-name Lovenox. Aventis' sales of Lovenox in the U.S. in 2004 totalled approximately \$1.6 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. Aventis has 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 are 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 that is currently pending. 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. Recently, the Company 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.

Enoxaparin is difficult to manufacture because the active pharmaceutical ingredient is not easily obtained. We have entered into an exclusive long-term supply agreement with a biochemical company in China for raw heparin, the starting material used for the active pharmaceutical ingredient in our enoxaparin product candidate. The agreement has a term of ten years, which term expires in 2014. Our research and development team has developed a multi-step chemical process for converting the starting material to the active pharmaceutical ingredient, which we believe overcomes technical barriers to producing the active pharmaceutical ingredient.

On May 2, 2005, the Company entered into an agreement to grant certain exclusive marketing rights for its enoxaparin product candidate to Andrx Pharmaceuticals, Inc. Andrx Pharmaceuticals, Inc.'s marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain such rights, Andrx Pharmaceuticals, Inc. paid us \$4.5 million upon execution of the agreement and will make an additional \$5.5 million payment once certain milestones relating to the Product are achieved, including obtaining FDA marketing approval and a favorable resolution of the pending patent litigation with Aventis. Under the agreement, the parties will share the net profits from Andrx Pharmaceuticals, Inc.'s sales of the product in the Territory with the Company receiving up to 60% of the net profits. Under certain specified conditions, Andrx Pharmaceuticals, Inc. will have the right to receive a refund of the amounts paid to us.

*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 \$285 million in 2004. 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.

*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 joint venture of Baxter Healthcare Corporation ("Baxter") and Gensia Sicor Pharmaceuticals ("Gensia"), a predecessor of Teva. Combined sales in the U.S. in 2004 for these products was approximately \$556 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.

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.

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 anticipate filing a 505(b)(2) NDA for Ampofol with the FDA in the second quarter of 2005.

*Fluticasone Propionate*

Fluticasone propionate is a synthetic corticosteroid which is chemically manufactured to replicate the natural steroid produced by the cortex of the adrenal gland. 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 2004 was approximately \$1.1 billion and \$600 million, respectively, according to IMS Health. We intend to file ANDAs with the FDA for our formulation of Flonase in the fourth quarter of 2005 and for our formulation of Flovent in 2006.

*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 \$1.8 billion in 2004 in its oral suspension, tablet, and injectable formulations. According to IMS Health, the injectable form

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

of Zithromax had U.S. sales of \$69.2 million in 2004. We expect to file an ANDA with the FDA covering the injectable form of the product in the fourth quarter of 2005.

### *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 2006.

### *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 the second half of 2005. We expect to file an NDA in 2007.

### *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 2007. 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 an innovative injectable sustained-release system that enables 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 31 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, 2004 were approximately \$8.5 million or 14% 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 oncologic 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 constructed by 2006 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. Certain of these materials may only be available from one or a limited number of sources, such as raw heparin, the raw material used in our enoxaparin product candidate, and the hyaluronidase active pharmaceutical ingredient used in our Amphadase product. We have entered into exclusive supply agreements to secure these materials from third parties. 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. Further, a significant portion of raw materials may be available only from foreign sources.

**Sales and Marketing**

Our products are primarily marketed and sold to hospitals, long-term care facilities, alternate care sites, clinics, and doctors' offices. Most of these facilities are members of one or more group purchasing organizations, which negotiate collective purchasing agreements on behalf of their members. These facilities purchase products through specialty distributors and wholesalers. We have relationships with all of the major group purchasing organizations in the U.S., which we believe gives us access to most, if not all, of the injectable markets in the U.S. We also have relationships with all of the major specialty distributors and wholesalers who distribute pharmaceutical products nationwide.

The following table provides net revenue information from our major customers:

	<b>% of net revenues For the year ended December 31,</b>		
	<b>2002</b>	<b>2003</b>	<b>2004</b>
AmerisourceBergen Corporation	20%	20%	17%
Cardinal Health, Inc.	17%	21%	18%
McKesson Corporation	15%	14%	18%

Our sales, marketing and customer service department has 11 employees. Our marketing department is responsible for establishing and maintaining contracts and relationships with the group purchasing organizations, distributors, and wholesalers and occasionally large end-users. In connection with the expansion of our product offerings to include metered-dose inhaler and nasal spray products, we are expanding our sales and marketing efforts to develop retail distribution channels. In addition, one or more of our branded product candidates may require deployment of a field sales force either directly or through a strategic partner.

**Competition**

We face significant competition in our current product line from major, brand-name pharmaceutical companies such as GlaxoSmithKline, Schering-Plough Corporation, and Wyeth, and

from generic manufacturers such as Hospira, Inc. and Warrick Pharmaceuticals, a subsidiary of Schering-Plough. In addition to these competitors, we also face competition from other companies in the generic injectable and inhalation market such as American Pharmaceutical Partners, Inc., Eon Labs, Inc., Faulding Inc., a subsidiary of the Mayne Group Limited, ISTA Pharmaceuticals, IVAX Corporation, and Teva. We face additional competition from brand-name competitors that have entered the generic pharmaceutical industry by creating generic subsidiaries, purchasing generic companies, or licensing their products to generic manufacturers prior to 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 has filed an ANDA for approval of its generic version. Pfizer currently markets DepoProvera, its branded medroxyprogesterone product, and Teva recently received FDA approval for a generic version. AstraZeneca is the innovator of Diprivan, and the generic version of propofol is marketed by Baxter-Teva.

For pharmaceutical products, the most important competitive factors are scope of product line, individual product characteristics, relationships with group purchasing organizations, retailers, wholesalers and customers, delivery record, ability to develop new products, and pricing. Sales of generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors. As patents for brand-name products and related exclusivity periods expire, the first generic pharmaceuticals manufacturer to receive regulatory approvals for generic versions of their products is generally able to achieve significant market penetration and higher margins. As competing generic manufacturers receive regulatory approval on similar products, market size, revenue, and gross profit typically decline. The level of market share, revenue, and gross profit attributable to a particular generic pharmaceutical product is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch in relation to competing approvals and launches. We must continue to develop and introduce new products in a timely and cost effective manner and identify niche products with significant barriers to entry in order to grow our business.

### **Regulatory Considerations**

Prescription proprietary and generic pharmaceutical products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of such products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. FDA approval is required before any new unapproved drug or dosage form, including a generic equivalent of a previously approved drug, can be marketed in the U.S. All applications for FDA approval must contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, and quality control.

#### *Generic Drug Approval*

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act), established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its New Drug Application, or NDA, process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application, or ANDA, with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Pre-market applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data

to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials. We generally file ANDAs to obtain approval to manufacture and market our generic products. ANDAs submitted for our products may not receive FDA approval on a timely basis, if at all.

Upon NDA approval, the FDA lists in the Orange Book the approved drug product and any patents identified by the NDA applicant that relate to the drug product. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book before expiration of the referenced patent(s), must certify to the FDA that (1) no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV certification. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. Before the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (also known as the Medicare Act), which amended the Hatch-Waxman Act, if the NDA holder or patent owner(s) asserted a patent challenge within 45 days of its receipt of the certification notice, the FDA was prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in an ANDA applicant's favor, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In some cases, NDA owners and patent holders have obtained additional patents for their products after an ANDA had been filed but before that ANDA received final marketing approval, and then initiated a new patent challenge, which resulted in more than one 30-month stay.

The Medicare Act amended the Hatch-Waxman Act to eliminate certain unfair advantages of patent holders in the implementation of the Hatch-Waxman Act. As a result, the NDA owner remains entitled to an automatic 30-month stay if it initiates a patent infringement lawsuit within 45 days of its receipt of notice of a Paragraph IV certification, but only if the patent infringement lawsuit is directed to patents that were listed in the Orange Book before the ANDA was filed. An ANDA applicant is now permitted to take legal action to enjoin or prohibit the listing of certain of these patents as a counterclaim in response to a claim by the NDA owner that its patent covers its approved drug product.

If an ANDA applicant is the first-to-file a substantially complete ANDA with a Paragraph IV certification and provides appropriate notice to the FDA, the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a 180-day period of marketing exclusivity against other companies that subsequently file ANDAs for that same product. A substantially complete ANDA is one that contains all the information required by the Hatch-Waxman Act and the FDA's regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for a 180-day period of marketing exclusivity for the generic product. The Medicare Act also modified the

rules governing when the 180-day marketing exclusivity period is triggered or forfeited and shared exclusivity. Prior to the legislation, the 180-day marketing exclusivity period was triggered upon the first commercial marketing of the ANDA or a court decision holding the patent invalid, unenforceable, or not infringed. For ANDAs accepted for filing before March 2000, that court decision had to be final and non-appealable (other than a petition to the U.S. Supreme Court for a writ of certiorari). In March 2000, the FDA changed its position in response to two court cases that challenged the FDA's original interpretation of what constituted a court decision under the Hatch-Waxman Act. Under the changed policy, the 180-day marketing exclusivity period began running immediately upon a district court decision holding the patent at issue invalid, unenforceable, or not infringed, 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. As 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 75 days after a final and nonappealable court decision by the first-to-file or other ANDA applicant, or if the FDA does not tentatively approve the first-to-file applicant's ANDA within 30 months.

The Medicare Act also prospectively eliminated shared exclusivity for first-to-file ANDAs containing Paragraph IV certifications to different patents listed in the Orange Book for the same product. 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. This interpretation was recently challenged in two cases in 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 Act prospectively eliminated this type of shared exclusivity. Until this issue is resolved, it is unclear how the 180-day marketing exclusivity period will apply to 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).

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an ANDA. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent product for up to five years following approval of the NDA for the new chemical entity. If the listed drug is not a new chemical entity but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for a bioequivalent product before expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for treatment of a rare disease or is studied for pediatric indications.

We are currently a party to a patent infringement action brought against us by Aventis relating to our Paragraph IV certification for a generic version of enoxaparin, as well as a citizen petition proceeding before the FDA relating to the same matter. See "Business Legal and Regulatory Proceedings Enoxaparin Paragraph IV Litigation" and " Enoxaparin Citizen Petition."

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

### *New Drug Approval*

A new drug approval by the FDA is required before a new drug that is not equivalent to a previously approved drug may be marketed in the U.S. This process generally involves:

completion of preclinical laboratory and animal testing in compliance with the FDA's good laboratory practice or GLP regulations;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and

submission to and approval by the FDA of an NDA application.

The results of preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. Further, each clinical trial must be reviewed and approved by an Independent Institutional Review Board. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

Phase I, during which the drug is introduced into healthy human subjects or, on occasion, patients, and is tested for safety, stability, dose tolerance, and metabolism;

Phase II, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks; and

Phase III, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate clinical efficacy, optimal dosage, and safety.

The drug sponsor, the FDA or the Independent Institutional Review Board at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

The results of preclinical animal studies and human clinical studies, together with other detailed information, are submitted to the FDA as part of the NDA. The NDA also must contain extensive manufacturing information. The FDA may approve or disapprove the NDA if applicable FDA regulatory criteria are not satisfied or it may require additional clinical data. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Satisfaction of FDA new drug approval requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer's activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be subject to varying interpretations that could delay, limit



or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

*Section 505(b)(2) New Drug Applications*

As an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product, has expired.

If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have filed citizen petitions objecting to the FDA's interpretation of Section 505(b)(2). In October 2003, the FDA responded to the citizen petitions and declined to alter its interpretation of Section 505(b)(2). In November 2003, Pfizer Inc. sued the FDA in the U.S. District Court for the District of Columbia to challenge the FDA's approval of a Section 505(b)(2) NDA for a product that is a modified version of one of Pfizer's currently marketed drugs. Pfizer alleges that the FDA improperly relied upon studies in Pfizer's NDA to approve the competitor's product. Recently, the FDA announced that it was staying approval of the Section 505(b)(2) NDA at issue in the Pfizer case to conduct a reevaluation of the application. The FDA also filed a motion for a stay of the Pfizer lawsuit pending the completion of this reevaluation. If



the FDA does not prevail in this lawsuit, the FDA may be required to change its interpretation of Section 505(b)(2), which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

#### *Manufacturing cGMP Requirements*

We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control, and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

#### *Medical Device Regulation*

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Class I medical devices are subject to the FDA's general controls, which include compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's general controls and may also be subject to other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Class III medical devices are subject to the FDA's general controls, special controls, and pre-market approval prior to marketing.

We currently market a small number of Class I and Class II medical devices. Most Class II devices require pre-market clearance by the FDA through the 510(k) pre-market notification process. When a 510(k) is required, the manufacturer must submit to the FDA a pre-market notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to another commercially available, similar device which was subsequently cleared through the 510(k) process. By regulation, the FDA is required to clear a 510(k) within 90 days of submission of the application. As a practical matter, clearance often takes longer. All of our devices have been cleared for marketing pursuant to the 510(k) process.

The FDA has broad post-market regulatory and enforcement powers with respect to medical devices, similar to those for drug products. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future pre-market clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

## Other Regulatory Requirements

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Outside the U.S., our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing, and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

## DEA Regulation

We maintain registrations with the U.S. Drug Enforcement Administration ("DEA"), that enable us to receive, manufacture, store, and distribute controlled substances in connection with our operations. Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. The CSA governs, among other things, the distribution, recordkeeping, handling, security, and disposal of controlled substances. We are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess our ongoing compliance with DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of our DEA registration, injunctions, or civil or criminal penalties.

## Reimbursement Legislation

Our sales are dependent upon the availability of coverage and reimbursement from third-party payors, including federal, state, and private organizations. Thus, our business may be significantly impacted by changes in coverage and reimbursement policies and legislation aimed at reducing health care costs.

Coverage and reimbursement under Medicare, Medicaid, or other programs are governed through legislation for such programs. The recently enacted Medicare Act is an example of legislation of a health insurance program that impacts our industry. The Medicare Act imposes significant changes to Medicare Part B payments for products, including the payment methodology for certain drugs, including drugs administered by physicians in their offices and in hospital outpatient departments and certain drugs dispensed by pharmacies such as those inhaled through a nebulizer and oral cancer drugs. For a number of our drugs, the Medicare Act reduced payment to 85% from 95% of the average wholesale price beginning January 1, 2004. In 2005, the Medicare Act requires that certain drugs covered under Medicare Part B be paid at 106% of the manufacturer's average sales price, calculated

by a formula that accounts for the average of the total number of units sold. In addition, physicians will have the option to enter into competitive bidding programs for drugs administered by physicians.

In addition to revising Medicare payment methodologies under Medicare Part B, the Medicare Act established a prescription drug benefit (under new Part D), which is scheduled to go into effect on January 1, 2006. In the interim, beginning June 1, 2004, a prescription drug discount program became effective for eligible individuals. The drugs covered under the new prescription drug benefit and the transitional drug discount card program do not include those currently covered in the form administered under the current Medicare Part B benefit. Drugs not covered under Part B include inhalation drugs that are administered through a metered-dose inhaler, and these may be covered under Part D. Under the prescription drug discount card program, beneficiaries receive a variety of discount and drug options supported by Medicare contracts with private companies. Although this may increase beneficiaries' utilization of prescription drugs, it is not clear whether and to what extent pharmaceutical companies will be affected by Medicare restrictions on drug coverage and pricing requirements.

Under the Medicaid program, pharmaceutical manufacturers must remit a rebate, equal to a certain percentage of their revenue arising from Medicaid-reimbursed, qualifying outpatient drug sales to Medicaid recipients in the individual states. Under the drug rebate program, Medicaid covers the pharmaceutical manufacturer's FDA-approved drugs (with some exceptions). Agreements with federal and state governments provide that manufacturers of single source and innovator multiple source drugs must remit quarterly rebates based on the greater of 15.1% of the average manufacturer's price per unit or the product of the total number of units of each dosage form and strength paid for under the state plan in the rebate period and the difference between the average manufacturer's price and the best price per unit. Manufacturers of covered outpatient drugs, other than single source drugs and innovator multiple source drugs, will remit on a quarterly basis to each state Medicaid agency 11% of the average manufacturer price per unit of its products marketed under ANDAs covered by the state's Medicaid program based on the total number of units for such dosage form and strength reimbursed under the state program for the rebate period.

#### **Environmental Considerations**

We are subject to environmental laws, including those promulgated by the Occupational Safety and Health Administration, the Environmental Protection Agency ("EPA"), the Department of Health Services, and the Air Quality Management District, that govern activities and operations that may have adverse environmental effects such as discharges to air and water, as well as handling and disposal practices for solid and hazardous wastes. These laws impose strict liability for the costs of cleaning up, and for damages resulting from, sites of past spills, disposals, or other releases of hazardous substances and materials and for the investigation and remediation of environmental contamination at properties operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. If it is determined that our operations or facilities are not in compliance with current environmental laws, we could be subject to fines and penalties, the amount of which could be material.

We have made and will continue to make expenditures to comply with current and future environmental laws. We anticipate that we will incur additional capital and operating costs in the future to comply with existing environmental laws and new requirements arising from new or amended statutes and regulations. We cannot accurately predict the impact and costs that future regulations will impose on our business. See "Legal and Regulatory Proceedings Environmental Litigation and EPA Proceedings" for additional information.

## Intellectual Property

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. We cannot determine with certainty whether patents or patent applications of other parties will materially adversely affect our ability to make, use, or sell any products. A number of pharmaceutical companies, biotechnology companies, universities, and research institutions may have filed patent applications or may have been granted patents that cover aspects of our or our licensors' products, product candidates, or other technologies.

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 does not cover the majority of our existing products and product candidates. We own 11 patents issued by the U.S. Patent and Trademark Office ("PTO"), covering formulations, processes, and equipment used in the manufacture of a few of our products. These patents have expiration dates ranging from 2006 to 2022. We also own 14 trademarks registered with the PTO. We have also licensed three U.S. patents relevant to our Albuterol HFA product candidate from Virginia Commonwealth University. In addition, we are prosecuting our prefilled disposable pipette and Ampofol patents in various countries in Europe and Asia.

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.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed, or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us.

Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around, or independently develop similar or alternative technologies to ours or those of our licensors.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. PTO interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. We could incur substantial costs and our management's attention would be diverted if:

litigation is required to defend against patent suits brought by third parties;

we participate in patent suits brought against or initiated by our licensors;

we initiate similar suits; or

we participate in an interference proceeding.

In addition, we may not prevail in any of these actions or proceedings.

## Employees

As of December 31, 2004, we had a total of 729 full-time employees, of which 31 were engaged in research and development, 12 in clinical research and regulatory affairs, 44 in quality assurance/quality control, 25 in validations, 77 in scientific affairs (including chemistry and microbiology), 440 in manufacturing, 11 in sales and marketing and 89 in administration. We have 55 employees in Massachusetts who are represented by a labor union and are subject to a collective bargaining agreement. We have not experienced any work stoppages and consider our relations with our employees to be good.

## Facilities

We own or lease a total of 23 buildings at five locations in Rancho Cucamonga, Chino and South El Monte, California, and Canton and West Roxbury, Massachusetts comprising research and development, laboratory, manufacturing, packaging, distribution, warehouse, and office space. Three of the facilities, including our headquarters and principal manufacturing facilities in Rancho Cucamonga, California, totaling more than 217,000 square feet, are owned by us. All of the remaining facilities, totaling more than 517,000 square feet, are leased by us until expiration dates ranging from 2004 to 2018 (with certain renewal options). Our headquarters in Rancho Cucamonga secures our \$6.2 million credit facility.

Each of Amphastar, IMS, and Armstrong are operating companies: they each develop, manufacture and distribute pharmaceutical products and have offices, laboratories, manufacturing plants and warehouses to carry out their activities. In the case of Amphastar and IMS, their facilities specialize in injectable products filled in syringes and vials. These products include solutions, suspensions, emulsions and lyophilized drugs. In the case of Armstrong, its facilities specialize in inhalation products delivered by metered dose inhaler and nasal spray devices.

All of Amphastar's operations are in Rancho Cucamonga (where the three owned facilities are), except for its New Drug Research Center which is located in Chino. The three Amphastar facilities secure approximately \$12 million in debt. All of IMS's operations are located in leased facilities within a campus in South El Monte. All of Armstrong's operations are located in two leased facilities in Canton and West Roxbury, Massachusetts.

We believe that Amphastar's current manufacturing capacity is adequate until mid-2007. One of its three buildings, when renovated and equipped and approved by the FDA, will substantially increase its manufacturing capacity, extending our capacity for several years after mid-2007. We believe that IMS's and Armstrong's manufacturing capacities will be adequate for several years.

## Legal and Regulatory Proceedings

### *Enoxaparin Paragraph IV Litigation*

In March 2003, we filed an ANDA, which is pending with the FDA, for enoxaparin sodium, seeking approval to engage in the commercial manufacture, sale, and use of the enoxaparin product in the U.S. Aventis has two listed patents for Lovenox in the FDA's Orange Book, which is the FDA's listing of approved drug products. Our ANDA includes a Paragraph IV certification that the existing patents associated with Aventis' branded enoxaparin product, Lovenox®, are invalid or will not be infringed by our generic product candidate. Teva also filed an ANDA with the FDA on this product; however, we believe that we are the first to file a substantially complete ANDA with the FDA for this drug with a Paragraph IV certification.

As a result of the filing of the ANDAs by us and Teva, Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. filed lawsuits against us and Teva in August 2003 in the United States District Court for the District of New Jersey (the "New Jersey Court") and the United States District Court,

Central District of California, Eastern Division (the "California Court"), alleging infringement of one of the two patents on the product. We and Teva both answered the complaint brought in the California Court and filed a counterclaim, which sought a declaration that the patent-in-suit is invalid, unenforceable and/or not infringed by ours or Teva's products. In February 2004, the New Jersey Court granted Teva's motion to transfer jurisdiction of the lawsuit to the California Court and subsequently the New Jersey Court action was consolidated with the California Court action. The FDA is stayed 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. We subsequently amended our answer to allege patent unenforceability due to inequitable conduct and to assert a counterclaim alleging that Aventis violated U.S. antitrust laws. In August 2004, we filed a motion seeking a summary judgment that the Aventis patent in suit is unenforceable due to Aventis' inequitable conduct in procuring the patent and seeking to dismiss the litigation. In November 2004, we filed a second motion seeking a summary judgment that the Aventis patent-in-suit is invalid based on indefiniteness of its claims following a claim construction hearing by the judge in the case. In March 2005, we filed a third motion seeking a summary judgment that the Aventis patent-in-suit is invalid based on prior art. Our motions are currently under consideration by the California Court.

