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

AMENDMENT NO. 1  
TO  
**FORM S-1**

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**MonoSol Rx, 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)

**20-8623253**  
(I.R.S. Employer  
Identification Number)

**30 Technology Drive  
Warren, New Jersey 07059  
(732) 564-5000**

(Address, including zip code, and telephone number, including area code,  
of registrant's principal executive offices)

**A. Mark Schobel  
MonoSol Rx, Inc.  
30 Technology Drive  
Warren, New Jersey 07059  
Telephone: (732) 564-5000**

(Name, address, including zip code, and telephone  
number, including area code, of agent for service)

**With copies to:**

**Harva R. Dockery  
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New York, New York 10019-6099  
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**Approximate date of commencement of proposed sale of securities to the public:** As soon as practicable after the effective date of this registration statement.

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, 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, please 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 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 statement number of the earlier effective registration statement for the same offering.

**Calculation of Registration Fee**

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Title of each class of securities to be Registered	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee
Common Stock, par value \$.01 per share	\$86,250,000	\$2,647.87

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- (1) In accordance with Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act"), the number of shares being registered and the proposed maximum offering price per share are not included in this table.
- (2) Estimated solely for purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

**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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities 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.

**PROSPECTUS (Subject to Completion)**

**Dated June 26, 2007**

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## Shares



## Common Stock

This is the initial public offering of shares of our common stock. We are offering \_\_\_\_\_ shares of our common stock. Prior to this offering, there has been no public market for our common stock. We will apply for quotation of our common stock on The Nasdaq Global Market, Inc. under the symbol "MSRX." We expect that the public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

**Our business and an investment in our common stock involve significant risks. These risks are described under the caption "Risk Factors" beginning on page 9 of this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

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	<u>Per Share</u>	<u>Total</u>
<b>Public offering price</b>	\$ _____	\$ _____
<b>Underwriting discount</b>	\$ _____	\$ _____
<b>Proceeds, before expenses, to MonoSol Rx</b>	\$ _____	\$ _____

The underwriters may also purchase up to an additional \_\_\_\_\_ shares from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallocments.

The underwriters expect to deliver the shares against payment in New York, New York on \_\_\_\_\_, 2007.

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**Cowen and Company**

**CIBC World Markets**

**Susquehanna Financial Group, LLLP**

, 2007

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**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 different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.**

**Information contained on our website is not part of this prospectus.**

## PROSPECTUS SUMMARY

*This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read the prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under "Risk Factors" beginning on page 9 and the financial statements and notes thereto that appear elsewhere in this prospectus. Unless otherwise indicated, all information in this prospectus assumes the underwriters do not exercise their option to purchase up to \_\_\_\_\_ shares of our common stock to cover overallotments.*

### Overview of Our Business

We are a drug delivery company specializing in proprietary dissolving thin film pharmaceutical products. Our thin film, which is similar in size, shape and thickness to a postage stamp, dissolves rapidly and utilizes a novel process and proprietary encapsulation compositions to mask the taste of the drug contained within the film. We believe these qualities render our thin film easy to use and consequently will improve patient compliance, providing a significant benefit to patients and their prescribing physicians and healthcare institutions. Our thin film drug delivery technology has been commercialized in the over-the-counter, or OTC, marketplace and we are currently developing thin film containing prescription drugs. By incorporating approved drugs with soon-to-expire or expired patents into our thin film, we believe we can protect drug revenues important to our existing and future pharmaceutical partners. Furthermore, we are building the infrastructure required to produce our thin film rapidly and at scale.

We believe our thin film drug delivery technology has several material benefits over existing drug delivery forms and should enjoy strong physician, patient and consumer acceptance. Our thin film improves convenience and ease of use through discretion and portability and precludes the need for water or liquids. Our thin film may also improve dosing accuracy relative to liquid formulations thereby ensuring proper dosing for the pediatric, geriatric and mentally ill patients where proper administration is often difficult. In addition, our thin film provides ease of dosing for patients with conditions that make it difficult to swallow other solid dosage forms such as tablets or capsules.

Our proprietary thin film drug delivery technology is supported by a significant portfolio of intellectual property, which we believe differentiates us from our competitors. We believe this technology will enable pharmaceutical companies to better manage the life cycle of their products. By combining our thin film drug delivery technology with existing drugs, we believe our thin film can strategically differentiate existing or soon-to-be genericized drugs from potential generic competitors and can help protect branded prescription products against existing or new generic entries by providing additional patent protection or exclusivity in the marketplace. Additionally, we believe our thin film drug delivery technology can also be used to create new drug products with improved efficacy.

We believe we are the only company completely dedicated to thin film as a drug delivery dosage form and have created a vertically integrated infrastructure to ensure leadership capabilities in the critical activities of drug tastemasking, analytical development, global formulation development, manufacturing and packaging. We have invested significantly in our model of vertical integration to develop an operational infrastructure that we believe will position us to seamlessly commercialize products in concert with our partners' respective sales forces.

### Our Product Development

We plan to develop and market our innovative thin film strip products in the prescription drug and OTC markets by pursuing four distinct revenue-generating strategies: (i) self-funded initiatives, or SFIs; (ii) partnered existing prescription products; (iii) partnered new prescription products; and (iv) partnered OTC pharmaceuticals and other products. We have identified and undertaken a number

of SFIs to develop thin film versions of existing products, which we ultimately intend to bring to market with a partner. We have also been engaged by pharmaceutical partners to develop thin film versions of existing prescription products. In the future, we expect to partner with pharmaceutical companies to deliver new prescription products with improved efficacy. We also expect to continue to develop and commercialize thin film products in the OTC and consumer marketplace.

### **Self-Funded Initiatives**

We are developing thin film versions of a series of existing blockbuster prescription drugs. We believe that these products can be approved by the Food and Drug Administration, or FDA, utilizing a 505(j) or NDA 505(b)(2) regulatory pathway, on the basis of limited clinical data and on a development to approval timeline of 24 to 30 months. To date, we have not filed with the FDA for approval of any products. We plan to advance development of these initiatives until we realize certain product-specific development milestones, at which point we expect to attract partners with whom we will commercialize these thin film products. We will be seeking partners at various stages of development and anticipate partnership opportunities upon attainment of milestones such as successful prototype development and stability, clinical bioequivalence, Chemistry, Manufacturing and Controls completion, post-filing with regulatory authorities or post-approval. We prefer to wait until we have reached more advanced milestones because we believe that the more complete an SFI project becomes, the more favorable the deal structure and terms we can secure from a potential partner. We have a large pool of drugs to choose from for thin film development due to our ability to carry a broad range of prescribed doses, up to 80 mgs of active ingredient, in our thin film compositions. We estimate there to be over 400 drug candidates suitable for development utilizing our thin film drug delivery technology and we intend to carefully evaluate those candidates to determine their suitability for internal development.

We are currently self-funding the development of the following pharmaceutical products:

#### **Self-Funded Initiatives**

<b>Brand Name</b>	<b>Drug</b>	<b>Patent Expiration</b>	<b>Category</b>	<b>U.S. Sales (Billions)*</b>	<b>Status</b>
Ambien®	Zolpidem Tartrate	Expired	Sleep	\$ 2.3	In Pilot Bioavailability/Bioequivalence Clinical Trial
Zofran®	Ondansetron HCl	Expired	Nausea/Vomiting	\$ 1.3	Pre-Clinical Work Complete; Pilot Bioavailability/Bioequivalence Clinical Trials Expected Third Quarter 2007
Aricept®	Donepezil HCl	11/2010	Alzheimer's Disease	\$ 1.1	In Pre-Clinical Development; Pilot Bioavailability/Bioequivalence Clinical Trials Expected First Half 2008
Lexapro®	Escitalopram Oxalate	3/2012	Anti-Depressant	\$ 2.0	In Pre-Clinical Development; Pilot Bioavailability/Bioequivalence Clinical Trials Expected First Half 2008

\* The numbers presented represent the U.S. sales of the existing prescription drugs listed in the table for fiscal year 2006 and are only intended to represent the current size of the market for these prescription drugs for that year. Additionally, these numbers are not meant to be representative of our future thin film product revenues as we, as a potential thin film drug delivery partner, may only receive a portion of the available revenue at any point in time. The drug targets that we have identified may change in revenue opportunity over time and could decline or increase based upon competing products and relative thin film acceptance within the market.

### Our Partnered Products

We are currently engaged with pharmaceutical partners to develop thin film versions of their existing prescription products. The following is a chart summarizing our disclosed partnered prescription products:

#### Disclosed Partnered Prescription Products

Product	Category	Partner	Status
Ketorolac	Menstrual Pain	UMD Inc.	Pre-Clinical Work Complete
Multiple Products	Respiratory	Adams Respiratory Therapeutics, Inc.	In Product Development(1)

(1) Our products are in various stages of the product development process including drug sourcing, tastemasking (if appropriate), film composition development and preliminary stability to support clinical investigation and potency requirements.

### Our OTC Pharmaceuticals and Other Products

We are developing and expect to market a number of OTC and other products with our partners. The following is a chart summarizing our partnered OTC and other products:

#### Partnered OTC Pharmaceuticals and Other Products

Product Brand Name	Category	Partner	Status
Dextromethorphan	Cough	Vita Health Products, Inc.	Commercialized(1)
Diphenhydramine HCl	Cough	L. Perrigo Company	Prototypes Complete
Benzocaine <i>Chloraseptic</i> <sup>®</sup>	Sore Throat	Medtech Products Inc.	Commercialized(1)
Benzydamine	Sore Throat	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Prototypes Complete
Undisclosed	Undisclosed	C.B. Fleet Company, Inc.	Prototypes Complete
Pectin and Menthol <i>Breathe Right</i> <sup>®</sup>	Anti-Snore	GlaxoSmithKline plc	Commercialized(1)
Specialty Application <i>Marlboro</i> <sup>®</sup>	Tobacco	Philip Morris USA Inc.	Commercialized(1)
Chlorine Dioxide <i>TheraBreath</i> <sup>®</sup>	Halitosis	Dr. Harold Katz LLC	Commercialized(1)

(1) Commercialized products are being manufactured when ordered by the partner and sold for revenue in accordance with a supply agreement or other arrangement with that partner.

## **Our Business Strategy**

Our strategy is to develop and partner to commercialize innovative thin film strip products in the prescription and OTC pharmaceutical markets. We seek to establish and maintain a leadership position in thin film drug delivery technology through continued development of our technology and our intellectual property portfolio. We believe that pharmaceutical companies will want to partner with us to extend the life cycle of their products, defend against patent expiration, protect against generic encroachment and differentiate their products in competitive categories. To achieve these goals, our strategy includes the following key elements:

- Self-fund the development of thin film versions of existing prescription products with a goal of partnering later;
- Develop thin film versions of existing prescription products with pharmaceutical partners;
- Partner with pharmaceutical companies to deliver new prescription products with improved efficacy;
- Position ourselves to be a partner of choice for thin film drug delivery technology through vertical integration;
- Continue to develop our intellectual property portfolio to position ourselves as the market leader in thin film drug delivery technology; and
- Continue to commercialize products in the OTC marketplace to leverage our existing infrastructure to generate near-term revenue and cash flow.

## **Our Risks**

We are subject to a number of risks which could adversely affect our business, offset or eliminate any advantages of our approach or prevent us from successfully implementing our business strategy.