In May, 2003, Aventis filed a patent application with the 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 April 2005, the California Court denied Aventis' motion to stay the proceedings until the PTO had reissued the patent-in-suit and denied Aventis' motion requesting that the judge reconsider his prior claim construction ruling.

#### *Enoxaparin Citizen Petition*

Under FDA regulations, interested persons may petition the FDA to take or refrain from taking certain regulatory or administrative actions. In February 2003, 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 a generic version of enoxaparin, marketed by Aventis under the brand-name Lovenox. In its citizen petition, Aventis asks the FDA to withhold approval of any ANDA for enoxaparin unless the ANDA applicant demonstrates either that the manufacturing process used in producing the generic drug is equivalent to Aventis' manufacturing process or the safety and effectiveness of the generic product through clinical trials. The citizen petition also requests that the FDA withhold approval of any ANDA for enoxaparin unless the generic product contains a specific anhydro ring structure. Both of these requests are based on an assertion by Aventis in the citizen petition that, because enoxaparin is not fully characterized, the only way to ensure that all of the pharmacologically active components of enoxaparin are present is to use the same manufacturing process that Aventis uses in producing the drug, and that the specific anhydro ring structure, which Aventis claims may make important contributions to the effectiveness of the product, may not be present in a generic product that is not produced by an equivalent manufacturing process.

In October 2003, we filed comments with the FDA in opposition to Aventis' citizen petition. Our comments argued that there is no regulatory or legal basis for Aventis' request that an ANDA applicant demonstrate that the manufacturing process used in producing the generic product is equivalent to the process used by Aventis. Our comments also noted that we manufacture our enoxaparin sodium injection product pursuant to the established specifications which adequately characterize enoxaparin, the same specifications upon which Aventis relies. In February 2004, Aventis filed a supplement to its citizen petition to submit what it asserted were new discoveries in support of the citizen petition.

We have made additional submissions to the FDA reiterating our position that there is no scientific or regulatory basis for Aventis' request that the FDA withhold approval of generic versions of Lovenox, and providing additional data intended to demonstrate the equivalency of our enoxaparin to Lovenox under ANDA approval criteria. Among other things, this data is designed to demonstrate that our enoxaparin product contains the specific anhydro ring structure cited by Aventis, which is now identified on Aventis' approved labeling for Lovenox.

The FDA may reject Aventis' citizen petition, approve Aventis' citizen petition in whole or in part, or grant such other relief or take such other action as the petition warrants. Although we do not believe that Aventis' citizen petition will prevent the approval of our generic enoxaparin sodium injection product, the FDA has yet to rule on Aventis' citizen petition, and the FDA may not grant approval of our ANDA submission.

*Environmental Litigation and EPA Proceedings*

Our subsidiary, IMS, is one of approximately 39 defendants in six lawsuits brought by approximately 218 plaintiffs alleging negligence, strict liability, wrongful death, permanent trespass, continuing trespass, public permanent nuisance, public continuing nuisance, strict liability for hazardous activity and fraudulent concealment, and claiming personal injury and/or property damage from exposure to contaminated drinking water. Because of the similarity in the cases, they have been consolidated and are being referenced under In Re: Groundwater Cases (Judicial Council Coordination Proceeding No. 4135), Superior Court for the State of California, County of Los Angeles, Central Civil West District. These cases are being handled by the Los Angeles County Superior Court in a special forum for complex litigation. The plaintiffs have not definitely stated how much they are seeking in damages. IMS denies all substantive allegations of the plaintiffs and is actively defending its position to minimize any potential liability or damages. The litigation is in the discovery stage. Two of IMS's past insurance carriers are currently paying the costs and the majority of legal fees in defending these claims. There is no limit on the dollar amount of defense coverage that the two carriers might be obligated to pay. Both insurance companies have reserved their rights to be indemnified by IMS if IMS is later found to not merit insurance coverage, and both carriers have reserved their rights as to whether they are obligated to indemnify IMS for underlying claims, should a judgment be rendered against IMS in the future.

Along with approximately 35 other local businesses we were notified by the EPA in August 1995 that we were deemed potentially responsible parties, or PRPs, with respect to a groundwater contamination problem in the main San Gabriel Basin in the vicinity of IMS's primary manufacturing plant in South El Monte, California. Without admitting liability, we entered into a private agreement with another PRP to conduct a Remedial Investigation and Feasibility Study as demanded by the EPA. The study was performed pursuant to an Administrative Order on Consent that was agreed to by the EPA. In conjunction with the Administrative Order on Consent and under the approval of the California Regional Water Quality Control Board, Los Angeles Region, the Company performed certain subsurface investigatory work on our property to determine whether any land we use could be a source of the groundwater contamination. Based upon such tests, management determined that our operations did not contribute significantly to the groundwater contamination and we had minimal liability to clean up our former leasehold or the groundwater contamination. In 2000, the EPA drew upon the findings of the study to adopt an Interim Record of Decision, or ROD, for remediation of groundwater in the portion of the San Gabriel Basin known as the South El Monte Operable Unit, or SEMOU. In response, certain water purveyors in or hydrologically downgradient from the SEMOU have implemented various projects to contain, extract and/or treat eight chemicals of concern in the groundwater in order to implement the ROD. These water purveyors then moved to obtain reimbursement for their expenses incurred in implementing the ROD. In the spring of 2002, the EPA named IMS and approximately 67 other entities as responsible parties, or RPs, relative to remediation

costs in the SEMOU. In response, 13 companies, including IMS, entered into an agreement with the water purveyors to fund certain agreed upon work that included, but was not limited to, elements of the EPA's ROD. By entering into this agreement, IMS settled certain potential claims against it that were alleged by the water purveyors. Moreover, this settlement also addressed many of the claims that the EPA would have otherwise been able to bring against IMS as an RP in the SEMOU. Collectively, the 13 settling parties raised \$4.7 million. As part of the settlement, the 13 settling entities also received past and future credit for all matching public monies that were triggered as part of the settlement. During 2002, IMS paid its equal share of the settlement of \$365,000, which had been accrued in prior years.

In 2003, IMS and the other PRPs were notified that another chemical of concern (outside of the eight chemicals covered by the settlement agreement), perchlorate, was detected in the SEMOU groundwater and that it would have to be treated immediately. The PRPs are in conversations with the EPA to discuss a settlement of this liability. On April 12, 2004, IMS and several other of the settling companies were made third-party defendants in litigation between the water purveyors and the non-settling industrial defendants in the SEMOU. The third-party plaintiffs allege, among other things, a failure to adequately contribute to the groundwater cleanup costs in the SEMOU. We deny all liability relating to any and all claims in the third-party complaints. Further, since these claims overlap with some of the EPA's claims, they may be extinguished as part of any settlement with the EPA. We have tendered the third-party complaints to its insurance carriers, and the carriers are currently paying the costs and the majority of legal fees in defending these claims.

In addition to the foregoing matters, from time to time we are party to additional legal proceedings arising in the ordinary course of our business.



## MANAGEMENT

## Directors and Executive Officers

Our directors and executive officers and their ages and positions as of March 31, 2005 are as follows:

Name	Age	Position(s)
Jack Y. Zhang, Ph.D.	58	President, Chief Executive Officer and Director
Mary Z. Luo, Ph.D.	55	Chief Operating Officer and Chairman of the Board
David W. Nassif, J.D.	50	Chief Financial Officer, Senior Vice President Global Licensing, Treasurer
Stephen A. Campbell, J.D.	57	Senior Vice President, Regulatory Affairs
Peter Langosh	52	Vice President, Operations, and Secretary
Kenneth Chang, M.D.(1)	61	Director
Richard Koo(2)	65	Director
Floyd F. Petersen(1)	61	Director
Richard Prins(1)(2)	48	Director
Gordon P. Treweek, Ph.D.(2)	62	Director

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

**Jack Y. Zhang, Ph.D.** has served as our President and Chief Executive Officer since our inception in 1996 and has served as a member of our board of directors since 1996. Dr. Zhang has over 30 years of experience in chemistry, physics, management, and training including operations management of a chemical manufacturing facility with more than 2,000 employees to the start-up of an analytical laboratory serving defense cleanup. Dr. Zhang is the co-founder of Applied Physics & Chemistry Laboratory ("APCL"), a full service, chemical analytical laboratory in Chino, California and our largest stockholder, where he held the position of President for 15 years. Dr. Zhang is named as the inventor on several U.S. and foreign patents and has authored numerous academic publications. He received a Ph.D. in chemistry from the State University of New York at Stony Brook and was a Post Doctoral Research Associate at the California Institute of Technology.

**Mary Z. Luo, Ph.D.** has served as our Chief Operating Officer and Chairman of our board of directors since our inception in 1996, and served as our Secretary until April 2004. Dr. Luo has over 25 years of both academic and practical experience in the field of chemistry. Dr. Luo is the co-founder of APCL. Dr. Luo provides scientific leadership through her research and activities in technology transfer, regulatory submission, intellectual property, clinical research, recruitment, and training. In addition, Dr. Luo is a full professor of chemistry at California State Polytechnic University, Pomona. Dr. Luo is named as the inventor on several U.S. and foreign patents. Dr. Luo received a Ph.D. in chemistry from Princeton University and was a Post Doctoral Research Associate at the California Institute of Technology.

**David W. Nassif, J.D.** has served as our Chief Financial Officer since May 2002. Mr. Nassif also served as Vice President of Global Licensing from May 2002 until his promotion to Senior Vice President of Global Licensing in July 2002. From March 2001 to May 2002, Mr. Nassif was a principal in Strategic Consulting Services, providing capital raising, mergers and acquisitions, licensing, and investor relations services to various public and private life science and technology companies, including Amphastar. From January 2000 to March 2001, Mr. Nassif was the Senior Vice President, Chief Financial Officer, Treasurer, and Secretary of RealAge, Inc., a privately held health care database information marketing company. From August 1993 to December 1999, Mr. Nassif held various positions with Cypros Pharmaceutical Corporation, an AMEX-listed specialty pharmaceutical company, culminating in the position of Senior Vice President, Chief Financial Officer, Treasurer and Secretary.

Mr. Nassif received a B.S. in finance and management information systems from the University of Virginia and a J.D. from the University of Virginia School of Law.

**Stephen A. Campbell, J.D.** has served as our Senior Vice President for Regulatory Affairs since August 2002. From December 1998 until December 2002, Mr. Campbell practiced civil litigation, first as a sole practitioner and then as a partner with Campbell, Paiva & Associates. Mr. Campbell entered the pharmaceutical industry in 1976 and has held positions of increasing responsibility in quality assurance, manufacturing, and regulatory affairs, with experience in biologics, diagnostics, medical devices, and pharmaceuticals. Mr. Campbell received a B.A. in microbiology from California State University, Los Angeles, an M.B.A. from Azusa Pacific College, and a J.D. from the University of La Verne College of Law. Mr. Campbell remains an active member of the State Bar of California.

**Peter Langosh** has served as the Corporate Vice President of Operations for us and IMS since 2001 and served as a member of our board of directors from 2002 to August 2004. In April 2004, Mr. Langosh was appointed our Secretary. Mr. Langosh began at IMS in 1979, and his experience includes management responsibilities in quality control, research and development, engineering, facilities, and operations. He received a B.S. in chemistry from California State University, Long Beach and an E.M.B.A. from Claremont Graduate University.

**Kenneth Chang, M.D.** has served as a member of our board of directors since July 2004. Dr. Chang also served as a member of our board of directors from 1997 to 2003. Dr. Chang has been practicing medicine for more than 30 years with more than 26 years of experience in anesthesiology in the U.S. Dr. Chang has been the Attending Physician Anesthesiologist at the Hemet Valley Medical Center, Hemet, California since 1981, and at the Menifee Valley Medical Center, Menifee, California since 1989. Dr. Chang received a medical degree from Taipei Medical College.

**Richard Koo** has served as a member of our board of directors since 2003. Mr. Koo is also Chairman of our audit committee. For over five years, Mr. Koo has been the managing partner of Koo, Chow and Company, Certified Public Accountants, and also serves as CEO and President of K.C. Group International Inc. Mr. Koo has extensive experience as a CPA in auditing and taxation and has worked with PricewaterhouseCoopers LLP in various public offering audit assignments. Mr. Koo has worked as a finance and taxation expert for the United Nations and has written numerous books and publications.

**Floyd F. Petersen** has served as a member of our board of directors since August 2004. From 1990 to the present, Mr. Petersen has been the Director of the Loma Linda University Health Research Consulting Group, which consults on health research study design and data analysis. Since 1988, Mr. Petersen has been an Assistant Professor of Biostatistics at the School of Public Health and School of Medicine of Loma Linda University. From 1996 to 2004, Mr. Petersen served as the Mayor of the City of Loma Linda, California. Mr. Petersen received an M.P.H. in public health with a concentration in biostatistics from Loma Linda University.

**Richard Prins** has served as a member of our board of directors since 2002. Since 1996, Mr. Prins has been Director of Investment Banking for Ferris, Baker Watts, Inc. where he heads all of the firm's corporate finance activities and is responsible for executing a variety of transactions, including public offerings, mergers and acquisitions, private placements, restructurings, as well as other corporate advisory services. Mr. Prins has 21 years of experience in corporate finance and has participated directly in more than 100 transactions with a broad cross-section of both private and public companies. Mr. Prins currently serves on the board of directors of Startec Global Communications. Mr. Prins received a B.A. in Liberal Arts from Colgate University and an M.B.A. from Oral Roberts University.

**Gordon P. Treweek, Ph.D.** has served as a member of our board of directors since 1999. Dr. Treweek has been the President of Environmental Defense Sciences, a firm which provides forensic environmental expertise to a wide range of clients, since its inception in 1997. Previously, Dr. Treweek

was a Division Manager and Vice President for 11 years with a major hazardous waste consulting engineering firm, and Department Manager and Vice President for 10 years with a water and wastewater consulting engineering firm. Dr. Treweek received a B.S. in civil engineering from the United States Military Academy, and an M.S. in engineering science, and a Ph.D. in environmental engineering from the California Institute of Technology.

#### **Executive Officers**

Our executive officers are elected by and serve at the discretion of our board of directors. Dr. Zhang, our Chief Executive Officer, and Dr. Luo, our Chief Operating Officer, are husband and wife.

#### **Board Composition**

Our board of directors currently consists of seven members. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal.

#### **Board Committees**

Our board of directors has an audit committee and a compensation committee. We may appoint additional committees of our board of directors in the future, including for purposes of complying with all applicable corporate governance rules of the NASDAQ National Market.

*Audit Committee.* Our audit committee currently consists of Mr. Koo, Dr. Treweek and Mr. Prins, each of whom is an independent member of our board of directors. The functions of this committee include:

overseeing the engagement of our independent public accountants;

reviewing our audited financial statements and discussing them with the independent public accountants and our management;

meeting with the independent public accountants and our management to consider the adequacy of our internal controls; and

reviewing our financial plans and reporting recommendations to our full board for approval and to authorize action.

Both our independent registered accounting firm and internal financial personnel regularly meet with our audit committee and have unrestricted access to this committee.

*Compensation Committee.* Our compensation committee currently consists of Dr. Chang, Mr. Petersen and Mr. Prins, each of whom are independent members of our board of directors. The functions of this committee include:

reviewing and, as it deems appropriate, recommending to our board of directors, policies, practices, and procedures relating to the compensation of our directors, officers, and other managerial employees and the establishment and administration of our employee benefit plans;

determining or recommending to the board of directors the compensation of our executive officers; and

advising and consulting with our officers regarding managerial personnel and development.

**Compensation Committee Interlocks and Insider Participation**

Dr. Luo and Mr. Prins served as members of our compensation committee during the last fiscal year. During 2003, Dr. Luo also served as our Chief Operating Officer. In August 2004, Dr. Luo resigned her membership on our compensation committee and was replaced by Dr. Chang.

No member of our compensation committee serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

**Director Compensation**

Our directors receive a fee of \$2,500 for attendance in person (\$500 for attendance by phone) at meetings of our board of directors, and they are reimbursed for travel expenses and other out-of-pocket costs incurred in connection with their attendance at meetings. They also receive options exercisable for 4,000 shares of our common stock annually at the fair market value of our common stock at the time of grant under our Amended and Restated 2002 Stock Option/Stock Issuance Plan (the "2002 Plan").

Mr. Petersen received a fee of \$2,400 in 2005 for consulting services.

**Scientific Advisory Board**

Our scientific advisory board is made up of a group of experienced scientists and clinicians chosen for their particular expertise. Members of our scientific advisory board consult with us regularly on matters relating to:

- our research and development programs;
- the design and implementation of our clinical trials;
- market opportunities from a clinical perspective;
- new technologies relevant to our research and development programs; and
- scientific and technical issues relevant to our business.

We compensate scientific advisory board members with stock options pursuant to the 2002 Plan and an annual fee for attendance at meetings and other advisory services. We may add additional members to our scientific advisory board in the future. The current scientific advisory board members are:

<b>Name</b>	<b>Professional Affiliation</b>
Chen Ning Yang, Ph.D.	Einstein Professor, Institute of Theoretical Physics, State University of New York, Stony Brook Nobel Prize Laureate, Physics, 1957
Rudy Marcus, Ph.D.	Noyes Professor, Department of Chemistry, California Institute of Technology Nobel Prize Laureate, Chemistry, 1992
Richard Porter, Ph.D.	Professor, Department of Chemistry, State University of New York, Stony Brook
Paul White, M.D., Ph.D.	Professor, Anesthesiology, University of Texas Southwestern Medical Center

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

Name

Professional Affiliation

---

Steven Shafer, M.D.

Professor of Anesthesia, Stanford University  
Staff Anesthesiologist,  
Palo Alto VA Health Care System  
Adjunct Professor of Biopharmaceutical Science,  
University of California at San Francisco

Herschel Rabitz, Ph.D.

Professor, Department of Chemistry,  
Princeton University

68

---

**Executive Compensation**

The following table sets forth information concerning all compensation paid to our Chief Executive Officer and each of our other four most highly compensated executive officers whose salary and bonus exceeded \$100,000 for services rendered to us during the fiscal year ended December 31, 2004, who we refer to in this prospectus as our named executive officers.

**Summary Compensation Table**

Name and Principal Position(s)	Year	Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)(1)	Securities Underlying Long Term Options (#)
Jack Zhang, Ph.D. <i>President and Chief Executive Officer(2)(3)</i>	2004	493,113			128,000
	2003	325,000	10,000		244,000
	2002	394,471	7,000		274,000
Mary Luo, Ph.D. <i>Chief Operating Officer(3)(4)</i>	2004	396,500			108,000
	2003	273,000	12,500		204,000
	2002	331,356	10,075		234,000
David Nassif <i>Chief Financial Officer, Treasurer and Senior Vice President of Global Licensing(5)</i>	2004	216,000			15,000
	2003	200,000	6,000		20,000
	2002	119,618			100,000
Stephen Campbell <i>Senior Vice President of Regulatory Affairs(6)</i>	2004	213,926	6,300		22,000
	2003	195,397	5,150		40,000
	2002	34,615			10,000
Peter Langosh <i>Vice President of Operations And Secretary(3)</i>	2004	152,141	10,500		8,000
	2003	138,457	6,500		4,000
	2002	141,070	3,000		10,000

- (1) In accordance with the rules of the SEC, the other annual compensation described in this table does not include various perquisites and other personal benefits received by a named executive officer that do not exceed the lesser of \$50,000 or 10% of such officer's salary and bonus disclosed in this table.
- (2) The salary figures for Dr. Zhang for 2002 and 2004 include \$78,125 and \$60,721, respectively, in accrued paid vacation which he decided to take in the form of cash.
- (3) The option figures for Dr. Zhang, Dr. Luo and Mr. Langosh include 8,000, 8,000 and 0, respectively, for board of directors service in 2004 and 4,000, 4,000, and 4,000 options, respectively, for Board service in 2003, and 34,000, 34,000, and 4,000 options, respectively, for board of directors service between 1998 and 2002.
- (4) The salary figures for Dr. Luo for 2002 and 2004 include \$65,625 and \$48,750, respectively, in accrued paid vacation, which she decided to take in the form of cash.
- (5) Mr. Nassif began his employment with us in May 2002.
- (6) Mr. Campbell began his employment with us in August 2002.

**Option Grants in 2004**

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

The following table sets forth information with respect to stock options granted to each of our named executive officers during 2004. The percentage of total options set forth below is based on options to purchase an aggregate of 804,500 shares of common stock granted to employees in 2004. All of these options were granted under the 2002 Plan at an exercise price per share equal to the fair market value of our common stock at the time of grant, as determined by our board of directors. Potential realizable values are net of exercise price but before taxes associated with exercise. Amounts represent hypothetical gains that could be achieved for the options if exercised at the end of the option term. The assumed 5% and 10% rates of stock price appreciation are provided in accordance with the rules of the SEC and do not represent our estimate or projection of the future common stock price.

Actual gains, if any, on stock option exercises will be dependent on the future performance of our common stock.

**Individual Grants**

Name	Number of Securities Underlying Options Granted	% of Total Options Granted to Employees in Fiscal Year	Exercise Price Per Share	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Appreciation for Option Term	
					5%	10%
Jack Zhang, Ph.D.	120,000	14.92%	\$ 13.75	1/1/2010	\$ 561,158	\$ 1,273,076
	6,000	.75%	\$ 13.75	10/13/2012	\$ 39,390	\$ 94,346
	2,000	.25%	\$ 13.75	10/13/2011	\$ 11,195	\$ 26,090
Mary Luo, Ph.D.	100,000	12.43%	\$ 13.75	1/1/2010	\$ 467,632	\$ 1,060,896
	6,000	.75%	\$ 13.75	10/13/2012	\$ 39,390	\$ 94,346
	2,000	.25%	\$ 13.75	10/13/2011	\$ 11,195	\$ 26,090
David Nassif	15,000	1.86%	\$ 12.50	7/29/2014	\$ 117,918	\$ 298,827
Stephen Campbell	12,000	1.49%	\$ 12.50	7/29/2014	\$ 94,334	\$ 239,061
	10,000	1.24%	\$ 12.50	10/13/2014	\$ 78,612	\$ 199,218
Peter Langosh	8,000	.99%	\$ 12.50	7/29/2014	\$ 62,889	\$ 159,374

**Aggregated Option Exercises in 2004 and Option Values at December 31, 2004**

The following table sets forth information concerning exercisable and unexercisable stock options held by each of the named executive officers at the end of the fiscal year ended December 31, 2004. The value realized upon exercise is based on per share exercise price multiplied by number of shares acquired upon exercise. The value of unexercised in-the-money options is based on the assumed initial public offering price of \$ per share less the per share exercise price, multiplied by the number of shares underlying the options.

Name	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at December 31, 2004		Value of Unexercised In-the-Money Options at December 31, 2004	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Jack Zhang, Ph.D.			1,120,000	66,000		
Mary Luo, Ph.D.			933,334	66,000		
David Nassif			5,000	130,000		
Stephen Campbell			23,000	49,000		
Peter Langosh			9,800	52,200		

**Employee Benefit Plans**

**Amended and Restated 2002 Stock Option/Stock Issuance Plan**

*Introduction.* The 2002 Plan was adopted by our board of directors in November 2002, and approved by our stockholders in August 2003. The board of directors approved an amendment to the 2002 Plan in April 2004 increasing the number of options for grant under the 2002 Plan, which was approved by our stockholders in June 2004.

*Share Reserve.* 6,400,000 shares of common stock have been authorized for issuance under the 2002 Plan. In addition, no participant in the 2002 Plan may be granted stock options, and/or stock awards for more than 400,000 shares of common stock per calendar year.



*Structure.* The 2002 Plan provides for two types of equity incentives:

option grants, pursuant to which eligible individuals in our employ or service may be granted options to purchase shares of common stock at an exercise price not less than 85% of the fair market value of those shares on the grant date; and

stock awards, under which such individuals may be issued shares of common stock directly, through the purchase of such shares at a price not less than 100% of their fair market value at the time of issuance; however, the purchase price for such shares may be paid through the cancellation of indebtedness to our company or performance of services.

*Eligibility.* The individuals eligible to participate in the 2002 Plan include our employees, our non-employee board members and any consultants we hire.

*Administration.* The 2002 Plan is administered by our compensation committee and/or our board of directors (for purposes of this description, the compensation committee and our board will be referred to generally, as the "plan administrator"). The plan administrator will determine which eligible individuals are to receive option grants or stock awards under the 2002 Plan, the time or times when such option grants or stock awards are to be made, the number of shares subject to each such grant or award, the vesting schedule to be in effect for the option grant or stock award, and the maximum term for which any granted option is to remain outstanding.

*Plan Features.* The 2002 Plan includes the following features:

The exercise price for the shares of common stock subject to option grants made under the 2002 Plan may be paid in cash or in shares of common stock valued at fair market value on the exercise date. Options may also be exercised through a same-day sale program without any cash outlay by the optionee. In addition, the plan administrator may provide financial assistance to one or more optionees in the exercise of their outstanding options or the purchase of their unvested shares by allowing such individuals to deliver a full-recourse, interest-bearing promissory note in payment of the exercise price and any associated withholding taxes incurred in connection with such exercise or purchase.

In the event we merge or are acquired, options outstanding under the 2002 Plan shall be treated in one of the following ways:

the options shall continue (in the event we are the surviving corporation);

the options will be assumed by the acquiror;

the options will be substituted by the acquiror;

the options will fully vest and then cancel; or

the options will be cashed out and then cancelled.

The board may amend or modify the 2002 Plan at any time, subject to any required stockholder approval. The 2002 Plan will terminate no later than November 2012.

As of December 31, 2004, options to purchase 3,000,420 shares of common stock were outstanding, and 3,393,580 shares were available for future grants or awards under the 2002 Plan.

***Stock Options Granted From 1998 Through 2001 (98-01 Plans)***

From 1998 through 2001, our board of directors granted options to purchase shares of our common stock pursuant to the terms of certain stand-alone option agreements. Under these agreements, stock options were granted to employees, including key officers, non-employee board members, advisory board members, and consultants. Options granted to employees and non-employees



were non-statutory stock options. The terms of each option grant were determined by our board of directors or a committee appointed by the board for such purpose.

The following is a summary generally describing the terms of such grants. The options vest pursuant to an optionee's continued service with our company over a three-year period, have a term of seven years, are non-transferable, and have an exercise price of not less than 100% of fair market value, as determined by our board of directors. The options expire 30 days following an optionee's termination of service, except in event of termination due to death or disability, in which cases, the options expire six months following such termination. In the event of a change of control of our company, the treatment of the options, including the accelerated vesting, assumption, or substitution of such options, is to be determined by our board of directors, unless the terms of certain specific option agreements provide otherwise.

In the aggregate, a total of 3,264,844 shares were granted subject to standalone option agreements, 2,073,734 of which were outstanding as of December 31, 2004.

#### **401(k) Plan**

We have a defined contribution 401(k) plan, whereby eligible employees can voluntarily contribute up to a defined percentage of their annual compensation up to the maximum statutory limit. We match 50% of each 1% of employee contributions up to 4% of total employee contributions or 2% of their annual compensation and pay the administrative costs of the plan. Employer contributions vest ratably over five years.

#### **Limitation of Liability and Indemnification Matters**

Our certificate of incorporation and bylaws contain provisions indemnifying our directors and officers to the fullest extent permitted by law. Prior to the completion of this offering, we intend to enter into indemnification agreements with each of our directors that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law.

In addition, as permitted by Delaware law, our certificate of incorporation provides that no director will be liable to us or our stockholders for monetary damages for breach of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of certain fiduciary duties as a director, except that a director will be personally liable for:

any breach of the director's duty of loyalty to us or our stockholders;

acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

the payment of dividends or the redemption or purchase of stock in violation of Delaware law; or

any transaction from which the director derived an improper personal benefit.

To the extent that our directors, officers, and controlling persons are indemnified under the provisions contained in our certificate of incorporation, Delaware law, or contractual arrangements against liabilities arising under the Securities Act, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2005 by:

each person known by us to own beneficially more than 5% of our common stock,

each of our directors,

each of our named executive officers, and

all of our directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, including options that are currently exercisable or exercisable within 60 days. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed below, based on the information each of them has given to us, have sole investment and voting power with respect to their shares, except where community property laws may apply.

This table lists applicable percentage ownership based on 35,921,416 shares of common stock outstanding as of March 31, 2005. Options to purchase shares of our common stock that are exercisable within 60 days of March 31, 2005 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person but are not treated as outstanding for the purpose of computing any other person's ownership percentage. Shares underlying options that are deemed beneficially owned are included in the shares listed under "Amount and Nature of Beneficial Ownership" and are also listed in this table separately in the column labeled "Shares Subject to Options."

Except as otherwise noted, the address of each person or entity in the following table is c/o Amphastar Pharmaceuticals, Inc., 11570 Sixth Street, Rancho Cucamonga, California 91730.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Shares Subject to Options	Percentage of Shares Beneficially Owned	
			Before Offering	After Offering
<b>Directors and Named Executive Officers</b>				
Jack Zhang, Ph.D.(1)(7)	10,119,663	1,120,000	27.32%	
Mary Luo, Ph.D.(1)(8)	9,924,507	933,334	26.93%	
David Nassif	5,000	5,000	*	
Stephen Campbell	23,000	23,000	*	
Richard Koo(2)	364,402	30,000	1.01%	
Peter Langosh	9,800	9,800	*	
Floyd Petersen	10,000	10,000	*	
Kenneth Chang, M.D.(3)	258,582	32,400	*	
Richard Prins	8,000	8,000	*	
Gordon Treweek, Ph.D.(4)	180,000	20,000	*	
All executive officers and directors as a group (ten persons)(1)	13,069,760	2,191,534	34.29%	
<b>5% Stockholders</b>				
Applied Physics & Chemistry Laboratory(5)	7,811,594		21.75%	
China Development Industrial Bank(6)	3,400,000		9.47%	

\* Represents beneficial ownership of less than 1% at the outstanding shares of common stock.



Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

- (1) Includes 7,811,594 shares held of record by Applied Physics & Chemistry Laboratory, the sole owners of which were Drs. Zhang and Luo.
- (2) Includes 324,402 shares owned by Mr. Koo and 10,000 shares owned by Richard Y. Koo, a sole proprietorship.
- (3) Includes 140,000 shares owned by the Kenneth C. Chang, M.D., Inc. Retirement Trust.
- (4) Includes 80,000 shares in the name of the Treweek Family Revocable Trust UAD 10/25/88 and 80,000 shares in the name of the Treweek Family Revocable Trust UAD 10/25/90. Mr. Treweek is the trustee of both trusts.
- (5) The business address of Applied Physics & Chemistry Laboratories is 13760 Magnolia Avenue, Chino, California 91710.
- (6) The business address of China Development Industrial Bank is 9F, 125 Nanking East Road, Section 5, Taipei, Taiwan, R.O.C.
- (7) Excludes 736,359 shares owned by Jack Y. Zhang 2004 GRAT No. 2, a grantor reserved annuity trust.
- (8) Excludes 736,359 shares owned by Mary Luo 2004 GRAT No. 2, a grantor reserved annuity trust.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

### Agreements with Applied Physics & Chemistry Laboratories

Prior to completion of this offering, Applied Physics & Chemistry Laboratories ("APCL") owned approximately 22% of our outstanding shares of common stock. APCL is owned 100% by Dr. Zhang and Dr. Luo, our President and Chief Executive Officer and Chief Operating Officer, respectively. In 1997, we entered into an equipment agreement with APCL, whereby we agreed to purchase or lease equipment from APCL with an aggregate cost not to exceed \$9.1 million. Under the agreement, APCL managed leasing arrangements and paid all costs associated with the purchase or lease of the equipment on the Company's behalf. APCL purchased or leased equipment based on the Company's technical requirements. Certain equipment lease agreements made by APCL on our behalf are guaranteed by us. Title to the equipment passes to us at the end of the lease. As of December 31, 2002, 2003 and 2004, we had guaranteed future aggregate lease payments of APCL made on our behalf of \$0.7 million, \$0.6 million and \$0.2 million, respectively, through 2006.

Annually, the Company compensated APCL for related equipment costs plus a management fee equal to 2.5% of all related costs incurred by APCL, in the form of shares of common stock until a total of 6,087,334 shares were to be issued. In 2001, the Company issued 973,986 shares of common stock for equipment amounting to \$1.5 million received under capital lease obligations of APCL. For equipment and services provided through December 31, 2002, 5,113,344 shares were issued in total. At December 31, 2002, an additional 279,313 shares valued at \$0.4 million were not issued, but earned and, accordingly classified, as common stock to be issued under the agreement.

In 2003, the Company issued the remaining 973,990 shares due under the agreement, comprised of the 279,313 shares due to be issued from 2002 and 694,677 shares earned in 2003, which were valued at \$1.0 million. In April 2003, the Company amended the equipment agreement to clarify terms related to the management fee, which resulted in the Company owing APCL an additional 517,671 shares for management fees which were valued at \$776,000. Of the 694,677 shares issued in 2003, 517,671 shares related to the management fees and 177,006 shares related to equipment and services provided in 2003. As of December 31, 2003, we had no further obligation to APCL under the equipment agreement.

In addition, we lease office and laboratory facilities and office equipment from APCL to conduct our research and development activities. The audit committee of the board of directors has authorized this arrangement until the earlier of the acquisition of permanent space for these activities or December 31, 2007, up to a maximum lease amount of \$292,000 per year.

In 2002, 2003 and 2004, the Company incurred rental expense of \$138,000, \$145,000 and \$204,000 related to the equipment and lease agreements with APCL.

From time to time, we outsource laboratory test work to APCL. The total amount paid to APCL in 2002, 2003 and 2004 for laboratory test work was approximately \$14,437, \$19,000 and \$17,000, respectively. This arrangement has also been approved by the audit committee of the board of directors.

In 2002, we charged APCL approximately \$65,000 for certain labor services. No labor services were provided in 2003 and 2004.

### Other Related Party Transactions

We engaged in various consulting arrangements with one of our directors, Dr. Kenneth Chang, during 2002, 2003 and 2004. For the years ended December 31, 2002, 2003 and 2004, we expensed \$27,300, \$15,600 and \$8,500, respectively, for Dr. Chang's consulting services and issued 5,460 and 1,950 shares of common stock to Dr. Chang in lieu of cash for such consulting services performed in 2002

and 2003, respectively. In January 2005, Dr. Chang received 4,400 options to purchase common stock of the Company with a per share exercise price of \$12.50 per share for consulting services.

**Employment Agreements**

We previously entered into employment agreements dated January 1, 2004 with Dr. Zhang, our President and Chief Executive Officer, and Dr. Luo, our Chief Operating Officer, which had a one-year term expiring on December 31, 2004. Dr. Zhang's agreement provided for a base salary of \$421,000 and a stock option grant of 120,000 shares with an exercise price of \$13.75 per share, which vested on December 31, 2004, and has a term of five years. Dr. Luo's agreement provided for a base salary of \$338,000, and a stock option grant of 100,000 shares with an exercise price of \$13.75 per share, which vested on December 31, 2004 and has a term of five years.



## DESCRIPTION OF CAPITAL STOCK

### General

Under our certificate of incorporation, we are authorized to issue up to 120,000,000 shares, \$.0001 par value per share, 100,000,000 shares of which may be common stock and 20,000,000 shares of which may be preferred stock. The following description of our capital stock is subject to, and qualified in its entirety by, the provisions of our certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus is a part, and by the provisions of applicable law.

### Common Stock

As of December 31, 2004, there were 35,245,740 shares of our common stock outstanding that were held of record by 255 stockholders. As of that same date, there were no shares of preferred stock outstanding.

The holders of our common stock are entitled to one vote for each share held of record upon such matters and in such manner as may be provided by law. Under the Delaware General Corporation Law and our bylaws, our board of directors may declare and pay dividends upon shares of our capital stock out of legally available funds, subject to any restrictions in our certificate of incorporation. In the event we liquidate, dissolve, or wind up, the holders of our common stock are entitled under the Delaware General Corporation Law to share ratably in all assets remaining after payment of liabilities and liquidation preferences of any outstanding shares of the preferred stock. Holders of our common stock have no preemptive rights or rights to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of our common stock are fully paid and nonassessable.

### Preferred Stock

Our board of directors has the authority to issue undesignated preferred stock in one or more series and to determine the powers, preferences, and rights and the qualifications, limitations, or restrictions granted to or imposed upon any wholly unissued series of undesignated preferred stock and to fix the number of shares constituting any series and the designation of the series, without any further vote or action by our stockholders. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock. We have no present plans to issue any shares of preferred stock.

### Registration Rights

After the closing of this offering, the holders of approximately 799,676 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. The holders of these shares are entitled to certain piggyback registration rights. If we register any securities for public sale other than for our initial public offering, these holders will have the right to include their shares in the registration statement. In an underwritten offering, we have agreed to use our best efforts to cause the shares to be included in the underwriting on the same terms and conditions as the securities being sold through any such underwriters. We have agreed to indemnify the holders of this registration right against liabilities under the Securities Act, the Exchange Act, or other federal or state securities law.

### Anti-Takeover Provision

Provisions of Delaware law and our certificate of incorporation and bylaws could make our acquisition by means of a tender offer, a proxy contest or otherwise, and the removal of incumbent

officers and directors, more difficult. These provisions are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweighs the disadvantages of discouraging proposals, including proposals that are priced above the then current market value of our common stock, because, among other things, negotiation of these proposals could result in an improvement of their terms.

#### **Delaware Law**

We are subject to Section 203 of the Delaware General Corporation Law. Under this provision, we may not engage in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

prior to that date our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock outstanding at the time the transaction began; or

on or following that date the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, lease, exchange, mortgage, transfer, pledge, or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to some exceptions, any transaction that results in the issuance or transfer by the corporation or any of its direct or indirect subsidiaries of any stock of the corporation or of any such subsidiary to the interested stockholder;

any transaction involving the corporation or any of its direct or indirect subsidiaries that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or of any such subsidiary beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as any entity or person who beneficially owns, or an affiliate or associate of the corporation that at any time within three years prior to the date of determination of interested stockholder status shares did beneficially own, 15% or more of the outstanding voting stock of the corporation, and affiliates and associates of such person.

#### **Certificate of Incorporation and Bylaws**

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. In particular, our certificate of incorporation and bylaws, as applicable, among other things:

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

provide that special meetings of the stockholders may be called only by our Chairman of the Board, Chief Executive Officer, President, Chief Operating Officer or the board of directors

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

pursuant to a resolution adopted by a majority of the total number of authorized directors of our board of directors;

establish procedures with respect to stockholder proposals and stockholder nominations, including requiring that advance written notice of a stockholder proposal or director nomination generally must be received at our principal executive offices not less than 90 nor more than 120 days prior to the first anniversary date of mailing of our proxy statement released to stockholders in connection with the previous year's annual meeting of stockholders;

do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the board of directors and, as a result, may have the effect of deterring a hostile takeover or delaying or preventing changes in control or management of our company;

provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum, and not by the stockholders;

require that the vote of holders of 66<sup>2</sup>/<sub>3</sub>% of the voting power of the outstanding shares entitled to vote generally in the election of directors is required to amend various provisions of our certificate of incorporation and bylaws, including provisions relating to:

the number of directors on our board of directors;

the election, qualification and term of office of our directors;

filling vacancies on our board of directors;

the indemnification of our officers and directors;

removal of members of our board of directors; and

certain amendments to our certificate of incorporation and by-laws; and

allow us to issue without stockholder approval up to 20,000,000 shares of undesignated preferred stock with rights senior to those of the common stock and that otherwise could adversely affect the rights and powers, including voting rights, of the holders of common stock. In some circumstances, this issuance could have the effect of decreasing the market price of the common stock as well as having the anti-takeover effect discussed above.

These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board and in the policies formulated by them and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

### **NASDAQ Stock Market National Market Listing**

We have applied to have our common stock approved for quotation on the NASDAQ National Market under the symbol "AMPR."

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market following this offering or the possibility of sales of this kind occurring could cause the prevailing market price of our common stock to fall and impede our ability to raise capital through an offering of equity securities.

Upon completion of this offering, we will have a total of \_\_\_\_\_ shares of common stock outstanding based upon \_\_\_\_\_ shares outstanding as of \_\_\_\_\_, 2005, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options prior to completion of this offering. The shares offered by this prospectus will be freely tradable unless they are purchased by our "affiliates," as defined in Rule 144 under the Securities Act. Shares purchased by affiliates may generally only be sold pursuant to an effective registration statement under the Securities Act or in compliance with Rule 144. The remaining \_\_\_\_\_ shares of our common stock are "restricted," which means they were originally sold in offerings that were not subject to a registration statement filed with the SEC. These restricted shares may generally be resold only through registration under the Securities Act or under an available exemption from registration, such as provided by Rule 144.

#### Lockup Agreements

All officers and directors and holders of over \_\_\_\_\_ % of our outstanding common stock have entered into the contractual "lockup" agreements described in "Underwriting." As a result of these contractual restrictions, notwithstanding possible earlier eligibility for sale under the provisions of Rules 144, 144(k) and 701, additional shares will be available for sale beginning 180 days after the date of this prospectus, subject in some cases to certain volume limitations.

For the purpose of underwriters to comply with NASD Rule 2711(f)(4), if (i) we issue an earnings release or material news or a material event relating to us occurs during the last 17 days of the 180-day lock-up period, or (ii) prior to the expiration of the 180-day lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day lock-up period, then in each case, the restrictions applicable during the 180-day lock-up period, unless otherwise waived in writing by Lehman Brothers Inc. and UBS Securities LLC in their sole discretion, will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. However, the restrictions in the prior sentence will not apply if any research published or distributed by any underwriter relating to us would be compliant under Rule 139 of the Securities Act and our shares of common stock are "actively traded securities" as defined in Rule 101(c)(1) of Regulation M of the Exchange Act.

#### Rule 144

In general, under Rule 144 as currently in effect, beginning three months after the date of this prospectus, a person or persons whose shares are aggregated, who has beneficially owned restricted shares for at least one year, including persons who may be deemed to be our "affiliates," would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; or

the average weekly trading volume of our common stock as reported through the NASDAQ National Market during the four calendar weeks preceding the filing of a Form 144 with respect to such sale.

Sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements and to the availability of certain public information about us.

**Rule 144(k)**

Under Rule 144(k), a person who is not deemed to have been one of our "affiliates" at any time during three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an "affiliate," is entitled to sell these shares without complying with the manner of sale, public information, volume limitation, or notice provisions of Rule 144.

**Rule 701**

Subject to certain limitations on the aggregate offering price of a transaction and other conditions, Rule 701 permits resales of shares issued prior to the date the issuer becomes subject to the reporting requirements of the Exchange Act, pursuant to certain compensatory benefit plans and contracts commencing 90 days after the issuer becomes subject to the reporting requirements of the Exchange Act, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirements. In addition, the SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of these options, including exercises after the date the issuer becomes so subject. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates" subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

**S-8 Registration Statement**

We intend to file a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to outstanding options or reserved for issuance under our various stock option plans. Upon the effectiveness of this registration statement, all of these shares will, subject to Rule 144 volume limitations applicable to affiliates, be available for sale in the open market, except to the extent that these shares are subject to vesting restrictions or the contractual restrictions described above.

**MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS**

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock to non-U.S. holders, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in United States federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance the IRS will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any foreign, state or local jurisdiction. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies, or other financial institutions;

persons subject to the alternative minimum tax;

tax-exempt organizations;

dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than five percent of our common stock (except to the extent specifically set forth below);

certain former citizens or long-term residents of the United States;

persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction; or

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships which hold our common stock, and partners in such partnerships, should consult their tax advisors.

*YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, FOREIGN, OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.*

**Non-U.S. Holder Defined**

For purposes of this discussion, you are a non-U.S. holder if you are a holder that, for U.S. federal income tax purposes, is not a U.S. person. For purposes of this discussion, you are a U.S. person if you are:

an individual citizen or resident of the United States;



## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

a corporation or other entity taxable as a corporation, or a partnership or entity taxable as a partnership, created or organized in the United States or under the laws of the United States or any political subdivision thereof, unless in the case of a partnership, U.S. Treasury Regulations provide otherwise;

an estate whose income is subject to U.S. federal income tax regardless of its source; or

a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (y) which has made an election to continue to be treated as a U.S. person.