- Our future growth will depend in large part on our ability to successfully develop, obtain regulatory approval (where required) for, and commercialize our product candidates and those products developed in collaboration with other companies.
- The commercial success of our products will depend primarily on achieving market acceptance among consumers and the medical community.
- We may be unable to develop, obtain regulatory approval where required and commercialize our product candidates as anticipated if the third parties with which we contract for pre-clinical studies, clinical trials, commercialization and marketing do not perform in an acceptable manner, or if we suffer setbacks in these clinical trials.
- Our success is dependent in part on obtaining, maintaining and enforcing patent and other intellectual property rights. We currently have 28 patent applications pending in the United States of which eight are currently undergoing active examination. Six of those applications have received substantive actions from the United States Patent and Trademark Office and appropriate responses have been or will be filed. One of these applications, directed to our proprietary drying process, is on appeal in an attempt to obtain broad coverage. The remaining two applications undergoing active examination have received requirements to split up the claimed inventions into separate patent applications. Our competitors may create or use methods that reduce or eliminate certain competitive advantages we may have based on our intellectual property portfolio. We are subject to substantial risks relating to protection of proprietary information, infringement of rights of others and potential litigation.



- We currently manufacture all of our products at our sole commercial manufacturing facility. Accordingly, we face risks inherent in operating a single manufacturing facility since any disruption could significantly interrupt our manufacturing capability.
- As of December 31, 2006, we had an accumulated deficit of approximately \$24.6 million and total members' equity of \$25.3 million. We expect to incur additional losses and we may never be profitable.

These and other risks of which you should be aware before you decide to buy our common stock are discussed more fully in the section of this prospectus entitled "Risk Factors."

### **Our Corporate Information**

We were incorporated in Delaware in March 2007. Our principal executive offices are located at 30 Technology Drive, Warren, New Jersey, and our telephone number is (732) 564-5000. We maintain a website at [www.MonoSolRx.com](http://www.MonoSolRx.com). We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

Unless the context indicates otherwise, the terms "MonoSol Rx," "we," "our," "us" or "the Company" refer to MonoSol Rx, Inc., a Delaware corporation, and the business of our predecessor company, Monosol Rx LLC, a Delaware limited liability company. Immediately prior to this offering, Monosol Rx LLC will merge with and into MonoSol Rx, Inc., a newly formed Delaware corporation, the shares of which are being sold in this offering. After completion of this offering, the existing equity owners of Monosol Rx LLC, as well as the holders of the performance units of Monosol Rx LLC, will own \_\_\_\_\_ shares of our common stock representing approximately \_\_\_\_\_ % of the voting power of our outstanding capital stock. See "Principal Stockholders" for more information regarding the ownership of our common stock.

## The Offering

Common stock offered	Shares
Common stock to be outstanding after this offering	Shares
Use of proceeds	Proceeds from this offering will be used for product development including <ul style="list-style-type: none"><li>• clinical trials,</li><li>• capital expenditures,</li><li>• working capital, and</li><li>• other general corporate purposes such as acquisitions of related technologies or products.</li></ul>
	For additional information, see "Use of Proceeds."
Risk factors	See "Risk Factors" beginning on page 9 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Market symbol	MSRX

The number of shares of our common stock outstanding after this offering is based on \_\_\_\_\_ shares outstanding as of \_\_\_\_\_ and excludes, as of that date \_\_\_\_\_ shares of our common stock available for future grant under our 2007 Stock Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes:

- the merger of Monosol Rx LLC into MonoSol Rx, Inc., which will occur immediately prior to the completion of this offering;
- an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the range set forth on the cover page of this prospectus;
- the underwriters do not exercise their option to purchase up to \_\_\_\_\_ shares of our common stock to cover overallocments; and
- the conversion of \_\_\_\_\_ performance units outstanding into \_\_\_\_\_ shares of our common stock.

## Summary Financial Data

The table below sets forth summary financial data as of the dates and for the periods indicated. The data for the years ended December 31, 2006, 2005 and 2004 is derived from the audited financial statements of our predecessor Monosol Rx LLC, included elsewhere in this prospectus. The data for the three months ended March 31, 2007 and 2006 is derived from the unaudited financial statements of our predecessor Monosol Rx LLC, included elsewhere in this prospectus. The historical results presented below are not necessarily indicative of the results to be expected in any future periods. This information is only a summary, and you should read this data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with the financial statements, the related notes and other financial information included in this prospectus.

	Year Ended December 31,			Three Months Ended March 31,	
	2006	2005	2004	2007	2006
(in thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Revenues:					
Manufacture and supply revenue	\$ 1,765	\$ 1,458	\$ 1,947	\$ 429	\$ 963
Co-development and research fees	950	665	100	80	190
<b>Total revenues</b>	<b>2,715</b>	<b>2,123</b>	<b>2,047</b>	<b>509</b>	<b>1,153</b>
Cost of goods sold:					
Manufacture and supply	1,623	1,282	1,388	251	644
<b>Gross profit</b>	<b>1,092</b>	<b>841</b>	<b>659</b>	<b>258</b>	<b>509</b>
Operating expenses:					
General and administrative	11,296	7,372	3,168	3,729	1,923
Research and development	1,993	1,258	1,010	685	379
<b>Operating expenses</b>	<b>13,289</b>	<b>8,630</b>	<b>4,178</b>	<b>4,414</b>	<b>2,302</b>
<b>Operating loss</b>	<b>(12,197)</b>	<b>(7,789)</b>	<b>(3,519)</b>	<b>(4,156)</b>	<b>(1,793)</b>
Other income, principally related-party	64	41	—	—	13
Interest income	226	46	—	170	3
Interest expense	(845)	(581)	(41)	—	(188)
<b>Net loss</b>	<b>\$ (12,752)</b>	<b>\$ (8,283)</b>	<b>\$ (3,560)</b>	<b>\$ (3,986)</b>	<b>(1,965)</b>