### **Distributions**

We have not made any distributions on our common stock, and we do not plan to make any distributions for the foreseeable future. If we do make distributions on our common stock, however, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business are exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may obtain a refund of any excess amounts currently withheld if you file an appropriate claim for refund with the IRS.

### **Gain on Disposition of Common Stock**

You generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with your conduct of a U.S. trade or business;

you are an individual who holds our common stock as a capital asset (generally, an asset held for investment purposes) and who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or your holding period for our common stock.

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

We believe that we are not currently and will not become a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, however, there can be no assurance we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and corporate non-U.S. holders described in the first bullet above may be subject to the branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though you are not considered a resident of the United States). You should consult any applicable income tax treaties that may provide for different rules.

### **Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report is sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence. Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding unless you establish an exemption, for example by properly certifying your non-United States status on an IRS Form W-8BEN or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a United States person.

Backup withholding is not an additional tax; rather, the U.S. income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may be obtained, provided that the required information is furnished to the IRS in a timely manner.

**UNDERWRITING**

Under the terms of an Underwriting Agreement, which is filed as an exhibit to the registration statement relating to this prospectus, each of the underwriters named below, for whom Lehman Brothers Inc., UBS Securities LLC (as joint bookrunners) and Deutsche Bank Securities Inc. are acting as representatives, have severally agreed to purchase from us the respective number of shares of common stock opposite their names below:

Underwriter	Number of Shares
Lehman Brothers Inc.	
UBS Securities LLC	
Deutsche Bank Securities Inc.	
Total	

The Underwriting Agreement provides that the underwriters' obligation to purchase shares of our common stock depends on the satisfaction of the conditions contained in the Underwriting Agreement, including:

the obligation to purchase all of the shares of common stock offered hereby, if any of the shares are purchased;

the representations and warranties made by us to the underwriters are true;

there is no material change in the financial markets; and

we deliver customary closing documents to the underwriters.

**Commissions and Expenses**

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting discount is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per share		
Total		

The representatives of the underwriters have advised us that the underwriters propose to offer shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, who may include the underwriters, at such offering price less a selling concession not in excess of \$ per share. The underwriters may allow, and the selected dealers may re-allow, a discount from the concession not in excess of \$ per share to other dealers. After the offering, the representatives may change the public offering price and other selling terms.

The expenses of the offering that are payable by us are estimated to be \$ (excluding underwriting discounts and commissions).

**Option to Purchase Additional Shares**

We have granted the underwriters an option exercisable for 30 days after the date of the Underwriting Agreement to purchase, from time to time, in whole or in part, up to an aggregate of shares at the public offering price less underwriting discounts and commissions. The option may be exercised if the underwriters sell more than shares in connection with the offering. To the extent that this option is exercised, each underwriter will be obligated, subject to



certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in the offering as indicated in the preceding table.

### **Lock-Up Agreements**

We, our directors and executive officers, and holders of more than % of our outstanding stock, have entered into lock-up agreements with the underwriters. Under these agreements, subject to certain exceptions and limited extensions in certain circumstances, we may not issue any new shares of common stock, and those holders of stock may not, directly or indirectly, offer, sell, contract to sell, pledge, or otherwise transfer, dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of our common stock, or publicly announce the intention to do any of the foregoing, without the prior written consent of Lehman Brothers Inc. and UBS Securities LLC for a period of 180 days from the date of this prospectus. This consent may be given at any time without public notice. In addition, during this 180 day period, we have also agreed not to file any registration statement for the registration of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock (other than on Form S-8) without the prior written consent of Lehman Brothers Inc. and UBS Securities LLC.

For the purpose of underwriters to comply with NASD Rule 2711(f)(4), if (i) we issue an earnings release or material news or a material event relating to us occurs during the last 17 days of the 180-day lock-up period, or (ii) prior to the expiration of the 180-day lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day lock-up period, then in each case, the restrictions applicable during the 180-day lock-up period, unless otherwise waived in writing by Lehman Brothers Inc. and UBS Securities LLC in their sole discretion, will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

### **Offering Price Determination**

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be negotiated between the representatives and us. In determining the initial public offering price of our common stock, the representatives will consider:

the history and prospects for the industry in which we compete,

our financial information,

the ability of our management and our business potential and earning prospectus,

the prevailing securities markets at the time of this offering, and

the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and to contribute to payments that the underwriters may be required to make for these liabilities.

### **Stabilization, Short Positions and Penalty Bids**

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock, in accordance with Regulation M under the Exchange Act:

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates a syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sale made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ National Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

### **Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's website and any information contained in any other website maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

**NASDAQ National Market**

We have applied to list our shares of common stock for quotation on the NASDAQ National Market under the symbol "AMPR."

**Discretionary Sales**

The underwriters have informed us that they do not intend to confirm sales to discretionary accounts that exceed 5% of the total number of shares offered by them.

**Stamp Taxes**

If you purchase shares of our common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

**Relationships**

The underwriters may in the future perform investment banking and advisory services for us from time to time for which they may in the future receive customary fees and expenses. The underwriters may, from time to time, engage in transactions with or perform services for us in the ordinary course of their business.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Latham & Watkins LLP, Los Angeles, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Clifford Chance US LLP, New York, New York.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule at December 31, 2003 and 2004, and for each of the three years in the period ended December 31, 2004, as set forth in their report. We've included our consolidated financial statements and schedule in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

The financial statements for Armstrong Pharmaceuticals, Inc. as of October 8, 2003 and December 31, 2002 and for the period from January 1, 2003 to October 8, 2003 and the year ended December 31, 2002 included in this registration statement have been so included in reliance on the report of Carlin, Charron & Rosen, LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC in Washington, D.C. a registration statement on Form S-1 under the Securities Act with respect to the common stock offered in this prospectus. This prospectus, filed as part of the registration statement, does not contain all of the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our common stock, we refer you to the registration statement and to its exhibits and schedules. Statements in this prospectus about the contents of any contract, agreement or other document are not necessarily complete and, in each instance, we refer you to the copy of such contract, agreement or document filed as an exhibit to the registration statement, with each such statement being qualified in all respects by reference to the document to which it refers. Anyone may inspect the registration statement and its exhibits and schedules without charge at the public reference facilities the SEC maintains at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain copies of all or any part of these materials from the SEC upon the payment of certain fees prescribed by the SEC. You may obtain further information about the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also inspect these reports and other information without charge at a website maintained by the SEC. The address of this site is <http://www.sec.gov>.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act and will be required to file reports, proxy statements and other information with the SEC. You will be able to inspect and copy these reports, proxy statements and other information at the public reference facilities maintained by the SEC and at the SEC's regional offices at the addresses noted above. You also will be able to obtain copies of this material from the Public Reference Section of the SEC as described above, or inspect them without charge at the SEC's website.



**Index to Consolidated Financial Statements**

**Amphastar Pharmaceuticals, Inc. Audited Consolidated Financial Statements**

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2003 and 2004	F-3
Consolidated Statements of Operations for the years ended December 31, 2002, 2003, and 2004	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2002, 2003 and 2004	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2003, and 2004	F-6
Notes to Consolidated Financial Statements	F-8

**Armstrong Pharmaceuticals, Inc. Audited Financial Statements**

Report of Independent Registered Public Accounting Firm	F-38
Balance Sheets as of October 8, 2003 and December 31, 2002	F-39
Statements of Operations for the period January 1, 2003 through October 8, 2003 and the year ended December 31, 2002	F-40
Statements of Changes in Stockholder's Equity (Deficit) for the period January 1, 2003 through October 8, 2003 and for the year ended December 31, 2002	F-41
Statements of Cash Flows for the period January 1, 2003 through October 8, 2003 and the year ended December 31, 2002	F-42
Notes to Financial Statements	F-43

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
Amphastar Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. as of December 31, 2003 and 2004, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed at Item 16.(b). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Amphastar Pharmaceuticals, Inc. at December 31, 2003 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related consolidated financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST &  
YOUNG LLP

Orange County, California  
March 4, 2005  
except for Notes 1 and 7, as to which the date is  
April 14, 2005,  
and Note 14, as to which the date is May 3, 2005

## Amphastar Pharmaceuticals, Inc.

## Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2003	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,111	\$ 4,274
Short-term investments restricted	612	1,733
Accounts receivable, net of allowance for doubtful accounts of \$433 in 2003 and \$434 in 2004	9,087	11,405
Inventories, net	14,438	23,151
Prepaid expenses and other assets	1,051	2,602
	<u>33,299</u>	<u>43,165</u>
Total current assets	33,299	43,165
Property, plant, and equipment, net	53,062	69,529
Product rights, net of accumulated amortization of \$918 in 2003 and \$2,980 in 2004	26,217	26,154
Other assets	693	601
	<u>113,271</u>	<u>139,449</u>
Total assets	\$ 113,271	\$ 139,449
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,468	\$ 6,955
Accrued liabilities	1,914	2,959
Accrued wholesaler chargebacks	3,982	3,673
Current portion of product return accrual	412	375
Accrued payroll and related benefits	2,106	2,413
Current portion of deferred revenue	546	546
Current portion of deferred royalty payments	2,630	2,478
Current portion of long-term debt and capital leases	13,212	15,156
	<u>25,724</u>	<u>34,555</u>
Total current liabilities	25,724	34,555
Product return accrual, net of current portion	464	403
Deferred revenue, net of current portion	470	470
Deferred royalty payments, net of current portion	4,815	2,890
Long-term debt and capital leases, net of current portion	8,392	14,956
	<u>39,395</u>	<u>53,274</u>
Total liabilities	39,395	53,274
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, par value \$.0001, Authorized shares 20,000,000, no shares outstanding		
Common stock, par value \$.0001: Authorized shares 100,000,000		
Issued and outstanding shares 33,808,300 in 2003, and 35,245,740 in 2004	4	4

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

	<b>December 31,</b>	
	<u>          </u>	<u>          </u>
Additional paid-in capital	88,398	106,033
Accumulated deficit	(14,526)	(19,862)
	<u>          </u>	<u>          </u>
Total stockholders' equity	73,876	86,175
	<u>          </u>	<u>          </u>
Total liabilities and stockholders' equity	\$ 113,271	\$ 139,449
	<u>          </u>	<u>          </u>

See accompanying notes.

F-3

---

## Amphastar Pharmaceuticals, Inc.

## Consolidated Statements of Operations

(In thousands, except share and per share data)

	Years ended December 31,		
	2002	2003	2004
Net revenues	\$ 33,045	\$ 48,197	\$ 61,193
Cost of revenues	22,528	35,508	46,660
Gross profit	10,517	12,689	14,533
Operating expenses:			
Selling, distribution, and marketing	2,289	3,194	3,561
General and administrative	6,954	5,537	9,212
Research and development	2,979	6,344	8,451
Impairment of long-lived assets		623	185
Management fees and rent expense related party	138	921	204
Total operating expenses	12,360	16,619	21,613
Loss from operations	(1,843)	(3,930)	(7,080)
Non-operating income (expense):			
Interest income	448	174	53
Interest expense	(59)	(767)	(774)
Gain from settlement with Organon			2,215
Other income (expense)	(448)	(15)	250
	(59)	(608)	1,744
Net loss before extraordinary gain	(1,902)	(4,538)	(5,336)
Extraordinary gain, net of taxes		1,341	
Net loss	\$ (1,902)	\$ (3,197)	\$ (5,336)
Net loss per share before extraordinary gain: basic and diluted	\$ (0.06)	\$ (0.14)	\$ (0.15)
Net loss per share: basic and diluted	\$ (0.06)	\$ (0.10)	\$ (0.15)
Weighted-average shares outstanding: basic and diluted	31,592,000	33,520,000	34,597,000

See accompanying notes.

**Amphastar Pharmaceuticals, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
(In thousands, except share and per share data)

	Common stock			Additional paid-in capital	Receivable from stockholders	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount	Common stock to be issued					
Balance at December 31, 2001	29,077,608	\$ 3	\$	\$ 60,593	\$ (1,245)	\$ (9,427)	\$ (266)	\$ 49,658
Comprehensive loss:								
Net loss						(1,902)		(1,902)
Reclassification adjustment for net realized loss included in net loss							266	266
<b>Total comprehensive loss</b>								<b>(1,636)</b>
Common stock issued for cash	3,130,602	1		25,044				25,045
Common stock issued for consulting services	24,790			136				136
Common stock to be issued for equipment and services related party			419					419
Receivable repaid with equipment					171			171
Stock-based compensation expense				170				170
Repayment of notes receivable from stockholders					1,074			1,074
Exercise of stock options, net	597,110			896	(110)			786
Balance at December 31, 2002	32,830,110	4	419	86,839	(110)	(11,329)		75,823
Net loss and comprehensive loss						(3,197)		(3,197)
Common stock issued for consulting services	4,200			33				33
Common stock issued for equipment and services related party	973,990		(419)	1,461				1,042
Stock-based compensation expense				65				65
Repayment of notes receivable from stockholders					110			110
Balance at December 31, 2003	33,808,300	4		88,398		(14,526)		73,876
Net loss and comprehensive loss						(5,336)		(5,336)
Common stock issued for cash	1,250,000			15,625				15,625
Exercise of stock options, net	62,000			458				458
Common stock issued for consulting services	1,440			18				18
Stock-based compensation expense				604				604
Exercise of warrants	124,000			930				930
Balance at December 31, 2004	35,245,740	\$ 4	\$	\$ 106,033	\$	\$ (19,862)	\$	\$ 86,175

See accompanying notes.

## Amphastar Pharmaceuticals, Inc.

## Consolidated Statements of Cash Flows

(In thousands)

	Years ended December 31,		
	2002	2003	2004
<b>Operating activities</b>			
Net loss	\$ (1,902)	\$ (3,197)	\$ (5,336)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Extraordinary gain, net of tax effect		(1,341)	
Impairment of long-lived assets		623	185
Gain on disposal of property, plant, and equipment			(132)
Depreciation and amortization of property, plant, and equipment	941	3,541	3,913
Interest accretion on obligation from the purchase of product rights		420	631
Amortization of product rights and patents		924	2,065
Gain from settlement with Organon			(2,215)
Loss on marketable securities	268		
Common stock issued or to be issued in lieu of cash for consulting and other services	520	906	18
Provision for doubtful accounts	(244)	176	372
Stock-based compensation expense	170	65	604
Changes in operating assets and liabilities:			
Accounts receivable	488	(5,024)	(2,690)
Inventories, net	(3,700)	1,092	(8,713)
Prepaid expenses and other assets	(59)	(420)	(166)
Receivable from stockholders	37		
Accounts payable, accrued expenses and deferred revenues	(538)	3,436	7,528
Net cash provided by (used in) operating activities	(4,019)	1,201	(3,936)
<b>Investing activities</b>			
Sales (purchases) of marketable securities and short-term investments, net	(481)	5,061	(1,121)
Acquisition of product rights		(16,400)	(2,000)
Acquisition of business		(3,200)	
Purchases of property, plant, and equipment	(3,805)	(2,618)	(17,035)
Capitalized labor and overhead on self-constructed assets	(3,040)	(4,298)	(2,212)
Proceeds from the sale of property, plant, and equipment			1,443
Other assets, net	(740)	(34)	92
Net cash used in investing activities	(8,066)	(21,489)	(20,833)

<b>Financing activities</b>			
Proceeds from issuance of common stock	\$ 25,045	\$	\$ 15,625
Net borrowings under line of credit		6,200	8,000
Proceeds from issuance of long-term debt			3,966
Principal payments on long-term debt	(12,313)	(899)	(4,585)
Proceeds from exercise of common stock options and warrants	786		1,388
Deferred offering costs			(1,385)
Repayment of notes receivable from stockholders	1,074	110	
Proceeds from deferred royalty		8,000	
Payments on deferred royalty		(555)	(2,077)
	<u>14,592</u>	<u>12,856</u>	<u>20,932</u>
Net increase (decrease) in cash and cash equivalents	2,507	(7,432)	(3,837)
Cash and cash equivalents, beginning of year	13,036	15,543	8,111
	<u>15,543</u>	<u>8,111</u>	<u>4,274</u>

<b>Noncash investing and financing activities</b>			
Equipment acquired in exchange for note receivable or common stock issued in 2001	\$ 171	\$ 169	\$
Equipment acquired under capital leases	\$ 568	\$ 22	\$
Property, plant, and equipment acquired under financing agreements	\$	\$ 1,029	\$ 2,632
Unrealized gain on marketable securities	\$	\$	\$
Common stock issued for notes receivable	\$ 110	\$	\$
Common stock to be issued for equipment	\$ 35	\$	\$
Purchase of product rights with financing arrangements	\$	\$ (10,735)	\$

<b>Supplemental cash flow information</b>			
Interest paid	\$ 481	\$ 767	\$ 529
Income taxes paid	\$ 2	\$ 2	\$ 3

See accompanying notes.



**Amphastar Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**Years Ended December 31 2002, 2003 and 2004**

**(In thousands, except share and per share data)**

**1. Description of the Business**

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated on February 29, 1996 and merged with and into Amphastar Pharmaceuticals, Inc., a Delaware corporation (the "Company" or "Amphastar") in July 2004. The Company is a specialty pharmaceutical company that develops, manufactures, markets and sells generic and proprietary injectable and inhalation products. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers.

The Company generated net losses for the years ended December 31, 2002, 2003, and 2004, and has an accumulated deficit of \$19,862 as of December 31, 2004.

On February 4, 2005, the Company received \$10,000 in cash from a private placement and on February 8, 2005, the Company obtained a \$3,440 equipment lease line (Note 14). The Company expects that cash received from these sources, along with additional revenues and cash flows from the re-launch of Cortrosyn in August 2004, the launch of Amphadase in November 2004, and the launch of Epinephrine Mist in December 2004 will significantly improve the profitability and cash flows of the Company, and when combined with the cash flow from its existing products, the Company expects to continue to meet its obligations as they become due, including scheduled debt and lease payments. The Company expects additional cash flows to be generated from the Wyeth supply agreement, additional future contract manufacturing agreements and potential strategic alliances related to the development of new products.

If the cash flows from operations is not sufficient to meet the Company's obligations as they come due, then the Company may seek to re-schedule debt payments and/or seek additional equity and debt financing which may not be available on acceptable terms, or at all. If the Company is not able to re-schedule debt payments and/or obtain funding from these financing activities, the Company will consider postponing research and development expenditures and postpone the acquisition of property, plant, and equipment. The Company expects that it will be able to meet its cash flows requirements for at least the next twelve months (see Note 14).

**2. Summary of Significant Accounting Policies**

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, International Medication Systems, Limited ("IMS") and Armstrong Pharmaceuticals, Inc. ("Armstrong"). The Company acquired Armstrong in October 2003, and the 2003 financial statements include the accounts of Armstrong since October 9, 2003, the date of acquisition. All significant intercompany transactions and balances have been eliminated in consolidation. Certain previously reported amounts have been reclassified to conform to the current period presentation.

**Use of Estimates**

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.

### **Revenue Recognition**

The Company's net revenues consist principally of product revenue generated from the sales of its pharmaceutical products. Product sales represented 98%, 96% and 97% of the Company's total net revenues for the years ended December 31, 2002, 2003, and 2004, respectively. Remaining revenues are derived principally from contract manufacturing services, which are recognized when development and other services are provided or manufactured third-party products are shipped to customers and customer acceptance is received.

In accordance with Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"), as well as the recently issued SAB No. 104, *Revenue Recognition*, the Company recognizes product revenue when the following fundamental criteria are met: (i) persuasive evidence of an arrangement, (ii) transfer of title has occurred, (iii) the price to the customer is fixed or determinable, and (iv) collection of the resulting receivable is reasonably assured. In addition, the Company does not recognize revenue until all customer acceptance requirements have been met. Generally, revenue is recognized at the time of product delivery for domestic customers and the time of product shipment for foreign customers. The Company estimates and records reductions to revenue for estimated product returns and pricing adjustments, such as wholesaler chargebacks, in the same period that the related revenue is recorded.

In accordance with EITF Issue No. 00-21 Revenue Arrangements with Multiple Deliverables, the Company's 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 the supply agreement with Wyeth, the Company recognizes revenue from non-refundable, upfront fees over the four year term of the underlying supply agreement. At December 31, 2004, the Company had received a \$500 non-refundable payment, which has been deferred. Revenue recognition will commence with the first delivery of product under the agreement and will be recognized ratably over the remaining term of the supply agreement.

### **Shipping and Handling Costs**

For the years ended December 31, 2002, 2003, and 2004 the Company included shipping and handling costs of approximately \$897, \$1,938, and \$2,126, respectively, in selling, distribution, and marketing expenses in the accompanying consolidated statements of operations.

### **Comprehensive Loss**

For the years ended December 31, 2002, 2003, and 2004, the Company has comprehensive losses as defined by Financial Accounting Standards Board ("FASB") Statement No. 130, *Reporting Comprehensive Income*, of \$(1,636), \$(3,197), and \$(5,336), respectively. For the year ended

December 31, 2002, comprehensive loss consists of the net loss and changes in unrealized gains or losses on marketable securities. For the year ended December 31, 2003, and 2004, net loss equals comprehensive loss.

#### **Cash and Cash Equivalents and Short-Term Investments**

Cash and cash equivalents consist of cash and highly liquid investments purchased with maturities of three months or less. The Company's short-term investments are classified as held-to-maturity and consist of certificates of deposit purchased with maturities greater than three months, which mature within one year of the date of purchase. Included in short-term investments restricted are certificates of deposit, which are used either as collateral to support a line of credit for a capital lease for equipment (Note 7) or is required for the Company to qualify for worker's compensation self insurance. The estimated fair value of each investment approximated its amortized cost and, therefore, there were no significant unrealized gains or losses.

#### **Allowance for Doubtful Accounts Receivable**

The Company evaluates the collectibility of accounts receivable based on a combination of factors. In cases where the Company is aware of circumstances that may impair a specific customer's ability to meet its financial obligations subsequent to the original sale, the Company will record a specific allowance against amounts due, and thereby reduce the net recognized receivable to the amount the Company reasonably believes will be collected. For all other customers, the Company recognizes an allowance for doubtful accounts based on the length of time the receivables are past due, industry and geographic concentrations, the current business environment and the Company's historical experience.

#### **Inventories**

Inventories are stated at the lower of cost or market, using the first-in, first-out method. Provision is made for slow moving, unsalable or obsolete items. Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval (i.e., pre-launch inventories), which are capitalized, based on management's judgment of probable commercialization within one year. Inventory awaiting regulatory approval principally relates to materials for the production of enoxaparin. See Note 11 for a description of the status of the enoxaparin litigation. As of December 31, 2003, and in prior periods, the Company had an insignificant amount of inventory awaiting regulatory approval. At December 31, 2004, inventory awaiting regulatory approval was \$6,760. In the event regulatory approval is not obtained, the Company will expense these inventory amounts.

**Property, Plant, and Equipment**

Property, plant, and equipment are stated at cost or in the case of assets acquired in a business combination at fair value. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the related assets as follows:

Buildings	31 years
Machinery and equipment	5-12 years
Furniture, fixtures and automobiles	5 years
Leasehold improvements	Lesser of remaining lease term or useful life

Labor and overhead costs, including those incurred in connection with initial validation to meet regulatory requirements and readying assets for their intended use, are capitalized as part of the effort required to acquire and construct long-lived assets and are amortized over the estimated useful life. During the years ended 2002, 2003, and 2004, the Company capitalized interest, labor, and overhead costs of \$3,040, \$4,298, and \$2,212, respectively.

Expenditures for repairs, maintenance and minor renewals and betterments are charged to expense as incurred. The Company capitalizes interest on financing related to self-constructed assets during the time period required to get the asset ready for its intended use.

**Product Rights**

Product rights are amortized on a straight-line basis over their estimated useful lives ranging from 5 to 15 years.

**Other Assets**

Included in other assets are intangible assets, deposits for equipment, and marketable securities. Intangible assets, consisting of patents and trademarks, are amortized on a straight-line basis over their estimated useful lives, generally ranging from 11 to 20 years. The gross carrying amount of the patents and trademarks as of December 31, 2003 and 2004 was \$344 and \$377, respectively. The accumulated amortization of the patents and trademarks as of December 31, 2003 and 2004 was \$29 and \$35, respectively.

Marketable equity securities, classified as available-for-sale, are carried at fair value, with the unrealized gains and losses, net of tax, reported in a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in other income. The cost of securities sold is based on the specific-identification method. Interest and dividends on securities classified as available-for-sale are included in other income.

In 2001, the Company held marketable securities with a recorded cost of \$273, which was offset by an unrealized loss of \$266, which was included as a separate component of stockholders' equity. In 2002, the Company determined the value of the marketable securities was permanently impaired. The total realized loss of \$268 on marketable securities was recognized in 2002, including the \$266 recorded

as a net adjustment to unrealized loss on available-for-sale securities. There were no marketable securities purchased or sold in 2002, 2003, and 2004.

#### **Impairment of Long-Lived Assets**

The Company reviews 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). All of the Company's impairments relate to the write-off of certain abandoned projects that were previously included in construction in progress. The Company recorded an impairment loss of \$0, \$623 and \$185, respectively, for the years ended December 31, 2002, 2003 and 2004.

#### **Accrual for Wholesaler Chargebacks**

The provision for chargebacks is a significant estimate the Company used in the recognition of revenue. As part of its sales terms to wholesale customers, the Company agrees to reimburse wholesalers for differences between the gross sales price of products sold to wholesalers and expected retail prices of such products under contractual arrangements with third parties such as hospitals and group purchasing organizations. The Company estimates 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 contract pricing. Changes in chargeback accruals from period to period are primarily dependent on the level of inventory held at the wholesalers. The Company monitors the provision for chargebacks and makes adjustments when the Company believes that the actual chargebacks may differ from estimates. At December 31, 2003 and 2004, chargebacks of \$3,982 and \$3,673 respectively, were recorded as current liabilities. Settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

#### **Accrual for Product Returns**

The Company offers certain distributors the right to return qualified excess or expired stock ("qualified returns") for credit. During 2002 and up through June 2003, qualified returns were accepted up to six months from the date of shipment and three months before and after the expiration date for credits ranging from 50% to 75% of the original selling price. Beginning effective as early as July 1, 2003, pursuant to revised terms with the Company's distributors, qualified returns were expanded to include new product lines and will be accepted in certain instances up to 12 months from the date of shipment and six months before and after the expiration date for credits ranging from 80% to 90% of the current list price. The Company estimates amounts that may be incurred under its product return policies and records 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 also considers amended contract terms. The Company classifies 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. During 2002, the Company reduced the sale return percentage from approximately 0.9% of qualified sales in 2001 to 0.4% of qualified sales in 2002 based upon experience rates, resulting in a reduction in the accrual of approximately \$400, which was recorded as an increase in revenues. During 2003, the Company increased its sales return percentage from 0.4% to 0.7% of qualified sales as a result of changes in wholesaler contract terms, resulting in an increase in the accrual of approximately \$457, which was recorded as a decrease in revenues. During 2004, the Company decreased its sales return percentage from 0.7% to 0.4% of qualified sales as a result of changes in wholesaler contract terms resulting in a decrease in the accrual of approximately \$482, which was recorded as an increase in revenue.

### **Research and Development Costs**

Research and development costs, including clinical trial costs, are charged to expense as incurred.

### **Income Taxes**

The Company utilizes the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards No. 109, *Income Taxes* ("SFAS 109"). Under the liability method, deferred taxes are determined based on the temporary differences between the financial statements and tax bases of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

### **Stock-based Compensation**

As permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), and as amended by No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, the Company accounts for stock options granted to its employees and non-employee 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 weighted-average minimum value of options granted to employees during the years ended 2002, 2003, 2004, was \$1.09, \$0.64, and \$1.50, respectively. Had compensation cost for grants of stock-based compensation to employees and non-employee members of the Board of Directors been

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

determined using the fair value method of accounting as prescribed by SFAS 123, the Company's net loss and loss per share would have been increased to the pro forma amounts indicated below:

	Year Ended December 31,		
	2002	2003	2004
Net loss, as reported	\$ (1,902)	\$ (3,197)	\$ (5,336)
Add: Stock-based employee compensation expenses included in reported net loss, net of related tax effects			530
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(604)	(443)	(936)
Pro forma net loss	\$ (2,506)	\$ (3,640)	\$ (5,742)
Net loss per common share:			
Basic and diluted as reported	\$ (.06)	\$ (.10)	\$ (.15)
Basic and diluted pro forma	\$ (.08)	\$ (.11)	\$ (.17)

For purposes of pro forma disclosures, the estimated fair value of the employee options is amortized to expense over the options' vesting period. Under SFAS 123, the fair value of stock based awards to employees is calculated through the use of option-pricing models (minimum-value option pricing model) even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions. Because the Company's employee options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect fair value estimates, in management's opinion, the existing models do not necessarily provide a single reliable measure of the fair value of its employee stock options.

For purposes of determining the pro forma effect under SFAS 123 of stock options granted to employees and directors, the fair value of each option is estimated on the date of grant based on the minimum value option pricing model with the following assumptions:

	Year Ended December 31,		
	2002	2003	2004
Risk-free interest rate	5 %	3 %	3 %
Dividend yield	0 %	0 %	0 %
Expected life in years	3.5	3.5	4.4

**Financial Instruments**

The carrying amounts of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and short-term borrowings approximate fair value due to the short maturity of these items. The carrying amount of long-term borrowings approximates fair value, as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities.

**Net Loss Per Share**

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards No. 128, *Earnings Per Share* ("SFAS 128"). SFAS 128 requires the presentation of basic and diluted income (loss) per-share amounts. Basic income (loss) per share is calculated based upon the weighted average number of common shares outstanding during the period, while diluted income (loss) per share also gives effect to all potential dilutive common shares outstanding during the period such as options and warrants.

As the Company reported net losses for the three years ended December 31, 2002, 2003 and 2004, the diluted net loss per share, as reported, is the same as basic net loss per share. The effect of the assumed exercise of stock options and warrants is antidilutive and not included in the Company's reported net loss per share. Total options and warrants which are not included in the net loss per share, because they are anti-dilutive, were 3,970,234, 4,490,334, and 5,074,154 in 2002, 2003, and 2004, respectively.

**Segment Reporting**

The Company's business is the development, manufacture and marketing of pharmaceutical products. The Company has determined that all of its product groups have similar economic characteristics and may be aggregated into a single operational segment for reporting purposes. Net revenues for significant product groups are as follows:

	Year ended December 31,		
	2002	2003	2004
Injectable products and services revenue	\$ 33,045	\$ 45,320	\$ 53,570
Inhalation products and services revenue		2,877	7,623
<b>Total net revenues</b>	<b>\$ 33,045</b>	<b>\$ 48,197</b>	<b>\$ 61,193</b>

**Concentrations of Business and Credit Risk**

The Company's financial instruments that potentially subject the Company to credit risk consist principally of accounts receivables. Sales to the Company's customers are generally made with net 30-day terms. The Company performs periodic credit evaluations of its ongoing customers and does not generally require collateral. However, there are no sales commitments with these wholesalers and there are various other customers who could purchase these products at comparable terms.



The following table provides accounts receivable and net revenue information on our major customers:

	% of total accounts receivable For the year ended December 31,		% of net revenues For the year ended December 31,		
	2003	2004	2002	2003	2004
AmerisourceBergen Corporation	17%	28%	20%	20%	17%
Cardinal Health, Inc.	18%	21%	17%	21%	18%
McKesson Corporation	19%	21%	15%	14%	18%

Foreign sales represent sales of products to non-U.S. customers. Revenues from foreign sales in 2002, 2003 and 2004 were approximately 13%, 5% and 7% of revenues, respectively. Most foreign sales are negotiated with payment terms in U.S. dollars. Therefore, the Company has little exposure to foreign currency price fluctuations.

The Company depends on suppliers for raw materials, active pharmaceutical ingredients and other components that are subject to stringent FDA requirements. Certain of these materials may only be available from one or a limited number of sources. 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 raw materials may be available only from foreign sources.

If the Company is unable to secure on a timely basis sufficient quantities of the materials it depends on to market its products, it could materially adversely affect the Company's business, financial condition, and results of operations.

The Company maintains the majority of its cash deposits and certificates of deposit at four banks. Certain bank balances exceed the amount insured by the Federal Deposit Insurance Corporation of \$100. At December 31, 2003 and 2004, the Company's cash deposits and certificates of deposit at banks included in cash and cash equivalents and restricted short-term investments aggregated \$8,723 and \$6,007, respectively.

As of December 31, 2004, approximately 5% of the Company's employees were subject to a collective bargaining agreement, assumed in connection with the acquisition of Armstrong (Note 3).

#### Self-Insured Claims

Effective June 1, 2004, the Company is primarily self-insured, up to certain limits, for workers' compensation claims. The Company has purchased stop loss insurance, which will reimburse the Company for individual claims in excess of \$350 annually or aggregate claims exceeding \$2,100 annually. Operations are charged with the cost of claims reported and an estimate of claims incurred but not reported. A liability for unpaid claims and the associated claim expenses, including incurred but not reported losses, is actuarially determined and reflected in accrued liabilities in the accompanying balance sheet. Total expense under the program was approximately \$595 for the year ended

December 31, 2004. The self-insured claims liability of \$595 includes incurred but not reported losses of \$581 at December 31, 2004. The determination of such claims and expenses and the appropriateness of the related liability is continually reviewed and updated. It is reasonably possible that the accrued estimated liability for self-insured claims may need to be revised materially in the future.

#### **New Accounting Pronouncements**

In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities" an interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements." The primary objectives of FIN 46 are to provide guidance on the identification of entities which the Company may control through means other than through voting rights ("variable interest entities") and to determine when and which business enterprise ("primary beneficiary") should consolidate the variable interest entity. FIN 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among the parties involved. Variable interest entities that effectively disperse risks will not be consolidated unless a single party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003. In December 2003, the FASB revised FIN 46 (FIN 46R) to address certain FIN 46 implementation issues. The revised provisions are applicable no later than the first reporting period ending after March 15, 2004. The Company adopted FIN 46 and FIN 46R and determined that it does not have any variable interest entities that require consolidation nor any material entities that require disclosure.

In September 2004, EITF reached a final consensus on EITF Issue No. 04-10, "Applying Paragraph 19 of FASB Statement No. 131, Disclosures about Segments of an Enterprise and Related Information, in Determining Whether to Aggregate Operating Segments That Do Not Meet the Quantitative Thresholds." Under EITF Issue No. 04-10, operating segments that do not meet the quantitative thresholds can be aggregated into a reportable segment if aggregation is consistent with the objective and basic principles of FASB Statement No. 131, the segments have similar economic characteristics, and the segments share a majority of the other aggregation criteria as defined by FASB Statement No. 131, paragraph 17. EITF Issue No. 04-10 is effective for fiscal years ending after October 13, 2004. The corresponding information for earlier periods, including interim periods, shall be restated unless it is impractical to do so. Restatement of previously issued financial statements is required. The adoption of EITF Issue No. 04-10 will not impact the Company's financial statements.

In November 2004, the Accounting Standards Board 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. The Company is currently assessing the impact of Statement No. 151.

On December 16, 2004, the Financial Accounting Standards Board issued FASB Statement No. 123 (revised 2004), Share-Based Payment. Statement 123(R) replaces FASB Statement No. 123, *Accounting for Stock-Based Compensation*, supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values (i.e., pro forma disclosure is no longer an alternative to financial statement recognition). The Company will need to comply with Statement 123R in the interim financial statements for the first quarter ended March 31, 2006. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified retrospective option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the modified retrospective method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

### **3. Acquisition**

#### **Armstrong Pharmaceuticals, Inc.**

On October 9, 2003, the Company acquired all of the outstanding common stock of Armstrong in a purchase business combination from Andrx Corporation ("Andrx"). Armstrong is a developer and manufacturer of inhalation pharmaceutical products. Management believes that Armstrong will not only provide the Company with the ability to enter the U.S. inhalation products market, as Armstrong is one of the few independent U.S. manufacturers of inhalation products, but also provide the Company with research and development capabilities to generate a steady stream of new products.

The purchase price was allocated to the assets and certain liabilities assumed based on their respective fair values. Inventory, consisting of raw materials, was valued at its replacement cost. A total of approximately \$1,341, representing the excess of the fair value of the tangible current net assets acquired, over the purchase price, net of tax effects, has been recorded as an extraordinary gain.

The accounting for the acquisition is summarized as follows:

Accounts receivable	\$ 167
Due from Andrx	299
Inventory	4,414
Prepaid expense	58
Assumed liabilities	(397)
	<hr/>
Fair value of assets and liabilities acquired	4,541
Less cash paid for the acquisition, including transaction costs	(3,200)
	<hr/>
Extraordinary gain, net of tax effect of \$40	\$ 1,341
	<hr/>

The Company's consolidated results of operations include the subsidiary's activities since the acquisition date.

#### Pro Forma Data (Unaudited)

The pro forma data of the Company set forth below gives effect to the acquisition of Armstrong completed in 2003 as if it had occurred at the beginning of 2002, but excludes the extraordinary gain of \$1,341 in 2003 and impairment charges on long-lived assets of \$8,557 recorded in early 2003 as a result of continued losses at Armstrong. This pro forma data is presented for informational purposes only and does not purport to be indicative of the results of future operations of the Company or of the results that would have actually occurred had the acquisition taken place at the beginning of 2002.

	<u>2002</u>	<u>2003</u>
Pro forma net revenue	\$ 53,517	\$ 57,874
Pro forma pre-tax net loss before extraordinary item	(7,265)	(7,439)
Pro forma pre-tax net loss per share before extraordinary item	(0.23)	(0.22)

#### 4. Product Rights

In June 2003, the Company acquired U.S. intellectual property rights for Cortrosyn from Organon USA Inc. ("Organon") in exchange for consideration of \$28,000. The Company paid \$16,000 in cash and agreed to pay the remaining \$12,000 in cash in two equal installments. Until these two installments are paid, Organon retains a security interest in the Cortrosyn intellectual property. The present value of the future cash flows of \$26,734 was recorded as products rights on the accompanying consolidated balance sheets at the acquisition date and is being amortized over its estimated useful life of 15 years using the straight-line method. In addition, the Company acquired Cortrosyn inventory for \$184 in cash at closing.

As part of the transaction, Organon agreed to manufacture finished product for the Company for three (3) years following the date of closing. In February 2004, the Company was notified that Organon's facility was flooded and would have to cease production. The Company has transferred the manufacturing from Organon's facility to a Company facility. As a result of the supply interruption, the

revenues from the sale of Cortrosyn products were adversely impacted in the second and third quarters of 2004.

In August 2003, the Company entered into a Royalty Purchase Agreement (the "RPA") with Drug Royalty USA, Inc. ("DRC"), whereby DRC provided \$8,000 in cash to the Company in exchange for a royalty on the future U.S. net sales of Cortrosyn. The Company has recorded the consideration received from DRC as deferred royalties on the accompanying consolidated balance sheets and will reduce the liability as royalty payments are made. 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. As of December 31, 2004, the carrying value of inventory and receivables securing the agreement is \$3,052, and the carrying value of the intangibles securing the agreement is \$24,061. Pursuant to the RPA, royalties are due quarterly through 2008. During 2003 and 2004, the Company paid royalties to DRC of \$555 and \$2,077, respectively. Royalties to be paid to DRC are calculated based upon net sales and may exceed the consideration received, at which time royalties will be expensed as incurred. The RPA does not require the Company to pay the unremitted portion of the original \$8,000 payment by DRC if the royalties from the sale of Cortrosyn do not meet or exceed \$8,000.

In September 2003, the Company acquired Canadian intellectual property rights for Cortrosyn in exchange for cash consideration of \$400.

In July, 2004, the Company acquired the product rights to Epinephrine Mist CFC from Alpharma USPD, Inc. for \$2,000 in cash paid at closing and purchased \$300 of inventory. The purchase agreement requires the Company to pay royalties on future product sales.

The products rights are recorded at fair value and are being amortized over their estimated useful life of 5 to 15 years, respectively (weighted average useful life of 13 years), using the straight-line method. Included in cost of revenues for the year ended December 31, 2003 and 2004, is products rights amortization of \$918 and \$2,065, respectively.

Product rights are recorded net of accumulated amortization of \$2,980 in the accompanying consolidated balance sheet at December 31, 2004. Expected amortization expense for the next five fiscal years ended December 31, 2004, related to the current balance of product rights is as follows:

2005	\$ 2,262
2006	2,262
2007	2,262
2008	2,236
2009	1,982
2010 and thereafter	15,150
	<hr/>
Total product rights	26,154
	<hr/>

**5. Inventories**

Inventories consist of the following:

	December 31,	
	2003	2004
Raw materials and supplies	\$ 8,306	\$ 15,751
Work-in-process	889	1,498
Subassemblies	2,358	2,478
Finished goods	5,904	5,584
	<u>17,457</u>	<u>25,311</u>
Less reserve for excess and obsolete inventories	(3,019)	(2,160)
	<u>\$ 14,438</u>	<u>\$ 23,151</u>

**6. Property, Plant, and Equipment, Net**

Property, plant, and equipment consists of the following:

	December 31,	
	2003	2004
Building	\$ 14,876	\$ 19,902
Leasehold improvements	11,085	11,832
Land	1,752	2,875
Machinery and equipment	31,075	35,130
Furniture, fixtures, and automobiles	1,027	1,090
Construction in progress	5,712	16,404
	<u>65,527</u>	<u>87,233</u>
Less accumulated depreciation and amortization	(12,465)	(17,704)
	<u>\$ 53,062</u>	<u>\$ 69,529</u>

Interest expense capitalized for the years ended December 31, 2002, 2003 and 2004 amounted to \$422, \$0, and \$436, respectively.

In July, 2004, the Company purchased a 104 square foot building adjacent to its headquarters in Rancho Cucamonga for \$6,624. Under the terms of the purchase agreement the Company paid \$3,992 and assumed a loan with a remaining principal balance of \$2,632. The building will be converted to a manufacturing facility. As consideration for early termination of a lease, at closing, the lessee paid the Company \$500, which has been included in other income in the accompanying statements of operations for the year ended December 31, 2004.

**7. Debt**

Debt consists of the following:

	December 31,	
	2003	2004
Revolving line of credit payable to Cathay Bank, secured by certain of the Company's buildings and equipment (carrying value of approximately \$12,849 at December 31, 2004), bearing interest at the prime rate as published in the <i>Wall Street Journal</i> (5.25% at December 31, 2004), monthly interest payment is \$28, principal and accrued interest are due and payable on or before November 30, 2005	\$ 6,200	\$ 6,200
Other loan payable to Cathay Bank, secured by equipment, bearing interest at the prime rate as published in <i>The Wall Street Journal</i> plus 1.00% to 1.25%, (6.25% to 6.5% at December 31, 2004), aggregate principal and interest payment of approximately \$20 is due monthly through August 2005	526	55
Contractual Product Rights obligation, secured by certain of the Company's product rights (carrying value of approximately \$24,061 at December 31, 2004), implicit interest rate of 7.5%, aggregate principal and interest payment due with an installment of \$4,311 due in June 2005 and a second installment of \$6,000 due in February 2006. Interest accretes monthly into the principal balance	11,155	9,652
Mortgage notes payable to Standard Savings Bank, secured by building (carrying value of approximately \$2,294 at December 31, 2004), with the interest at the bank's rate plus .25%, (5.25% at December 31, 2004), aggregate principal and interest payments due monthly of approximately \$10 with balloon payment at maturity in December 2008	2,408	1,606
Equipment loan due to a financial institution, secured by the equipment bearing interest at 11%, principal and interest payments due monthly aggregating \$2. Paid in full by September 2004	19	
Equipment loan due to Bank of the West, secured by equipment, (carrying value of approximately \$4,764 at December 31, 2004), bearing interest at the Bank of the West prime rate (5.25% at December 31, 2004), principal and interest payments due monthly ranging from \$107 to \$51 through October, 2008	904	4,376
Mortgage payable to Bank of the West, secured by real estate and property (carrying value of approximately \$6,597 at December 31, 2004), bearing interest at 4.86%, payments due monthly of approximately \$29 with a balloon payment at maturity in November 2009		5,000
Revolving line of credit payable to Bank of the West, secured by equipment and working capital, bearing interest at the Bank of the West prime rate (5.25% at December 31, 2004), monthly interest payment of approximately \$14, principal and interest payment due on or before April 30, 2005		3,000

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

Equipment under capital leases	392	223
	<u>          </u>	<u>          </u>
Total debt and capital leases	\$ 21,604	30,112
Less current portion of long-term debt and capital leases	13,212	15,156
	<u>          </u>	<u>          </u>
Long-term debt, net of current portion and capital leases	\$ 8,392	\$ 14,956
	<u>          </u>	<u>          </u>

**Credit Facility with Cathay Bank**

The Company has a credit facility with Cathay Bank, a stockholder of the Company, ("CB Credit Facility"), to provide for available borrowings under a \$6,200 convertible revolving line of credit ("CB convertible revolving line of credit") and equipment loans and other term loans in an amount not to exceed existing borrowings. In November 2004, the Company obtained an extension on the maturity date to November 30, 2005. As of December 31, 2004, there were no amounts available for borrowing under the CB Credit Facility. The convertible features of the credit line facility expired as of December 31, 2003.