Net loss applicable to common stockholders

Net loss per share:

Basic

Diluted

Weighted average number of shares outstanding:

Basic

Diluted

	As of December 31, 2006	As of March 31, 2007	
	Actual	Actual	Pro Forma(1) Pro Forma As adjusted(2)
(in thousands)			

### Balance Sheet Data:

Cash and cash equivalents	\$ 15,256	\$ 11,306	\$ 11,306
Working capital	14,830	9,990	9,990
Total assets	27,179	23,801	23,801
Total debt	—	—	
Accumulated deficit	(24,595)	(28,581)	
Members'/stockholders' equity	25,263	21,277	

- (1) On a pro forma basis to give effect to the merger of Monosol Rx LLC into MonoSol Rx, Inc.
- (2) On a pro forma as adjusted basis to give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of all of the shares of common stock in this offering at an initial public offering price of \$ \_\_\_\_\_ per share, after deducting underwriting discounts and commissions and our estimated offering expenses. See "Unaudited Pro Forma Financial Statements."

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the other information set forth in this prospectus and the registration statement before deciding to invest in shares of our common stock. If any of the events or developments described below occur, our business, financial condition or results of operations could be negatively affected. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment in our common stock.*

### **Risks Related to Our Business and Industry**

#### ***We have a history of net losses and may not achieve or maintain profitability.***

We were recently organized and have a limited history of operations and earnings. Since our inception in January 2004, we have experienced significant net losses. We had a net loss of approximately \$3.6 million for the year ended December 31, 2004, \$8.3 million for the year ended December 31, 2005, \$12.8 million for the year ended December 31, 2006 and \$4.0 million for the three months ended March 31, 2007. As of March 31, 2007, we had an accumulated deficit of approximately \$28.6 million and total members' equity of \$21.3 million. On a pro forma basis giving account to the merger of Monosol Rx LLC into MonoSol Rx, Inc. our net loss and our accumulated deficit for the three months ended March 31, 2007 would have been \$ million and \$ million, respectively, and \$ million and \$ million, respectively, for the year ended December 31, 2006. Our losses have resulted principally from expenses incurred in developing and administering our business and infrastructure, and costs associated with research and development of our technologies. Our losses may increase in the future as we expand our manufacturing capabilities, incur additional costs related to our research and development activities, and seek additional regulatory approvals. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and owners' equity. We have historically experienced considerable quarter-to-quarter variation in our results of operations and may not generate sufficient revenues from product sales to achieve or maintain profitable operations in the future. If we are unable to reduce our annual losses and achieve profitability, the value of our common stock will decline.

#### ***We may not be able to successfully develop and commercialize our product candidates.***

Our future growth will depend in large part on our ability to successfully develop, obtain regulatory approval for, and commercialize our product candidates and those products developed in collaboration with other companies. In many instances, we will have to conduct significant additional pre-clinical and/or clinical studies with respect to these product candidates, and may need to obtain regulatory approval before we can commercialize them. Unexpected results or delays in our clinical trials may result in increased development costs. In addition, if one or more of our clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly impaired.

Product development is a long, expensive and uncertain process and, in some cases, entails both pre-clinical testing, which consists of laboratory testing using biological, chemical and animal models, and human clinical testing.

We may suffer significant setbacks any time during the drug development process, even in advanced clinical trials, after obtaining promising results in earlier studies. At any point during clinical trials, undesirable side effects could be detected or the products may not exhibit the anticipated efficacy profile. These side effects and/or efficacy profiles could interrupt, delay or halt clinical trials of the product candidate being tested as well as related product candidates, and could result in the Food and

Drug Administration, or FDA, or other regulatory authorities denying approval of such product candidates for any or all targeted indications.

We may be required to conduct clinical studies in pediatric patient populations as a requirement for approval or as a post-market condition of approval. Pediatric studies can be difficult to conduct and can be quite costly and may not yield the anticipated results. According to the Code of Federal Regulations, pediatric trials with greater than minimal risk must confine research to children who have a condition or disorder, and the trial cannot pose any additional risks than would be normally encountered in the child's clinical care. For pediatric studies involving healthy subjects, the studies are generally more difficult to recruit because there are usually no direct benefits associated with this type of study. Serial blood samplings, blood drawing access, and trial design add to the cost of pediatric trials. Blood drawing volumes can also be a concern in clinical trials utilizing children less than two years of age thereby adding complexity and cost. In addition, many sites are largely ill equipped to entertain pediatric subjects for eight to 12 hours in the interest of adherence to a pharmacokinetic blood sampling schedule, this in turn limits site availability therein driving cost. The FDA's requests for more and longer trials are the main factors in boosting research expenditures year on year apart from the difficulties associated with recruiting child volunteers.

Based on results at any stage of product development, we may decide to repeat or redesign pre-clinical studies or clinical trials, conduct entirely new studies or discontinue development of one or more of our product candidates. In addition, our product candidates may not demonstrate sufficient safety and efficacy in pending or any future pre-clinical testing or clinical trials to meet regulatory standards or obtain the requisite regulatory approvals, and even if such approvals are obtained for a product candidate, it may never become a viable commercial product.

***If our products do not achieve market acceptance we will be unable to generate significant revenues from them.***

The commercial success of our products will depend primarily on achieving market acceptance among consumers and the medical community. To accomplish this, we, together with our collaborators, will have to convince physicians, patients, third party payors and other healthcare professionals that our products consistently offer benefits that are comparable to or superior to existing products and have acceptable safety profiles and costs. If we are not successful in these efforts, market acceptance of our products could be limited, if at all. Additionally, we do not have long-term safety data for many of our products. If long-term patient studies suggest that the use of our products or similar products produced by others are associated with adverse side effects, our products may not achieve market acceptance. Even if we demonstrate the safety and effectiveness of our products, the medical community and consumers may prefer already accepted products based upon established delivery technologies or competing new technologies. Additional factors that may influence market acceptance of our products include:

- convenience and ease of use;
- availability of alternative and competing products or therapies;
- effectiveness of our or our collaborators' marketing, distribution and pricing strategies; and
- publicity concerning our products as well as our competitors' products.

If, due to any of these factors, our products do not achieve broad market acceptance, we will be unable to generate significant revenues from them, which would have a material adverse effect on our business, cash flows and results of operations.

***If the third parties with which we contract for pre-clinical studies, clinical trials, commercialization, and marketing do not perform in an acceptable manner, or if we suffer setbacks in these clinical trials, we may be unable to develop, obtain regulatory approval where required and commercialize our product candidates as anticipated.***

We will, from time to time, after a quality review and assessment of their capabilities, engage and rely on third parties, contract research organizations and outside consultants to assist us in managing and monitoring our pre-clinical studies, clinical trials, obtaining regulatory approval, commercialization efforts, and marketing strategies.

These third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical, laboratory and manufacturing guidelines. We may also develop conflicting priorities or other conflicts of interest with our strategic partners. Our reliance on these third parties may result in increased costs and delays in completing, or in failing to complete, the testing, obtaining regulatory approval when required, and commercialization of our products. If clinical testing of our product candidates is compromised for any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business.

***If the suppliers on which we rely fail to supply us with the raw materials and other components we use in manufacturing our products, we may be unable to satisfy product demand.***

We depend on third parties for the supply of certain ingredients we use to produce our products. While many of these ingredients are available from multiple suppliers, some may be available from only one supplier or a limited number of suppliers. For example, we currently have an agreement with Tate & Lyle Sucralose, Inc. where we agreed to buy a particular raw material exclusively from it as long as they supply that raw material at the quantity forecasted. If Tate & Lyle does not meet its obligations we are free to purchase that raw material from other sources.

Our reliance on these suppliers exposes us to significant risks. These third parties may:

- be unable or unwilling to provide us with sufficient materials to meet our demands;
- fail to meet our standards of quality or other specifications;
- fail to meet current good manufacturing practices, or cGMP;
- increase significantly the prices they charge us for materials; or
- not carry out their contractual duties or meet anticipated deadlines, which could result in delays in obtaining or maintaining regulatory approvals or in satisfying customer orders.

If our suppliers are unwilling or unable to supply us with materials meeting our specifications, we may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with suppliers in a timely manner or at all. Even if we are able to locate, qualify and enter into an agreement with new suppliers, it could take several months or longer to obtain regulatory clearance before a new supplier could begin supplying the relevant product to us. If we are delayed in establishing a secondary supply source for any raw material or component that we purchase from a single source, or cannot do so at an acceptable cost, we may suffer a shortage of commercial supply of that product or a higher cost of procuring the product, either of which would have a material adverse effect on our revenues, business and financial prospects.

***A disruption at our sole manufacturing site would significantly interrupt our production capabilities, which could have drastic consequences to us, including threatening our financial viability.***

We currently manufacture all of our products at our sole commercial manufacturing facility, which is located in Portage, Indiana. Accordingly, we face risks inherent in operating a single manufacturing facility since any disruption, such as a fire, natural disaster, terrorist attack or military action, could significantly interrupt our manufacturing capability. If an inspection by the FDA or other regulatory body identifies significant regulatory issues with respect to our compliance with cGMP, this also could have a material adverse impact on our ability to manufacture products for commercial distribution. Should this occur, we may not be able to timely respond to such inspectional observations and the time it would take the FDA or other regulatory body to re-inspect our facility. This could adversely affect the time to approval and our ability to produce products for the commercial market. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months or years of production delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy customer orders on a timely basis, if at all. In addition, a disruption at our sole manufacturing site may impair or delay our ability to meet product demands from our customers. Also, operating any new facilities may be more expensive than operating our current facility. Furthermore, our business interruption insurance may not adequately compensate us for losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event at our manufacturing facility could have drastic consequences on us, including threatening our financial viability.

***If we are unable to expand our manufacturing capacity as planned, we may be unable to satisfy demand for our products.***

We need to expand our manufacturing capacity to meet anticipated demand for our products. In October 2006, we entered into an agreement to lease a 73,000 square foot facility in Portage, Indiana, the Ameriplex facility. We took possession of this facility in April 2007. The Ameriplex facility will become our primary research, development and manufacturing facility once it is retrofitted and occupied. We anticipate relocating our production and packaging equipment to the Ameriplex facility while we continue to make products for our existing customer base using such equipment. This relocation, if prolonged, could cause interruptions in our ability to make products, and our business could be adversely affected as a result. We may not be able to obtain the requisite regulatory approvals for the Ameriplex facility on a timely basis, or at all, and while we believe that the Ameriplex facility will be completed in phases through 2007 and the first half of 2008, we may not be able to complete the expansion of this facility within our anticipated time frame or budget. Even if we complete the construction in a timely manner, we may not be able to obtain the requisite regulatory approvals for the facility on a timely basis, or at all. If we cannot obtain necessary approvals for these contemplated expansions, or complete the planned construction in a timely manner, our ability to meet demand for our products would be adversely affected.

***We may not achieve our projected development goals in the time frames we announce and expect.***

We set goals for and make public statements regarding expected timing for the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. Our product development may not be completed, we may not make regulatory submissions or receive regulatory

approvals as planned, and we may not be able to adhere to our current schedule for the launch of any of our products. If we fail to achieve one or more of these milestones as planned, the market price of our common stock could decline.