The average dollar amount of borrowings under the CB convertible line of credit was \$5,117 for the year ended December 31, 2004 with an average interest rate of 4.54%.

The CB Credit Facility requires the Company to meet certain financial covenants including a minimum annual profitability test, a minimum current ratio and a debt to tangible net worth ratio of less than .75 to 1.00. At December 31, 2004, the Company was not in compliance with two of these tests as follows: the Company had a net loss of \$5.3 million, and had a debt to tangible net worth ratio of .89 to 1.0. The Company received a waiver from Cathay Bank for these defaults. In November 2004, Cathay Bank exercised its warrant to purchase 124,000 shares of the Company's common stock at an exercise price of \$7.50 per share, resulting in \$930 in cash proceeds.

**Equipment Under Capital Leases**

The Company entered into leases for certain equipment under capital leasing arrangements, which expire through 2008. The cost of equipment under capital leases approximated \$730, \$752 and \$590 at December 31, 2002, 2003 and 2004, respectively.

The accumulated depreciation of equipment under capital leases approximates \$32, \$185 and \$100 at December 31, 2002, 2003 and 2004, respectively. Amortization of assets recorded under capital leases is included in depreciation and amortization expense in the accompanying consolidated financial statements. Under the terms of one of the capital lease agreements, the Company is required to maintain a letter of credit which is supported by restricted short-term investments, as collateral, of approximately \$621 during the remainder of the lease term; this amount is included in "Short-term investments restricted" in the accompanying consolidated balance sheets.



### **Contractual Product Rights Obligation**

The Company had an obligation to pay \$12,000 of aggregate principal and interest related to the purchase of Cortrosyn. Due to the inability of Organon to fulfill its commitment to provide inventory to the Company, in December 2004 the payment amount was decreased and the due dates were extended. Under the original agreement, the payments were due in two equal installments of \$6,000 due in June 2004 and 2005. The Company entered into a settlement with Organon in December 2004 and the obligation is now due in two installments of \$4,311 and \$6,000 due in June 2005 and February 2006, respectively. The gain from the settlement of \$2,215 is classified as non-operating income on the Company's consolidated statement of operations for the year ended December 31, 2004.

### **Credit Facilities with Bank of the West**

In October 2002, as amended April 2003 and March 2004, the Company obtained a \$5,000 equipment purchase facility with Bank of the West (BOW), bearing interest at the BOW prime rate, expiring December 31, 2004. As of December 31, 2004 the total original principal amount of notes issued pursuant to the equipment purchase facility was \$5,000. As of December 2004, there were no amounts available under this facility.

In February 2004, the Company obtained a \$3,000 working capital revolving line of credit facility bearing interest at the BOW prime rate, expiring April 30, 2005. The average dollar amount of borrowings under the BOW credit line was \$833 for the year ended December 31, 2004 with an average interest rate of 4.75%. As of December 31, 2004, there were no amounts available for borrowing under this facility.

The Bank of the West facilities contain certain financial covenants, including a requirement that IMS maintain a minimum quick ratio (liquid assets plus net trade receivables divided by total liabilities) of 1.0 to 1.0, an effective tangible net worth of \$20,000, a maximum debt/effective tangible net worth ratio of 0.75 to 1.0 and impose limitations on the amount of funds that can be advanced from IMS to the Company. IMS was not in compliance with these covenants at December 31, 2004 and at such date had a quick ratio of 0.72 to 1.0, an effective tangible net worth of \$17,000, and a debt/effective tangible net worth ratio of 1.05 to 1.0. Bank of the West waived these defaults through April 12, 2005.

In November 2004, the Company borrowed \$5,000 from the Bank of the West on a 5-year note with a variable interest rate linked to the London Interbank Offered Rate. The loan is secured by a deed of trust on the Company's recently acquired building located at 11530 Sixth Street, Rancho Cucamonga. The Company netted \$1,942 from the loan after paying off the \$2,600 existing loan due to Manufacturers Life on the property and a prepayment penalty of \$458, which is included in non-operating income on the Company's consolidated statement of operations for the year ended December 31, 2004.

### **Mortgage Notes with Standard Savings Bank**

The Company had three mortgage notes outstanding with Standard Savings Bank for the purchase of buildings and land. The mortgage notes were payable over terms from two to seven years, with

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

amortization schedules of 25 to 30 years, with balloon payments at maturity in June 2004 and December 2008. In February and May 2004, respectively, the Company paid off two of the mortgage notes.

As of December 31, 2004, the principal amounts of long-term debt maturities, considering the effects of extensions obtained from lenders subsequent to December 31, 2004, during each of the next five fiscal years ending December 31, are as follows:

	<u>Debt</u>	<u>Capital Leases</u>	<u>Total</u>
2005	\$ 14,988	\$ 186	
2006	6,902	50	
2007	1,307	5	
2008	2,150		
2009	4,542		
	<u>29,889</u>	<u>241</u>	
Less amount representing interest		18	
Total	<u>\$ 29,889</u>	<u>\$ 223</u>	<u>\$ 30,112</u>

**8. Income Taxes**

A reconciliation of U.S. statutory federal income tax provision to the actual provision for continuing operations is as follows:

	<u>Year Ended December 31,</u>		
	<u>2002</u>	<u>2003</u>	<u>2004</u>
Statutory federal income tax expense	\$ (647)	\$ (1,543)	\$ (1,814)
Permanent differences	(370)	(438)	25
Federal valuation allowances	1,017	1,981	1,789
Total	<u>\$</u>	<u>\$</u>	<u>\$</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2003	2004
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 6,927	\$ 12,462
Depreciation/amortization	245	
Inventory capitalization and reserve	1,011	909
Accrued payroll and benefits	354	333
Product return allowance	387	390
Accrued chargebacks	1,586	1,463
Bad debt reserve	166	173
Excess capital losses over capital gain	254	147
Other	92	1,205
<b>Total deferred tax assets</b>	<b>11,022</b>	<b>17,082</b>
<b>Deferred tax liabilities:</b>		
Depreciation/amortization		2,023
<b>Total deferred tax liabilities</b>		<b>2,023</b>
<b>Net deferred tax asset before valuation allowance</b>	<b>11,022</b>	<b>15,059</b>
Valuation allowance	(11,022)	(15,059)
<b>Net deferred tax asset</b>	<b>\$</b>	<b>\$</b>

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax-planning strategies in making this assessment. Based upon the cumulative losses sustained, the Company recorded a valuation reserve against all net federal and state deferred tax assets. If or when recognized, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be accounted for as an increase in stockholders' equity of \$776, based on balances existing at December 31, 2004, for certain deductions related to the exercise of stock options and a reduction of income tax expense for the remainder.

At December 31, 2004, the Company had federal and California net operating loss carryforwards of approximately \$33,619 and \$17,701, respectively, which begin to expire in 2018 and 2008, respectively.

Utilization of the federal and state net operating loss carryforwards could be limited in future years, if the Company were to experience a greater than 50% change in ownership within a three-year period as defined in Sections 382 and 383 of the United States Internal Revenue Code of 1986.

## 9. Stockholders' Equity

### Common and Preferred Stock

In February 2002, the Board of Directors approved a two-for-one stock split effective April 30, 2002. In July, 2004, the Company reincorporated in Delaware. The Delaware certificate of incorporation provides for two classes of shares, Common Stock and Preferred Stock, each with a par value of \$.0001 per share. The Company is authorized to issue 100,000,000 shares of Common Stock and 20,000,000 shares of Preferred Stock. The common stock and additional paid-in capital balances have been retroactively adjusted to reflect the Company's reincorporation.

Pursuant to a private placement offering of nonvoting convertible preferred stock at \$8.00 per share, in 2001, the Company received subscriptions for 974,500 shares for \$7,796 (of which \$7,756 in cash was received prior to December 31, 2001, and \$40 was received shortly thereafter). In 2002, the Company received subscriptions for an additional 3,130,602 preferred shares for \$25,045 in cash. The preferred stock was convertible into common stock at a ratio of 1:1 if converted before April 1, 2002, or a ratio of 1:0.8 if converted thereafter, but prior to January 1, 2003. In order to obtain the higher conversion rate, all of the shares of preferred stock were converted at the time of purchase and before preferred stock certificates were issued.

During 2001, 2002 and 2003, the Company acquired equipment from, and utilized services of, Applied Physics & Chemistry Laboratories ("APCL"), a company owned by the Chief Executive Officer and Chief Operating Officer of Amphastar, in exchange for shares of common stock and issued common stock in lieu of cash for consulting services (Note 10).

During the second quarter of 2004, the Company sold 1,250,000 shares of its common stock at a purchase price of \$12.50 per share for net cash proceeds of approximately \$15,625.

In September 2004, a consultant exercised options to purchase 50,000 shares of the Company's common stock at an exercise price of \$8.00 per share for total proceeds of \$400. In October 2004, two consultants exercised options to purchase 12,000 shares at a weighted average exercise price of \$4.88 for total proceeds of \$58.

In July 2004, the Company entered into an employee separation agreement that included provisions to extend the contractual life of the employee's options. This modification resulted in a charge to general and administrative expense of \$300. During 2004 the Company recorded compensation expense of \$230 related to stock option grants to employees that had an exercise price below the stock's deemed fair market value at the time that the grants were approved.

During the years ended December 31, 2002, 2003 and 2004 the Company issued options to consultants and advisory board members for services rendered having a fair value totaling \$170, \$65, and \$74 respectively.

During the years ended December 31, 2002, 2003, and 2004 the Company issued stock to consultants and advisory board members for services having a fair value totaling \$136, \$33, and \$18, respectively.

The Company has incurred offering costs of \$1,385 as of December 31, 2004 related to its anticipated initial public offering which are included in "Prepaid expenses and other assets" on the

accompanying consolidated balance sheets. Upon successful completion of the offering, these amounts will be reclassified to stockholder's equity. In the event the offering is unsuccessful or delayed, the Company will expense these costs.

### **Warrants**

On March 20, 2001, the Company granted Cathay Bank a warrant to purchase 124,000 shares of the Company's common stock at an exercise price of \$7.50 per share, subject to adjustment as defined, through January 1, 2005. The value ascribed to the warrant at the time of issuance was not significant. On April 6, 2004, the Company entered into an agreement with Cathay Bank to extend the exercise date of the warrants to June 30, 2005, in the event the Company does not complete an initial public offering by December 20, 2004. In November 2004, Cathay Bank exercised its warrants to purchase 124,000 shares of the Company's common stock at an exercise price of \$7.50 per share, resulting in \$930 in cash proceeds.

### **Stock Option Plans and Agreements**

The Company has in effect several stock-based plans and agreements under which non-qualified and incentive stock options have been granted to employees, non-employee members of the Board of Directors and other non-employees. The Company's 2002 Stock Option/Stock Issuance Plan (the "2002 Plan") is the successor equity incentive program to the Key Employee Stock Incentive Plan, 2001 Employee Incentive Plan, 2000 Employee Incentive Plan, 1999 Employee Incentive Plan, Key Employee Incentive Plan (together, the "Predecessor Plans"). Options have also been issued under employment, service and other agreements with officers, members of the Board of Directors, consultants and APCL (together, the "Option Agreements").

#### *The 2002 Plan*

In 2002, the Company and Board of Directors adopted, and in 2003 the stockholders approved, the 2002 Plan, whereby directors, officers, employees and consultants of the Company are eligible to receive incentive stock options and/or non-statutory stock options or to purchase restricted Common Stock of the Company as designated by the Compensation Committee of the Board of Directors, or in the case of stock option grants to the Chief Executive Officer and/or the Chief Operating Officer, as designated by the Board of Directors. In July 2004, the 2002 Plan was amended by the stockholders of the Company to increase the maximum number of shares of common stock authorized for issuance under the 2002 Plan from 2,800,000 to 6,400,000.

Options granted to the Chief Executive Officer and Chief Operating Officer are granted at 110% of fair market value and vest over a one-year period from the date of grant and expire in six years. Options granted to other key employees vest over three-to-five-year periods, and expire in ten years. Options issued to members of the Board of Directors or Advisory Board and consultants vest immediately after issuance and expire in seven years. During the year ended December 31, 2004, the Company granted 220,000 options to the chief executive officer and the chief operating officer.

*Predecessor Plans*

The Predecessor Plans provided for options to generally vest three years from the date of grant and expire in seven years. The maximum number of options for shares of common stock which may be issued under the Predecessor Plans is 1,471,800 (which includes a net 117,800 reduction in the shares available for grant approved by the Board of Directors in 2002).

*The Option Agreements*

The Option Agreements entered into during 2001 and 2002 generally provided for options issued to consultants for services performed and to key officers under 2001 employment agreements. Options for consultants vested immediately after issuance and expire three years from the date of grant. Options issued to key officers vested over a period of one year and expired in seven years. At December 31, 2004, there were 1,894,334 shares reserved for issuance under consulting and other agreements (which includes an additional 796,000 shares approved by the Board of Directors in 2002).

During 2002, the Company granted 110,000 options to the chief executive officer and chief operating officer.

In 1997, in connection with the transfer of intellectual property from APCL to Amphastar, options to purchase a total of 1,200,000 shares of common stock at \$1.50 per share were granted to APCL and the Chief Executive Officer and Chief Operating Officer of the Company. The options were exercisable immediately upon grant. In 2001 and 2002, options to purchase 800,000 and 400,000 shares, respectively, were exercised at \$1.50 per share.

The Board of Directors determines eligibility, vesting schedules and exercise prices for options granted under the Predecessor Plans and Option Agreements.

Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

Combined Option Plan Activity

Activity under the stock option plans and agreements in 2002, 2003 and 2004 is set forth below:

	Options Outstanding			
	Shares Available for Grant	Number of Shares	Exercise Price Range per Share	Weighted Average Exercise Price Per Share
Balance at December 31, 2001	404,400	2,936,644	\$ 1.50 - \$ 5.00	\$ 2.39
Increase in shares available for grant	3,478,200			
Options granted	(1,722,100)	1,722,100	8.00 - 8.80	8.06
Options canceled	215,400	(215,400)	1.75 - 5.00	3.58
Options exercised		(597,110)	1.50	1.50
Balance at December 31, 2002	2,375,900	3,846,234	1.50 - 8.80	5.06
Options granted	(660,500)	660,500	8.00 - 8.80	8.54
Options canceled	140,400	(140,400)	1.75 - 8.00	6.05
Options exercised				
Balance at December 31, 2003	1,855,800	4,366,334	\$ 1.50 - \$ 8.80	\$ 5.57
Increase in shares available for grant	3,600,000			
Options granted	(836,820)	836,820	12.50 - 13.75	12.85
Options canceled	67,000	(67,000)	1.75 - 8.00	5.33
Options exercised		(62,000)	1.75 - 8.00	7.40
Balance at December 31, 2004	4,685,980	5,074,154	\$ 1.50 - \$13.75	\$ 6.75

The weighted-average remaining contractual life and weighted-average exercise price of options outstanding and of options exercisable as of December 31, 2004, were as follows:

Range of Exercise Prices	Outstanding			Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
\$1.50 - \$1.75	1,492,334	3.47	\$ 1.57	1,492,334	\$ 1.57
\$5.00	521,400	5.80	5.00	521,400	5.00
\$8.00 - \$8.80	2,223,600	5.66	8.35	1,708,940	8.45
\$12.50	600,820	9.36	12.50	20,320	12.50
\$13.75	236,000	5.18	13.75	4,000	13.75
Total	5,074,154	5.45	\$ 6.75	3,746,994	\$ 5.26

**Shares Reserved for Future Issuance**

The Company has the following shares of common stock reserved for future issuance upon the exercise of stock options as of December 31, 2004:

	Number of Shares			Total
	2002 Plan	Predecessor Plans	Option Agreements	
Outstanding	3,000,420	1,134,400	939,334	5,074,154
Authorized for future grant	3,393,580	337,400	955,000	4,685,980
<b>Balance at December 31, 2004</b>	<b>6,394,000</b>	<b>1,471,800</b>	<b>1,894,334</b>	<b>9,760,134</b>

**10. Commitments**

**Consulting and Employment Agreements**

The Company entered into various long-term consulting agreements with Company stockholders and outside consultants. Consulting expenses are accrued as services are rendered. Consulting services are paid in the form of common stock or stock options at the estimated deemed fair market value at the grant date or cash upon completion of all services under the agreement. As of December 31, 2002, 2003 and 2004, the Company recorded expense of \$306, \$98 and \$92, respectively, for consulting services under these contracts.

The Company issued shares of common stock to members of the Board of Directors and consultants under consulting and other agreements as are as follows for the three years ended December 31, 2004:

	Members of Board of Directors		Consultants	
	Shares Issued	Price Per Share	Shares Issued	Price Per Share
2004		\$	1,440	\$ 12.50
2003	1,950	\$ 8.0	4,200	\$ 8.00
2002	5,460	\$ 5.00	22,540	\$ 8.00

Effective January 2002, 2003 and 2004, the Company entered into one-year employment agreements with the Chief Executive Officer and Chief Operating Officer. Under the agreements, the Company shall pay these officers base salaries and provides for the issuance of options under the 2002 Plan. Pursuant to the agreements, the Company granted the two officers options to purchase a total of 440,000 shares of common stock in 2002 and 2003 at an exercise price of \$8.80. Pursuant to the 2004 employment agreements, the Company granted the two officers options to purchase a total 220,000 shares at an exercise price of \$13.75 (Note 9).



### **Contract Manufacturing**

In December 2004, the Company signed a supply agreement with a pharmaceutical company in which the Company will provide technology transfer and development services to the customer prior to manufacturing a bronchodilator product for it. The agreement provides for aggregate payments to the Company of up to \$1,200 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, 2004, the Company had received a \$500 payment pursuant to the agreement.

### **Equipment Agreement with APCL**

Pursuant to a written agreement of May 4, 1997 and formalized on December 12, 1997, the Company entered into an equipment agreement with APCL whereby the Company agreed to purchase or lease equipment from APCL with an aggregate cost not to exceed \$9,131. Under the agreement, APCL managed leasing arrangements and paid all costs associated with the purchase or lease of the equipment on the Company's behalf. APCL purchased or leased equipment based on the Company's technical requirements. Certain equipment lease agreements made by APCL on behalf of Amphastar are guaranteed by Amphastar. Title to the equipment passes to the Company at the end of the lease.

Annually, the Company compensated APCL for related equipment costs plus a management fee equal to 2.5% of all related costs incurred by APCL, in the form of shares of common stock until a total of 6,087,334 shares were to be issued. In 2001, the Company issued 973,986 shares of common stock for equipment amounting to \$1,461 received under capital lease obligations of APCL. For equipment and services provided through December 31, 2002, 5,113,344 shares were issued in total. At December 31, 2002, an additional 279,313 shares valued at \$419 were not issued, but earned and, accordingly classified, as common stock to be issued under the agreement.

In 2003, the Company issued the remaining 973,990 shares due under the agreement, comprised of the 279,313 shares due to be issued from 2002 and 694,677 shares earned in 2003, which were valued at \$1,042. In April 2003, the Company amended the equipment agreement to clarify terms related to the management fee, which resulted in the Company owing APCL an additional 517,671 shares for management fees. Of the 694,677 shares issued in 2003, 517,671 shares related to the management fees and 177,006 shares related to equipment and services provided in 2003. As of December 31, 2003, the Company has no further obligation to APCL under the equipment agreement.

### **Operating Lease Agreements**

The Company leases real and personal property in the normal course of business under various noncancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various periods with renewal periods ranging from one to six years. Rental expense under these leases for the years ended December 31, 2002, 2003, 2004 was approximately \$1,310, \$2,036, and \$3,472, respectively.

Future minimum rental payments under operating leases that have initial or remaining noncancellable lease terms in excess of one-year fiscal year periods ending December 31, 2004, are as follows:

	<b>Operating Leases</b>
2005	\$ 3,579
2006	2,495
2007	1,761
2008	1,522
2009	1,344
Thereafter	941
<b>Total minimum lease payments</b>	<b>\$ 11,642</b>

The Company also leases office and laboratory facilities and office equipment from APCL for its New Drug Research Center (the "NDRC"). The Audit Committee of the Board of Directors has authorized the Company to continue this arrangement until the earlier of the acquisition of permanent space for the NDRC or December 31, 2007, up to a maximum of \$200. Rental expense was approximately \$138, \$145 and \$204 for the years ended December 31, 2002, 2003 and 2004, respectively. In November 2004, the Audit Committee of the Board of Directors approved an increase of the annual lease amount to \$292 per year.

#### **Purchase Commitments**

As of December 31, 2004, the Company has entered into commitments to purchase equipment for an aggregate of \$8,245 for which payments of \$2,929 have been made through December 31, 2004. The Company anticipates that these commitments will be fulfilled in 2005.

#### **11. Litigation**

##### **Environmental Litigation**

IMS, the Company's subsidiary, is one of the approximately 39 defendants in six lawsuits brought by approximately 218 plaintiffs alleging negligence, strict liability, wrongful death, permanent trespass, continuing trespass, public permanent nuisance, public continuing nuisance, strict liability for hazardous activity and fraudulent concealment, and claiming personal injury and/or property damage from exposure to contaminated drinking water. Because of the similarity in the cases, they have been consolidated and are being referenced under: In Re: Groundwater Cases (Judicial Council Coordination Proceeding No. 4135), Superior Court for the State of California, County of Los Angeles, Central Civil West District). These cases are being handled by the Los Angeles County Superior Court in a special forum for complex litigation. The plaintiffs have not definitely stated how much they are seeking in damages. IMS denies all substantive allegations of the plaintiffs, and is actively defending its position to minimize any potential liability or damages. The litigation is in the discovery stage. Two of IMS's past insurance carriers are paying all costs and the majority of fees in defending these claims.