***We may not be able to obtain additional capital that may be necessary for growth and market penetration or to continue our operations.***

The core of our strategy involves the development of our thin film drug delivery technology to targeted prescription pharmaceuticals. This area of product development is a multi-year process that requires formulation, stability, validation and analytical testing, clinical studies and necessary regulatory approvals prior to realizing any product revenue. We may need to raise additional funds through public or private debt or equity financings in order to develop or acquire new products or new product candidates, expand our manufacturing capacity, establish and expand our sales and marketing capabilities, obtain FDA approval for our product candidates and continue our commercial growth. Any additional equity financings may be on terms that are dilutive to our stockholders. Any debt financings we enter into may involve incurring significant interest expense and include covenants that restrict our operations. If we raise additional funds through collaborations or licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds will depend on financial, economic, and market conditions and other factors, many of which are beyond our control. We may not be able to obtain financing on terms acceptable to us or at all. If financing is insufficient or unavailable, we will have to modify our growth and marketing strategies and scale back operations by delaying, reducing the scope of, or eliminating one or more of our planned developments, commercialization, or expansion activities. This may negatively affect the commercial expansion of our existing products and our ability to bring new over-the-counter, or OTC, and prescription pharmaceutical products to market, which could have a material adverse effect on our business, financial condition and results of operations.

Our future need for additional funds may be significantly greater than we expect, and will depend on many factors, including:

- costs associated with conducting pre-clinical testing and clinical testing;
- costs associated with commercializing products we may develop;
- costs, timing and outcome of regulatory reviews;
- costs of obtaining, maintaining and defending patents on proprietary technology;
- costs of increased general and administrative activities; and
- costs associated with retrofitting our Ameriplex facility.

We anticipate the proceeds from this offering together with our existing cash balance will provide us with sufficient capital for approximately 24 months. During that time, any need we may have for additional capital will be in response to an unexpected opportunity to acquire technology, products or businesses that at this point are unknown to us or unexpected delays in the development of our product candidates.

***If our partners terminate their relationships with us it could result in decreased revenues and material harm to our business.***

Our contracts for the development of thin film drug candidates generally allow our customers to terminate development or elect to not commercialize a candidate that is developed for thin film. Our



partners could terminate development or not commercialize due to technical difficulties, issues with commercial acceptance, costs, regulatory barriers and other concerns. Such outcomes could have a material adverse effect on our business, financial condition and results of operations.

In April 2006, we had a partner who terminated its project with us under a proof of principle agreement entered into in August 2005. At the time of termination, all contracted deliverables from us had been met in a satisfactory manner. The partner cited market forces and a need to redirect resources as its reasons for terminating the project. The termination of our project with the partner did not represent or cause any material harm to our operations or financial condition.

Additionally, our relationship with some of our partners is on a purchase order basis and it is possible for these partners to discontinue placing product orders with us and thus terminate the relationship. This may impact our results of operations and future revenues.

***We may encounter difficulties managing our growth, which could adversely affect our results of operations.***

In connection with the growth of our business, we may experience rapid and significant growth in the number of our employees and the scope of our operations. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. This growth and expansion is expected to place a significant demand on our financial, managerial and operational resources, and will require rapid analysis of new technologies, new markets, and new business relationships with a variety of industry players. Rapid growth, or mismanagement of such growth, could cause our operating costs to rise at a faster pace than is currently anticipated and could have a material adverse effect on our business, financial condition and results of operations.

***Disputes may arise involving the contractual obligations of our partners to purchase our products or pay royalties on the sale of our products, and such disputes, if not resolved in our favor, could result in decreased revenues and material harm to our business.***

Disputes may arise between us and our partners and may involve the issue of the obligation to continue to purchase our products and pay royalties on the sale of our products. Such a dispute could result in expensive arbitration or litigation, which may not be resolved in our favor, or the termination of our relationship with the partner.

***If our competitors develop and market products faster than we do or if those products are less expensive or more effective than our products, our commercial opportunities will be reduced or eliminated.***

The drug delivery, biotechnology, and pharmaceutical industries are characterized by intense competition and rapidly evolving technology. Our competitors have longer operating histories than we do, greater name recognition, and significantly greater resources and expertise in product development, regulatory matters, finance, marketing and sales. These organizations also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring and licensing technologies. As a result, these competitors may be able to adapt more quickly to new or emerging technologies and changes in customer requirements. Competitors may use their extensive resources to develop products that are more effective, safer, more convenient or less costly than any that we are developing.

While there are several competitors in the thin film drug delivery market, we believe our two primary competitors are Adhesives Research and Lohmann Therapie Systems. Since both Adhesives Research and Lohmann Therapie Systems are privately owned companies, information is not readily

available regarding the status of their operations, the stage of development of their products, the identity of their partners or their historical or current revenues.

***If we lose the services of our key management, scientific personnel or scientific collaborators, our business would suffer.***

The success of our business is highly dependent on our management as well as our senior manufacturing and scientific personnel. In addition, we require additional skilled personnel in areas such as business and clinical development. Generally, we do not maintain key-person life insurance on any of our officers, employees or consultants. However, we do expect to maintain key-person insurance on A. Mark Schobel, our Chief Executive Officer. While we do have employment agreements and other retention inducements with certain key employees and consultants, those agreements do not prevent employees from leaving us to pursue other non-competing interests. The pool of individuals with relevant experience in the thin film drug delivery technology industry is very limited, and retaining and training personnel with the skills necessary to operate our business effectively is challenging, costly and time consuming. If we lose the services of any key personnel, our business, financial condition and results of operations could be materially and adversely affected.