There is no limit on the dollar amount of defense coverage that the two carriers might be obligated to pay. Both insurance companies have reserved their rights to be indemnified by IMS if IMS is later found to not merit insurance coverage, and both carriers have reserved their rights as to whether they are obligated to indemnify IMS for underlying claims, should a judgment be rendered against IMS in the future.

The Company and approximately 35 other local businesses were notified by the Environmental Protection Agency ("EPA") in August 1995 that they were deemed potentially responsible parties ("PRPs") with respect to a groundwater contamination problem (the "Problem") in the main San Gabriel Basin (the "Basin") in the vicinity of IMS' primary manufacturing plant in South El Monte, California. Without admitting liability, the Company entered into a private agreement with another PRP to conduct a Remedial Investigation and Feasibility Study as demanded by EPA (the "RI/FS"). The RI/FS was performed pursuant to an Administrative Order on Consent (the "AOC") that was agreed to by EPA. In conjunction with the AOC and under the approval of the California Regional Water Quality Control Board, Los Angeles Region, the Company performed certain subsurface investigatory work on the Company's property to determine whether any land used by the Company could be a source of the groundwater contamination. Based upon such tests, management determined that the Company's operations did not contribute significantly to the groundwater contamination and the Company had minimal liability to clean up the Company's former leasehold or the groundwater contamination. In 2000, the EPA drew upon the findings of the RI/FS to adopt an Interim Record of Decision ("ROD") for remediation of groundwater in the portion of the San Gabriel Basin known as the South El Monte Operable Unit ("SEMOU"). In response, certain water purveyors in or hydrologically downgradient from the SEMOU have implemented various projects to contain, extract and/or treat eight chemicals of concern in the groundwater in order to implement the ROD. These water purveyors then moved to obtain reimbursement for their expenses incurred in implementing the ROD. In the spring of 2002, the EPA named IMS and approximately 67 other entities as "Responsible Parties" ("RPs") relative to remediation costs in the SEMOU. In response, 13 companies, including IMS, entered into an agreement with the water purveyors to fund certain agreed upon work that included, but was not limited to, elements of EPA's ROD. By entering into this agreement, IMS settled certain potential claims against it that were alleged by the water purveyors. Moreover, this settlement also addressed many of the claims that EPA would have otherwise been able to bring against IMS as an RP in the SEMOU. Collectively, the 13 settling parties raised \$4,700. As part of the settlement, the 13 settling entities also received past and future credit for all matching public monies that were triggered as part of the settlement. During 2002, IMS paid its equal share of the settlement of \$365, which had been accrued in prior years.

In 2003, IMS and the other PRPs were notified that another chemical of concern (outside of the eight chemicals covered by the settlement agreement), perchlorate, has been detected in the SEMOU ground water and that it would have to be treated immediately. The PRPs are in conversations with the EPA to discuss a settlement of this liability. On April 12, 2004, IMS and several other of the settling companies were made third-party defendants in litigation between the water purveyors and the non-settling industrial defendants in the SEMOU. The third-party plaintiffs allege, among other things, a failure to adequately contribute to the groundwater cleanup costs in the SEMOU. The Company

denies all liability relating to any and all claims in the Third-Party Complaints. Further, since these claims overlap with some of the EPA claims, they may be extinguished as part of any settlement with the EPA. The Company has tendered the Third-Party Complaints to its insurance carriers and the carriers are paying all costs and the majority of fees in defending these claims. The ultimate outcome of this litigation cannot presently be determined. However, in management's opinion, the likelihood of a material adverse outcome is remote.

#### **Enoxaparin Sodium Litigation**

In March 2003, the Company filed an Abbreviated New Drug Application ("ANDA"), which is pending with the FDA, for enoxaparin sodium ("Lovenox®"), seeking approval to engage in the commercial manufacture, sale, and use of the enoxaparin product in the United States. The Company's ANDA includes a Paragraph IV certification that the existing patents in connection with Lovenox®, are invalid, unenforceable or will not be infringed by the Company's generic product. Teva Pharmaceuticals USA, Inc. ("Teva") also filed an ANDA on this product; however, the Company believes that its ANDA is the first to be filed for this drug with a Paragraph IV certification.

As a result of the filing of the ANDAs by the Company and Teva, Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. filed lawsuits against the Company and Teva in August 2003 in the United States District Court for the District of New Jersey and the United States District Court, Central District of California, Eastern Division (the "California Court") alleging infringement of one of the two patents on the product. The Company and Teva answered the complaint brought in the California Court and filed a counterclaim, which sought a declaration that the patents-in-suit are invalid, unenforceable and/or not infringed by the Company's and Teva's products. In February 2004, the District of New Jersey court granted Teva's motion to transfer jurisdiction of the lawsuit to the California Court and subsequently the New Jersey action was consolidated with the California action. The Company subsequently amended its answer to allege patent unenforceability due to inequitable conduct and to assert a counterclaim alleging that Aventis violated the United States antitrust laws. On August 31, 2004 the Company filed a motion seeking summary adjudication that the Aventis patent in suit was unenforceable due to Aventis inequitable conduct in procuring the patent and seeking to dismiss the litigation. In November 2004, we filed a second motion seeking a summary judgment that the Aventis patent-in-suit is invalid based on indefiniteness of its claims. In March 2005, the Company filed a third motion seeking a summary judgment that the Aventis patent-in-suit is invalid based on prior art. The Company's motions are currently under consideration by the California Court.

The Company intends to vigorously defend each of the foregoing lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to the Company, could have a material adverse effect on the Company's financial position, results of operations and cash flows.

### **Other Litigation**

The Company is also subject to various other claims and lawsuits arising in the ordinary course of business. In the opinion of management, the ultimate resolution of these matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company.

### **12. Related Party Transactions**

#### **Affiliated Companies**

The Company had an equipment agreement with APCL through December 31, 2003, whereby the Company has agreed to purchase or lease equipment from APCL with an aggregate cost up to \$9,131. In 2002 and 2003, the Company purchased equipment from APCL for approximately \$171 and \$169, respectively. Under this agreement, the Company accrued management fees payable to APCL of \$18 and \$0 in 2002 and 2003, respectively. In 2003, the Company issued common stock to APCL for management fees of \$776. Certain lease agreements of APCL are guaranteed by the Company or the Chief Executive Officer. The lease agreements guaranteed by the Company were entered into during 1998 through 2002 and have aggregate future minimum lease payments of \$241 at December 31, 2004, and mature in 2004 through 2006. Payment on the leases is expected to be remote (Note 10).

From time to time, the Company outsources laboratory test work to APCL under an arrangement approved by the Audit Committee of the Board of Directors. The total amount paid to APCL in 2002, 2003, 2004 was approximately \$14, \$19 and \$17, respectively. In addition, the Company leases and purchases certain equipment and leases part of a building from APCL (Note 10).

In 2001 and 2002, the Company charged APCL approximately \$57 and \$65, respectively, for certain labor services. No labor services were provided in 2003 and 2004.

#### **Other Related Party Transactions**

The Company engaged in various consulting arrangements with one of its directors during 2002, 2003 and 2004. For the years ended December 31, 2002, 2003 and 2004, the Company expensed \$27, \$16 and \$9 respectively, for the Director's consulting services and issued 5,460, 1,950 and -0- shares of common stock to the Director in lieu of cash for such consulting services performed.

### **13. Employee Benefits**

The Company has a defined contribution 401(k) plan ("Plan"), whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches 50% of each 1% of employee contributions up to 4% of total employee contributions or 2% of their annual compensation and pays the administrative costs of the Plan. Employer contributions vest over five years. Total employer contributions during 2002, 2003, and 2004 were approximately \$171, \$158, and \$218, respectively.

#### 14. Subsequent Events

In January 2005, the Company entered into a subscription agreement (the "Agreement") with an institutional investor (the "Investor") whereby the investor has agreed to purchase 675,676 shares of the Common Stock of the Company (the "Shares") at a purchase price of \$14.80 per share (the "Price"). The Agreement contains a price protection provision, such that, prior to the earlier of (i) an initial public offering by the Company, or (ii) three years from the date of the Agreement, if the Company closes a private placement of Common Stock for cash proceeds above \$5,000 at a price lower than the Price (the "Subsequent Private Placement"), then the Investor will be entitled to receive additional shares of Common Stock so that the Investor's effective purchase price per share will equal the purchase price per share of the Subsequent Private Placement. The Agreement also provides "piggyback" registration rights to the Investor allowing for the Shares to be registered in certain circumstances subsequent to an initial public offering. On February 4, 2005, the Company closed the private placement, receiving gross proceeds of \$10,000.

On February 8, 2005, the Company obtained \$3,440 in equipment lease financing. The terms of the financing will require the Company to secure the loan with a line of credit of \$1,700 which will require setting aside \$1,700 in restricted investments.

In March 2005, the Company repaid all outstanding borrowings under the Bank of the West line of credit facility.

On April 14, 2005, the Company amended the terms of the Bank of the West line of credit facility to extend the maturity date to April 2006. In the event the Company completes a successful initial public offering (IPO), the Company is required to repay \$5,000 of debt owed to Bank of the West. In the event an IPO is not completed by September 1, 2005, any amount outstanding under the line of credit facility must be repaid in the amount of \$500 per month commencing September 1, 2005.

On May 2, 2005, the Company entered into an agreement to grant certain exclusive marketing rights for its enoxaparin product candidate (the "Product") to Andrx Pharmaceuticals, Inc. Andrx Pharmaceuticals, Inc.'s marketing rights generally extend to the U.S. retail pharmacy market (the "Territory"). To obtain such rights, Andrx Pharmaceuticals, Inc. paid \$4,500 to the Company upon execution of the agreement and will make an additional \$5,500 payment once certain milestones relating to the Product are achieved, including obtaining FDA marketing approval and a favorable resolution of the pending patent litigation with Aventis. Under the agreement, the parties will share the net profits from Andrx Pharmaceuticals, Inc.'s sales of the product in the Territory with the Company receiving up to 60% of the net profits. Under certain specified conditions, Andrx Pharmaceuticals, Inc. will have the right to receive a refund of the amounts paid to the Company.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholder  
Armstrong Pharmaceuticals, Inc.  
Canton, Massachusetts

We have audited the accompanying balance sheets of Armstrong Pharmaceuticals, Inc. (the Company) as of October 8, 2003 and December 31, 2002, and the related statements of operations, changes in stockholder's equity (deficit), and cash flows for the period January 1, 2003 to October 8, 2003 and the year ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Armstrong Pharmaceuticals, Inc. as of October 8, 2003 and December 31, 2002, and the results of its operations and its cash flows for the period January 1, 2003 to October 8, 2003 and the year ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

/s/ CARLIN, CHARRON & ROSEN, LLP

Carlin, Charron & Rosen, LLP

Worcester, Massachusetts  
August 20, 2004

## ARMSTRONG PHARMACEUTICALS, INC.

## Balance Sheets

October 8, 2003 and December 31, 2002

	2003	2002
<b>Assets</b>		
Current assets		
Cash	\$	\$ 624,016
Accounts receivable, net		1,610,627
Receivable from Parent	166,288	
Inventories, net	3,747,374	7,511,705
Prepaid expenses	99,257	163,972
	<b>4,012,919</b>	<b>9,910,320</b>
Property and equipment, net		
Total assets	<b>\$ 4,012,919</b>	<b>\$ 9,910,320</b>
<b>Liabilities and Stockholder's Deficit</b>		
Current liabilities		
Bank overdraft	\$ 572,417	\$ 303,399
Accounts payable	94,902	201,009
Accrued expenses	475,491	517,353
Accrued restructuring	5,756,771	7,229,703
Payable to Parent	6,491,814	7,355,594
	<b>13,391,395</b>	<b>15,607,058</b>
Commitments and contingencies		
Stockholder's deficit		
Common stock		
Additional paid-in capital	18,218,000	18,218,000
Accumulated deficit	(27,596,476)	(23,914,738)
	<b>(9,378,476)</b>	<b>(5,696,738)</b>
Total liabilities and stockholder's deficit	<b>\$ 4,012,919</b>	<b>\$ 9,910,320</b>



## ARMSTRONG PHARMACEUTICALS, INC.

## Statements of Operations

For the Period January 1, 2003 to October 8, 2003  
and the Year Ended December 31, 2002

	2003	2002
Revenues		
Third party sales Albuterol	\$	\$ 2,158,886
Other third party sales	3,801,934	6,985,242
Sales to Parent	5,905,375	6,389,263
	<b>9,707,309</b>	<b>15,533,391</b>
Cost of goods sold		
Third party Albuterol		2,293,900
Other third party	3,003,402	6,462,436
Parent	5,905,375	6,389,263
Manufacturing variances	3,034,565	14,139,826
Inventory provision	133,034	2,229,007
	<b>12,076,376</b>	<b>31,514,432</b>
Gross margin	<b>(2,369,067)</b>	<b>(15,981,041)</b>
Operating expenses		
General and administrative	650,875	1,131,236
Research and development	670,469	2,066,470
Impairment of property and equipment		7,818,809
	<b>1,321,344</b>	<b>11,016,515</b>
Loss from operations	<b>(3,690,411)</b>	<b>(26,997,556)</b>
Other income		
Interest income	8,673	14,062
Miscellaneous income		3,699
	<b>8,673</b>	<b>17,761</b>
Net loss	<b>\$ (3,681,738)</b>	<b>\$ (26,979,795)</b>

**ARMSTRONG PHARMACEUTICALS, INC.**

**Statements of Changes in Stockholder's Equity (Deficit)**

**For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002**

	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Retained Earnings (Accumulated Deficit)</b>	<b>Total Stockholder's Equity (Deficit)</b>
	<b>Shares</b>	<b>Amount</b>			
Balance, January 1, 2002	100	\$	\$ 18,218,000	\$ 3,065,057	\$ 21,283,057
Net loss				(26,979,795)	(26,979,795)
Balance, December 31, 2002	100		18,218,000	(23,914,738)	(5,696,738)
Net loss				(3,681,738)	(3,681,738)
Balance, October 8, 2003	100	\$	\$ 18,218,000	\$ (27,596,476)	\$ (9,378,476)

F-41

## ARMSTRONG PHARMACEUTICALS, INC.

## Statements of Cash Flows

For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002

	2003	2002
	<u>          </u>	<u>          </u>
Cash flows from operating activities		
Net loss	\$ (3,681,738)	\$ (26,979,795)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation		532,891
Provision for doubtful accounts		136,843
Provision for inventory reserve	133,034	2,229,007
Impairment charge on property and equipment		7,818,809
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Accounts receivable	1,610,627	439,584
Receivable from Parent	(166,288)	
Inventories	3,631,297	6,787,935
Prepaid expenses	64,715	232,728
Increase (decrease) in:		
Accounts payable	(106,107)	(1,336,610)
Accrued expenses	(41,862)	(95,192)
Accrued restructuring	(1,472,932)	7,229,703
	<u>          </u>	<u>          </u>
Net cash used for operating activities	<b>(29,254)</b>	<b>(3,004,097)</b>
	<u>          </u>	<u>          </u>
Cash flows from investing activities		
Acquisition of property and equipment		<b>(5,598,406)</b>
	<u>          </u>	<u>          </u>
Cash flows from financing activities		
Bank overdraft	269,018	6,841
Payments to Parent	(863,780)	
Advances from Parent		8,805,394
	<u>          </u>	<u>          </u>
Net cash provided by (used for) financing activities	<b>(594,762)</b>	<b>8,812,235</b>
	<u>          </u>	<u>          </u>
Net increase (decrease) in cash	<b>(624,016)</b>	<b>209,732</b>
Cash beginning	624,016	414,284
	<u>          </u>	<u>          </u>
Cash ending	<b>\$ 624,016</b>	<b>\$ 624,016</b>
	<u>          </u>	<u>          </u>

**ARMSTRONG PHARMACEUTICALS, INC.**

**Notes to Financial Statements**

**For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002**

**1. Nature of Operations**

Armstrong Pharmaceuticals, Inc. (the "Company" or "Armstrong") was incorporated in 2001 in the state of Delaware. The Company was founded in 1955 as Armstrong Laboratories, Inc., a manufacturer of specialty aerosol products. The Company's principal product during the period January 1, 2003 to October 8, 2003 and the year ended 2002 was Albuterol, which is used to prevent and treat wheezing, shortness of breath, and troubled breathing caused by asthma, chronic bronchitis, emphysema, and other lung diseases. Armstrong also provides contract manufacturing services for metered-dose inhalers (MDIs) and nasal spray products. In 2001, Armstrong became a wholly owned subsidiary of Andrx Corporation ("Andrx"; "Parent"), a publicly held company, after being purchased from Celltech Manufacturing, Inc. Armstrong is registered with the U.S. Food and Drug Administration (FDA) and the U.S. Drug Enforcement Agency.

**2. Summary of Significant Accounting Policies**

*Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

*Inventories*

Inventories are stated at the lower of cost or market value, with cost determined by the first-in, first-out method.

*Property and Equipment and Depreciation*

Property and equipment are stated at cost. Depreciation is computed using the straight-line method at rates sufficient to write off the cost of the assets over their estimated useful lives. Depreciation expense on property and equipment totaled \$0 and \$532,891 for the period January 1, 2003 to October 8, 2003 and the year ended December 31, 2002, respectively. In 2002, the Company determined that its property and equipment was impaired and accordingly recognized an impairment charge of \$7,818,809.

*Income Taxes*

The Company accounts for income taxes according to the liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and income tax bases of assets and liabilities and are measured using enacted tax laws and rates that will be in effect when the differences are expected to reverse.

*Deferred Rent*

The Company accounts for escalating rental payments on a straight line basis over the term of the lease. The difference between the straight line amounts and the amounts actually expended is included

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

in accrued expenses in the accompanying balance sheets and totaled approximately \$245,000 and \$163,000 at October 8, 2003 and December 31, 2002, respectively.

### *Revenue Recognition*

Revenue is recognized when products are shipped to customers.

### *Shipping Fees*

Shipping charges to customers are included in revenues; shipping costs are included in cost of goods sold.

## **3. Concentrations**

### *Major Customers and Suppliers*

The Company has only one operating segment, the pharmaceuticals industry. The Company reduces its credit risk on accounts receivable by only extending credit to customers with established credit worthiness on a case-by-case basis. The Company has three customers that accounted for 100% of revenues for the period January 1, 2003 to October 8, 2003, with the parent company providing 61% and two third-party customers providing 21% and 18% of revenues, respectively. Four customers accounted for 99% of revenues for the year ended December 31, 2002, with the parent company providing 41% and three third-party customers providing 19%, 25% and 14%, respectively. These customers also represented 100% of accounts receivable as October 8, 2003 and December 31, 2002. The Company also has three vendors that accounted for 51% of purchases in 2003 and 38% in 2002.

### *Collective Bargaining Agreements*

As of October 8, 2003, the Company had approximately 80 employees, of which approximately 49% were covered by collective bargaining agreements which expire in December 2004.

### *Cash Balances*

The Company also has a concentration of credit represented by cash balances in certain large commercial banks in amounts which occasionally exceed current federal deposit insurance limits. The financial stability of these institutions is monitored by management.

## **4. Accounts Receivable**

Accounts receivable represent balances due from customers and are presented net of an allowance for doubtful collections of approximately \$115,000 and \$140,000 at October 8, 2003 and December 31, 2002, respectively. In determining the allowance, objective evidence that a single receivable is uncollectible as well as a historical pattern of collections of accounts receivable that indicate that the entire face amount of a portfolio of accounts receivable may not be collectible is considered at each balance sheet date.

**5. Inventories**

Inventories consist of the following:

	2003	2002
Raw materials	\$ 3,123,546	\$ 7,638,965
Work in process	1,168,026	670,846
Finished goods	409,202	155,294
	4,700,774	8,465,105
Less: Reserve for obsolescence	953,400	953,400
	\$ 3,747,374	\$ 7,511,705

**6. Restructuring and Asset Impairment**

Andrx initiated restructuring actions at the Company in the fourth quarter of 2002 to reduce costs and record impairment charges on unproductive assets. The restructuring and related actions primarily consist of personnel reductions and the recording of a lease loss reserve for the Company's operating lease for its Canton facility. The Company reduced its personnel by 38 employees and recorded a severance charge of approximately \$405,000. All amounts related to severance were paid out during 2003. Additionally, the Company recorded a lease loss reserve of approximately \$6,825,000 which included all future lease payments as well as estimates for insurance and taxes for the remaining life of the lease. At October 8, 2003 and December 31, 2002, accrued restructuring costs totaled approximately \$5,757,000 and \$7,230,000, respectively.

In the year ended December 31, 2002, management determined that fixed assets were impaired based on an analysis comparing carrying value to estimated future cash flows. This impairment was caused by excess manufacturing capacity due to expiration of customer contracts and uncertainty of any replacement products for future revenue.

**7. Related Party Transactions***Sales to Parent*

The Company sells Albuterol to Andrx at cost.

*Other Transactions with Parent*

The Company's operating losses have been funded by Andrx. As a result, the Company has significant amounts due to Andrx at October 8, 2003 and December 31, 2002. There are no set repayment terms or interest charges to the Company for this liability. Also, see Note 12.

**8. Stockholders' Equity**

The Company has authorized 100 shares of common stock, which have a par value of \$.001 each. As of October 8, 2003 and December 31, 2002, all 100 shares were issued and outstanding and owned by Andrx.

## 9. Pension Plan

The Company has a defined contribution pension plan available to all eligible non union employees. Employees may contribute pre-tax income up to the maximum allowable by law. The Company matched 50% of employee contributions up to a maximum of 6% of employee pre-tax income. The Company also contributes \$.65 per hour for its union employees to a pension plan sponsored by the International Association of Machinists and Aerospace Workers. Company contributions to both plans totaled \$44,857 and \$81,247 in 2003 and 2002, respectively

Andrx has a stock option plan available to all eligible employees. Employees received stock option grants periodically which they were allowed to exercise once the stock options were fully vested. As of October 8, 2003, all Company employees who held fully vested stock options were allowed to exercise their stock options within ninety days. None of the stock options were exercised within ninety days and thus were cancelled.

## 10. Income Taxes

For the period January 1, 2003 to October 8, 2003 and for the year ended December 31, 2002, the Company had certain book and tax timing differences and significant operating losses that would have resulted in net operating loss carryforwards. As the Company could not reasonably expect to generate sufficient net income to utilize any net operating loss carryforwards, deferred tax assets have been fully reserved. Also, see Note 12.