The principal members of management include the following individuals: A. Mark Schobel, our Chief Executive Officer; Keith Kendall, our Chief Financial Officer; Joseph Fuisz, our Senior Vice President, Business Development; Larry Kranking, our Senior Vice President, Manufacturing and Operations; and Dr. Pradeep Sanghvi, our Vice President, Pharmaceutical Development. Additionally, key members of our scientific staff include Garry Meyers, our Senior Director of Pharmaceutical Development, and Dr. Richard Fuisz, a Consultant.

With the exception of Larry Kranking and Garry Meyers, all of the individuals named have employment or consulting agreements with us that extend at least through 2008. A further discussion of the terms and conditions of the employment agreements of certain key executives can be found in the Compensation Discussion and Analysis section of this prospectus. A further discussion of the terms and conditions of the consulting agreement with Dr. Fuisz can be found in the Certain Relationships and Related Party Transactions section of this prospectus.

***If product liability lawsuits are brought against us as a result of, for example, product recalls, or serious, unexpected adverse events, we may incur substantial liabilities and could be required to limit the commercialization of our products.***

We are exposed to the risk of product liability claims inherent in businesses that test, manufacture, market and sell pharmaceutical products. We may be subject to claims against us even if the injury is due to the actions of others. We currently have several insurance policies to help protect against product liability claims. One policy covers product recall costs and liability dangers. This policy provides coverage of \$2.5 million for each covered incident. Additionally, we have up to \$50 million of product liability coverage.

If we are involved in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and may result in adverse publicity regardless of the ultimate outcome of the litigation, decreased demand for our product candidates, withdrawal of clinical trial participants, significant litigation costs and substantial monetary awards to, or costs of settlement with, patients, product recalls and loss of revenues, and the inability to commercialize our product candidates. Although we believe we have appropriate insurance coverage, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost or at all. In any event, liability insurance is subject to deductibles and coverage limitations and may not provide

adequate coverage against potential claims or losses. A successful product liability claim brought against us could cause us to incur substantial liabilities.

***If we or others identify serious adverse events after any of our products are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.***

If we or others identify serious, adverse events after any of our products are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our products;
- we may have to recall the affected products from the market and may not be able to reintroduce them onto the market;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing or marketing these products.

***Our operations involve hazardous materials that may cause injury for which we could be liable for damages.***

Our manufacturing and research and development activities sometimes involve the controlled use and disposal of potentially hazardous materials or controlled substances and chemicals. As such, we are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes, and the cleanup of contaminated sites. The cost of compliance with these laws and regulations could be significant and accidental contamination or injury may occur. Although we believe that our safety and control procedures for handling, storing and disposing of such materials comply with the standards prescribed by applicable regulations, we cannot completely eliminate the risk of contamination or injury from use or mishandling of these materials. We also occasionally contract with third parties for the disposal of some of these materials. In addition, our collaborators and service providers may be working with these types of materials in connection with our collaborations. In the event of an accident or contamination, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these materials and could be held liable for significant damages, civil penalties or fines, which may not be covered by or may exceed our insurance coverage.

Additionally, we are subject on an ongoing basis to a variety of laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of continued compliance with current or new laws and regulations may be significant and could negatively affect our profitability, and current or future environmental regulation may impair our ongoing research, development or manufacturing efforts.

#### **Risks Related to Our Intellectual Property**

***The validity, enforceability and commercial value of our intellectual property rights are highly uncertain.***

Our success is dependent in part on obtaining, maintaining and enforcing patent and other intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that compete with our products. We currently

have 28 patent applications pending in the U.S. of which eight are currently undergoing active examination. Six of these applications have received substantive actions from the United States Patent and Trademark Office, or USPTO, meaning we have received communications from the patent examiner relating to the substance of the claims as they are currently written and that appropriate responses have been or will be filed. In all cases, the examiner has initially rejected the claims of our applications as they are currently worded on the basis of prior art. One of these applications, directed to our proprietary drying process, is on appeal to the USPTO Board of Appeals and Interferences, or Board of Appeals, an administrative appeal body within the USPTO, requesting that the Board of Appeals reverse the examiner and grant the patent claims as they are currently worded in an attempt to obtain broad coverage. Broad claims, as opposed to narrower claims, mean that a wider range of competitive activities and processes may be prevented from impacting our business. Should the claims issue with such broad scope, they will limit the available ways in which others may achieve uniformity of drug content in oral dosage forms, or ODFs. Uniformity of content is a critical factor in obtaining FDA approval for ODFs. If the decision on appeal is favorable, then we will obtain the broad patent protection to which we believe we are entitled. We believe such a patent would represent a significant advantage in the field of ODFs. In the event the appeal is unfavorably or partially unfavorably decided, we have the opportunity to appeal further to the courts, or may elect to continue the case further at the USPTO by filing a continuation case, with claims more limited in scope. We have already filed continuation cases on the proprietary drying process with claims having a more narrow scope and with emphasis on new aspects of the process not previously claimed. These applications are being prosecuted before the USPTO contemporaneously with, but independent from the case on appeal. The remaining two of the applications undergoing active examination in the U.S. have received requirements to split up the claimed inventions into separate patent applications.

Because of the many complex legal and technical issues involved, the patent position of pharmaceutical firms is highly uncertain. The process for obtaining a patent in the U.S. involves a number of varying factors, including the subjectivity inherent in the normal examination process. Such factors may make it difficult to obtain the issuance of a patent or a patent with scope that is competitively meaningful. Patent applications we file or license from others may not result in the issuance of a patent. Moreover, although issued patents in the U.S. enjoy the presumption of validity, this may be challenged and potentially overturned as the result of litigation. Patents, if issued, may be challenged and invalidated altogether, substantially narrowed as to scope or determined to be unenforceable. Consequently, it is not entirely certain how much protection, if any, patents will provide to us if we attempt to enforce them.