## 11. Commitments and Contingencies

### *Legal Proceedings*

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, principally product liability. In the opinion of management, the ultimate disposition of such proceedings will not have a materially adverse effect on the Company's financial position or future results of operations.

### *Alpharma Breach of Contract Litigation*

In September 2003, Alpharma USPD Inc. ("Alpharma") filed a complaint against the Company in the United States District Court for the Southern District of New York. Alpharma alleged that a contractual breach by Armstrong resulted in the recall of Epinephrine Mist, a product manufactured by Armstrong for Alpharma. In the complaint, Alpharma sought to recover damages for breach of contract, damages for negligent misrepresentations, and punitive damages. On January 22, 2004, Alpharma filed an amended complaint, which added Andrx and Celltech Manufacturing Inc. (Celltech), from which Andrx purchased Armstrong in March 2001, as additional named defendants. Management expects that any resulting liability will not be the responsibility of Armstrong. Accordingly, no liability has been accrued for this matter. See also Note 12.

### *Leases*

The Company rents office, laboratory, warehouse and production space in Canton, Massachusetts, under a lease agreement that expires in November 2011. See Note 6. The Company also rents office, laboratory, warehouse and production space in West Roxbury, Massachusetts, under a lease agreement

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

that expires in March 2005. The terms of certain lease arrangements include options to renew for additional periods and additional payments for real estate taxes, insurance, and other operating expenses applicable to the property. Rent expense under these agreements totaled \$85,670 and \$1,769,733 for the period January 1, 2003 to October 8, 2003 and for the year ended December 31, 2002, respectively.

The Company leases machinery and equipment under operating leases with various expiration dates through July 2006. Equipment lease expense charged to operations totaled \$15,036 for the period January 1, 2003 to October 8, 2003 and \$21,904 for the year ended December 31, 2002.

Future minimum payments under non-cancelable operating leases having remaining terms in excess of one year as of October 8, 2003 are as follows:

<b>Year Ending October 8,</b>	
2004	\$ 1,443,108
2005	1,357,095
2006	1,218,611
2007	1,211,793
2008	1,322,874
Thereafter	2,777,026
	<hr/>
	\$ 9,330,507
	<hr/>

### 12. Subsequent Events

On October 9, 2003, the Company was acquired by Amphastar Pharmaceuticals, Inc (Amphastar), a specialty and generic pharmaceutical company, for \$3,000,000 in cash. Amphastar acquired all outstanding stock of the Company. In accordance with the stock purchase agreement certain liabilities, including the outstanding payable to parent (net of the receivable from parent) and any liability associated with the AlphaPharma lawsuit, remain with Andrx, and do not become an obligation of Amphastar. The stock purchase agreement also required that Amphastar and Andrx join in making an election under Internal Revenue Service Code Section 338(h)(10). The related tax return, filed by Andrx, reflected a loss with respect to Armstrong. As a result of the 338(h)(10) election, all unused tax attributes Armstrong had accumulated were forfeited as of October 8, 2003.

Also, on October 8, 2003 the Company and Andrx entered into a one year supply agreement. The agreement requires the Company to manufacture and supply Albuterol to Andrx based upon firm orders. Andrx does not have an obligation to purchase any minimum quantities under this agreement except for the firm orders. The Company has agreed to sell the Albuterol to Andrx at a \$1.90 per unit. The supply agreement with Andrx does not represent a loss contract. On November 1, 2004, the Company renewed its supply agreement with an Andrx subsidiary. The total purchase commitment is substantially lower than the initial agreement. All terms and conditions are similar to the original agreement.



On June 30, 2004, a settlement was reached on the Alharma lawsuit, requiring the payment of \$5,250,000 to Alharma by Andrx and Celltech equally for the dismissal of the complaint described in Note 11. All parties' claims against each other in connection with this matter were released.

On July 1, 2004, the Company acquired the product rights to Epinephrine Mist CFC from Alharma for \$2,000,000 in cash. The Company has agreed to pay royalties on future product sales and, in the event of recertification, will acquire inventory from Alharma valued at approximately \$300,000.

In December 2004, the Company signed a supply agreement with a pharmaceutical company in which the Company will provide technology transfer and development services to the customer prior to manufacturing a bronchodilator product for it. The agreement provides for aggregate payments to the Company of up to \$1,200,000 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, 2004, the Company had received a \$500,000 payment pursuant to the agreement.

F-48

---

**Shares**

**Amphastar Pharmaceuticals, Inc.**

**Common Stock**

---

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the National Association of Securities Dealers Inc. filing fee.

	<b>Amount</b>
Securities and Exchange Commission Filing Fee	\$13,536.00
NASD Filing Fee	\$12,000.00
NASDAQ National Market Listing Fee	*
Accounting Fees and Expenses	*
Legal Fees and Expenses	*
Blue Sky Fees and Expenses	*
Transfer Agent and Registrar Fees and Expenses	*
Printing and Engraving Expenses	*
Miscellaneous Expenses	*
Total	*

\*

To be filed by amendment.

**Item 14. Indemnification of Directors and Officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except for breaches of the director's duty of loyalty to the corporation or its stockholders, acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of a law, authorizations of the payments of a dividend or approval of a stock repurchase or redemption in violation of Delaware corporate law or for any transactions from which the director derived an improper personal benefit. Our certificate of incorporation provides that no director will be liable to us or our stockholders for monetary damages for breach of fiduciary duties as a director, subject to the same exceptions as described above. Prior to the completion of this offering, we intend to enter into indemnification agreements with each of our directors which may, in some cases, be broader than the specific indemnification provisions contained under Delaware law.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlements actually and reasonably incurred by the person in connection with a threatened, pending, or completed action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, indemnification is limited to expenses (including attorney fees) actually and reasonably incurred by the person in connection with defense or settlement of such action or suit and no indemnification shall be made with respect to any claim, issue, or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of

all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper. In addition, to the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit, or proceeding described above (or claim, issue, or matter therein), such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative, or investigative action, suit, or proceeding may be advanced by the corporation upon receipt of an undertaking by such person to repay such amount if it is ultimately determined that such person is not entitled to indemnification by the corporation under Section 145 of the General Corporation Law of the State of Delaware.

Our certificate of incorporation provides that we will, to the fullest extent permitted by law, indemnify any person made or threatened to be made a party to an action or proceeding by reason of the fact that he or she (or his or her testators or intestate) is or was our director or officer or serves or served at any other corporation, partnership, joint venture, trust or other enterprise in a similar capacity or as an employee or agent at our request, including service with respect to employee benefit plans maintained or sponsored by us, against expenses (including attorneys' fees and expenses), judgments, fines, penalties, and amounts paid in settlement incurred in connection with the investigation, preparation to defend, or defense of such action, suit, proceeding, or claim. However, we are not required to indemnify or advances expenses in connection with any action, suit, proceeding, claim, or counterclaim initiated by us or on behalf of us. Our bylaws provide that we will indemnify and hold harmless each person who was or is a party or threatened to be made a party to any action, suit, or proceeding by reason of the fact that he or she is or was our director or officer, or is or was serving at our request in a similar capacity of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans (whether the basis of such action, suit, or proceeding is an action in an official capacity as a director or officer or in any other capacity while serving as a director of officer) to the fullest extent authorized by the Delaware General Corporation Law against all expense, liability and loss (including attorneys fees, judgments, fines, ERISA excise taxes, or penalties and amounts paid in settlement) reasonably incurred or suffered by such person in connection such action, suit, or proceeding, and this indemnification continues after such person has ceased to be an officer or director and inures to the benefit of such person's heirs, executors, and administrators. The indemnification rights also include the right generally to be advanced expenses, subject to any undertaking required under Delaware General Corporation Law, and the right generally to recover expenses to enforce an indemnification claim or to defend specified suits with respect to advances of indemnification expenses.

#### **Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding securities sold by the Registrant since December 31, 2001 which were not registered under the Securities Act.

(a) Issuances of Preferred Stock and Common Stock.

(1) During the period December 2001 through March 2002, the Registrant issued and sold an aggregate of 4,105,102 shares of non-voting convertible preferred stock at a price per share of \$8.00 to various accredited investors.

(2) During the period April through June 2004, the Registrant issued and sold 1,250,000 shares of common stock at a price per share of \$12.50 to various accredited investors.

(3) In November 2004 a warrant to purchase 124,000 shares of the Registrant's common stock was exercised at \$7.50 per share.

(4) In February 2005 the Registrant issued and sold 675,676 shares of common stock at a price per share of \$14.80 to an institutional investor.

No underwriters were involved in the foregoing sales of securities. The securities described in this paragraph (a) of Item 15 were issued to a combination of foreign and U.S. investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Rule 506 of Regulation D promulgated thereunder relative to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. The purchasers of shares of our stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. The sales of these securities were made without general solicitation or advertising.

(b) Stock Option Grants.

(1) Since December 31, 2002, the Registrant has granted stock options under its various stock option plans to directors, officers, employees and consultants to purchase an aggregate of 3,219,420 shares of common stock with an aggregate exercise price of \$9.40 per share, and has issued 659,110 shares of common stock for an aggregate purchase price of \$1,354,500 upon exercise of such options.

The stock option grants and the common stock issuances described in this paragraph (b)(1) of Item 15 were made pursuant to written compensatory plans or agreements in reliance on the exemption provided by Rule 701 promulgated under the Securities Act.

**Item 16. Exhibits and Financial Statement Schedules.**

(a)  
Exhibits

Exhibit No.	Description
1.1*	Underwriting Agreement
3.1	Certificate of Incorporation
3.2*	By-laws
4.1*	Specimen certificate evidencing shares of common stock
5.1*	Opinion of Latham & Watkins LLP
10.1**	Amended and Restated 2002 Stock Option/Stock Issuance Plan
10.2	Forms of 1998-2001 option agreements
10.3	Lease Agreement dated December 17, 2001 between Applied Financial, Inc. and the Registrant, as amended
10.4**	Asset Sale Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.5**	Security Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.6**	Toll Manufacturing Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.7	Royalty Purchase Agreement, dated August 5, 2003, between Drug Royalty USA, Inc. and the Registrant
10.8**	Security Agreement, dated August 5, 2003, between Drug Royalty USA, Inc. and the Registrant
10.9**	Subordination Agreement, dated August 5, 2003, between Organon USA Inc., Drug Royalty USA, Inc. and the Registrant

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

- 10.10 Settlement Agreement between the Registrant and Organon USA Inc. dated December 20, 2004
- 10.11a\*\* Promissory Note, dated February 8, 2001, in favor of Cathay Bank, as amended
- 10.11b Business Loan Agreement, dated February 8, 2001, between the Registrant and Cathay Bank, as amended
- 10.12\*\* Commercial Security Agreement, dated February 8, 2001, in favor of Cathay Bank, as amended
- 10.13\*\* Lease Agreement, dated July 24, 1990, between Dennis and Gloria Jebbia and International Medication Systems, Limited
- 10.14\*\* Lease Agreement, dated March 9, 2000, between Owen Bros. Enterprise and International Medication Systems, Limited, as amended
- 10.15\*\* Lease Agreement, dated June 11, 2001, between John C. Armstrong and Armstrong, as amended
- 10.16\*\* Stock Purchase Warrant dated March 20, 2001 with Cathay Bank
- 10.17 Equipment Purchase Facility, dated October 10, 2002, between International Medication Systems, Limited and Bank of the West, as amended
- 10.18 Continuing Guaranty of Equipment Purchase Facility, dated October 10, 2002, between the International Medication Systems, Limited and Bank of the West
- 10.19a Business Loan Agreement Line of Credit, dated February 25, 2004, between International Medication Systems, Limited and Bank of the West
- 10.19b Change in Terms Agreement, dated April 14, 2005, between International Medication Systems, Limited and Bank of the West
- 10.20 Commercial Guaranty, dated March 1, 2004, between the Registrant and Bank of the West
- 10.21 Commercial Security Agreement Line of Credit, dated March 1, 2004, between International Medication Systems, Limited and Bank of the West
- 10.22 Promissory Note Line of Credit, dated March 1, 2004, from International Medication Systems, Limited to Bank of the West
- 10.23 Promissory Note Building Loan, dated November 5, 2004, between International Medication Systems, Limited to Bank of the West
- 10.24 Commercial Guaranty Building Loan, dated November 5, 2004, between the Registrant and Bank of the West
- 10.25a Exclusivity Agreement, dated March 24, 2004, between the Registrant and Shanghai No. 1 Biochemical and Pharmaceutical Co., Ltd. for pharmaceutical active ingredient from porcine tissue
- 10.25b Exclusivity Agreement, dated March 24, 2004, between the Registrant and Shanghai No. 1 Biochemical and Pharmaceutical Co., Ltd. for pharmaceutical active ingredient from bovine tissue
- 10.26\* Supply Agreement, dated December 16, 2004, between Wyeth and Armstrong Pharmaceuticals, Inc.
- 10.27 Registration Rights Agreement, dated February 4, 2005, between the Registrant and Lotus China Fund, L.P.
- 10.28\* Distribution Agreement, dated May 2, 2005, between the Registrant and Andrx Pharmaceuticals, Inc.

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

- 21.1\*\* Subsidiaries of the Registrant
  - 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
  - 23.2 Consent of Carlin, Charron & Rosen LLP, Independent Registered Public Accounting Firm
  - 23.3\* Consent of Latham & Watkins LLP (included in Exhibit 5.1)
  - 24.1\*\* Power of Attorney (included in the signature page to this registration statement)
- 

\*

To be filed by amendment.

\*\*

Previously filed with the Form S-1 filed by the Registrant on February 11, 2005.

Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

(b)

Financial Statement Schedules.

Schedule II.

All other schedules are omitted because they are not required, are not applicable or the information is included in the financial statements or notes thereto.

### Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1)

For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective.

(2)

For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## Schedule II Valuation and Qualifying Accounts

## AMPHASTAR PHARMACEUTICALS, INC.

## SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

	Balance At Beginning of Period	Charged (Credited) to Cost and expenses	Acquired Balance	Deductions	Balance At End of Period
<b>Allowance for Doubtful Accounts:</b>					
Year ended December 31, 2002	\$ 501	\$ (242)	\$	\$ (2)	\$ 257
Year ended December 31, 2003	257	205		(29)	433
Year ended December 31, 2004	433	372		(371)	434
<b>Reserve for Inventory Obsolescence:</b>					
Year ended December 31, 2002	\$ 1,363	\$ 646	\$	\$ (587)	\$ 1,422
Year ended December 31, 2003	1,422	1,255	423	(81)	3,019
Year ended December 31, 2004	3,019	769		(1,628)	2,160

II-6



**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Rancho Cucamonga, California on this 12<sup>th</sup> day of May, 2005.

AMPHASTAR PHARMACEUTICALS, INC.

By:    /s/ DAVID NASSIF

    
David Nassif  
Chief Financial Officer

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>  </u> *		
<u>  </u> Jack Zhang	President, Chief Executive Officer and Director (Principal Executive Officer)	May 12, 2005
<u>  </u> *		
<u>  </u> Mary Luo	Chairman, Chief Operating Officer and Director	May 12, 2005
<u>  </u> /s/ DAVID NASSIF		
<u>  </u> David Nassif	Chief Financial Officer (Principal Financial and Accounting Officer)	May 12, 2005
<u>  </u> *		
<u>  </u> Kenneth Chang	Director	May 12, 2005
<u>  </u> *		
<u>  </u> Floyd Petersen	Director	May 12, 2005
<u>  </u> *		
<u>  </u> Richard Koo	Director	May 12, 2005
<u>  </u> *		
<u>  </u> Richard Prins	Director	May 12, 2005
<u>  </u> *		
<u>  </u> Gordon Treweek	Director	May 12, 2005

\*By:    /s/ DAVID NASSIF

    
David Nassif  
Attorney-in-fact

## EXHIBIT INDEX

Exhibit No.	Description
1.1*	Underwriting Agreement
3.1	Certificate of Incorporation
3.2*	By-laws
4.1*	Specimen certificate evidencing shares of common stock
5.1*	Opinion of Latham & Watkins LLP
10.1**	Amended and Restated 2002 Stock Option/Stock Issuance Plan
10.2	Forms of 1998-2001 option agreements
10.3	Lease Agreement dated December 17, 2001 between Applied Financial, Inc. and the Registrant, as amended
10.4**	Asset Sale Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.5**	Security Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.6**	Toll Manufacturing Agreement, dated June 26, 2003, between Organon USA Inc. and the Registrant
10.7	Royalty Purchase Agreement, dated August 5, 2003, between Drug Royalty USA, Inc. and the Registrant
10.8**	Security Agreement, dated August 5, 2003, between Drug Royalty USA, Inc. and the Registrant
10.9**	Subordination Agreement, dated August 5, 2003, between Organon USA Inc., Drug Royalty USA, Inc. and the Registrant
10.10	Settlement Agreement between the Registrant and Organon USA Inc. dated December 20, 2004
10.11a**	Promissory Note, dated February 8, 2001, in favor of Cathay Bank
10.11b	Business Loan Agreement, dated February 8, 2001, between the Registrant and Cathay Bank, as amended
10.12**	Commercial Security Agreement, dated February 8, 2001, in favor of Cathay Bank
10.13**	Lease Agreement, dated July 24, 1990, between Dennis and Gloria Jebbia and International Medication Systems, Limited
10.14**	Lease Agreement, dated March 9, 2000, between Owen Bros. Enterprise and International Medication Systems, Limited, as amended
10.15**	Lease Agreement, dated June 11, 2001, between John C. Armstrong and Armstrong, as amended
10.16**	Stock Purchase Warrant dated March 20, 2001 with Cathay Bank
10.17	Equipment Purchase Facility, dated October 10, 2002, between International Medication Systems, Limited and Bank of the West, as amended
10.18	Continuing Guaranty of Equipment Purchase Facility, dated October 10, 2002, between International Medication Systems, Limited and Bank of the West
10.19a	Business Loan Agreement Line of Credit, dated February 25, 2004, between International Medication Systems, Limited and Bank of the West
10.19b	Change in Terms Agreement, dated April 14, 2005, between International Medication Systems, Limited and Bank of the West
10.20	Commercial Guaranty, dated March 1, 2004, between the Registrant and Bank of the West

## Edgar Filing: Amphastar Pharmaceuticals, Inc. - Form S-1/A

- 10.21 Commercial Security Agreement Line of Credit, dated March 1, 2004, between International Medication Systems, Limited and Bank of the West
  - 10.22 Promissory Note Line of Credit, dated March 1, 2004, from International Medication Systems, Limited to Bank of the West
  - 10.23 Promissory Note Building Loan, dated November 5, 2004, between International Medication Systems, Limited to Bank of the West
  - 10.24 Commercial Guaranty Building Loan, dated November 5, 2004, between the Registrant and Bank of the West
  - 10.25a Exclusivity Agreement, dated March 24, 2004, between the Registrant and Shanghai No. 1 Biochemical and Pharmaceutical Co., Ltd. for pharmaceutical active ingredient from porcine tissue
  - 10.25b Exclusivity Agreement, dated March 24, 2004, between the Registrant and Shanghai No. 1 Biochemical and Pharmaceutical Co., Ltd. for pharmaceutical active ingredient from bovine tissue
  - 10.26\* Supply Agreement, dated December 16, 2004, between Wyeth and Armstrong Pharmaceuticals, Inc.
  - 10.27 Registration Rights Agreement, dated February 4, 2005, between the Registrant and Lotus China Fund, L.P.
  - 10.28\* Distribution Agreement, dated May 2, 2005, between the Registrant and Andrx Phramaceuticals, Inc.
  - 21.1\*\* Subsidiaries of the Registrant
    - 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
    - 23.2 Consent of Carlin, Charron & Rosen LLP, Independent Registered Public Accounting Firm
    - 23.3\* Consent of Latham & Watkins LLP (included in Exhibit 5.1)
  - 24.1\*\* Power of Attorney (included in the signature page to this registration statement)
- 

\*

To be filed by amendment.

\*\*

Previously filed with the Form S-1 filed by the Registrant on February 11, 2005.

Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

---

QuickLinks

TABLE OF CONTENTS

PROSPECTUS SUMMARY

Amphastar Pharmaceuticals, Inc.

Corporate Information

The Offering

Summary Consolidated Financial Information

RISK FACTORS

Risks Related to Our Business

Other Risks Related to Intellectual Property Rights

Risks Related to Our Industry

Risks Related to This Offering

FORWARD-LOOKING STATEMENTS

USE OF PROCEEDS

DIVIDEND POLICY

CAPITALIZATION

DILUTION

SELECTED CONSOLIDATED FINANCIAL DATA

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

BUSINESS

MANAGEMENT

Summary Compensation Table

PRINCIPAL STOCKHOLDERS

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

DESCRIPTION OF CAPITAL STOCK

SHARES ELIGIBLE FOR FUTURE SALE

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

UNDERWRITING

LEGAL MATTERS

EXPERTS

WHERE YOU CAN FIND MORE INFORMATION

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Amphastar Pharmaceuticals, Inc. Consolidated Balance Sheets (In thousands, except share and per share data)

Amphastar Pharmaceuticals, Inc. Consolidated Statements of Operations (In thousands, except share and per share data)

Consolidated Statements of Stockholders' Equity

Amphastar Pharmaceuticals, Inc. Consolidated Statements of Cash Flows (In thousands)

Amphastar Pharmaceuticals, Inc. Notes to Consolidated Financial Statements Years Ended December 31, 2002, 2003 and 2004 (In thousands, except share and per share data)

ARMSTRONG PHARMACEUTICALS, INC. Balance Sheets October 8, 2003 and December 31, 2002

ARMSTRONG PHARMACEUTICALS, INC. Statements of Operations For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002

ARMSTRONG PHARMACEUTICALS, INC. Statements of Changes in Stockholder's Equity (Deficit) For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002

ARMSTRONG PHARMACEUTICALS, INC. Statements of Cash Flows For the Period January 1, 2003 to October 8, 2003 and the Year Ended December 31, 2002

ARMSTRONG PHARMACEUTICALS, INC. Notes to Financial Statements For the Period January 1, 2003 to October 8, 2003 and the Year

Ended December 31, 2002

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

AMPHASTAR PHARMACEUTICALS, INC. SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS (in thousands)

SIGNATURES

EXHIBIT INDEX