The recent U.S. Supreme Court decision in *KSR International v. Teleflex Inc.*, or the KSR decision, may have far reaching effects on the patent system in general. One of the established tenets of U.S. patent law is that the patent examiner cannot rightfully reject a patent claim as being obvious, and therefore unpatentable, on the basis of a combination of prior art references, unless there was some teaching, suggestion or motivation, or TSM, to suggest that the invention would be apparent to one of ordinary skill in the art. In the KSR decision, the court stated that the TSM need not be explicitly recited in the prior art, but could be derived from a common sense reason to combine prior art references in making a rejection based on obviousness. In essence, combinations of old elements to produce a predictable result may be considered obvious. The court, in the KSR decision, thus adopted a more flexible approach to finding the presence of TSM from the prior art.

Although the KSR decision did not do away with the requirement for the examiner to show TSM in order to combine references in rejecting claims, many in the patent profession believe that this decision may make it easier for the examiner to find that TSM is present, thereby making it more difficult to obtain a patent. Additionally, as a result of the KSR decision, some patent practitioners also believe that many patents which are combination patents, meaning a combination of old elements, may be easier to attack on the basis of obviousness.

In response to the KSR decision, the USPTO has circulated an internal memo instructing examiners to be explicit with their reasoning for combining references in rejecting claims. The memo also reiterates that the requirement for demonstrating proper TSM still stands and the examiners must demonstrate that there is proper teaching, suggestion or motivations to combine references.

Patent rights are territorial. Thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and various European countries. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Additionally, the nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

Our patents, if issued, may not contain claims that are sufficiently broad to prevent others from practicing our technologies or developing competing products. Our competitors may create or use methods that reduce or eliminate any competitive advantage we may have based on our thin film development intellectual property portfolio. Additionally, technologies may exist that perform substantially the same as our technologies and avoid infringing our patent claims. Under such circumstances, our patents would be of little commercial value to us.

We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Thus, any patents that we own or license from third parties may not provide commercially meaningful protection from competition.

***If we are unable to protect the confidentiality of our trade secrets or know how, such proprietary information may be used by others to compete against us.***

We have concluded that certain competitively sensitive information is either not patentable or, for competitive reasons, it is not commercially advantageous to seek patent protection. In these circumstances, we seek to protect this know how and other proprietary information by maintaining it in confidence as a trade secret. Trade secret information is closely guarded and areas involving trade secrets have restricted access. To further maintain the confidentiality of our trade secrets, we generally enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also provide that inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with the terms of these agreements. The disclosure of our trade secrets would impair our competitive position. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. Further, to the extent that our employees, consultants or contractors use trade secret technology or know how owned by others in their work for us, disputes may arise as to the ownership of related inventions.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our products or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we know that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

If a third party claims that we infringe its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; or
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

In addition, employees, consultants, contractors and others may use the trade secret information of others in their work for us or disclose our trade secret information to others. Either of these events could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties. If any of these events occurs, our business will suffer and the market price of our common stock will likely decline.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.***

There has been substantial litigation and other proceedings regarding patent and intellectual property rights in the pharmaceutical industry. We may be forced to defend claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of intellectual property litigation is subject to substantial uncertainties and may, for example, turn on the interpretation of claim language by the court, which may not be to our advantage, or on the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. We, on the other hand, are a relatively small company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

Furthermore, the validity and scope of our patents may also be challenged by third parties in re-examination proceedings at the U.S. Patent and Trademark Office, which may either strengthen a patent, or result in a reduced claim scope or a loss of all rights to a patent.

In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings

with the U.S. Patent and Trademark Office or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly. At present, we have not received any threats of infringement or written demands from third parties that we take a license under their patents.

### **Risks Related to Government Regulation**

***Our products are subject to regulation by many federal, state, and local agencies, and our customers may require that we obtain certain regulatory approvals before purchasing our products.***

Many of our products are still under development, and we or our collaborating partners may not be able to commercialize these products until we comply with the requirements of federal, state and local regulatory authorities including the FDA, the Federal Trade Commission, or FTC, the Consumer Product Safety Commission, the U.S. Environmental Protection Agency, and various state and local agencies. In particular, the process of obtaining FDA approval for new drug products (including new dosage forms of previously approved drug products) can be costly and time-consuming, and the time required for obtaining such approval is uncertain. In addition, while the FDA has not made any definitive rulings on the regulatory status of film-based drug delivery systems, the FDA and state and local agencies could impose significant regulatory requirements on our products. Additionally, our customers may require that we obtain such approvals prior to licensing or purchasing our products. If the FDA or our customers require that we obtain regulatory approval of our products, we or our collaboration partners must demonstrate to the satisfaction of the applicable regulatory agency that such product candidate is safe and effective for its intended uses. In addition, we must show that the product can be consistently manufactured in compliance with cGMP. In general, these requirements mandate that manufacturers follow detailed design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. Despite the time, expense, and resources invested by us in the approval process, we may not be able to demonstrate that our product candidates are safe and effective. Therefore, we may not receive the regulatory approvals required to market them. Our current or future product candidates may not be approved by the FDA or any other governmental body, and FDA or other governmental reviews could be delayed by requests for further testing or other information that could adversely affect the time to market for our products. We currently have no prescription products filed with any regulatory authorities.

Moreover, we cannot predict the impact of new government regulations that may adversely affect the discovery, development and production of our product candidates and the manufacturing and marketing of our products. We may be required to incur significant costs to comply with future laws or regulations.

***Our product candidates will remain subject to ongoing regulatory requirements if they receive regulatory approval for marketing, and if we fail to comply with these requirements, we could lose these approvals, and the sales of any approved commercial products could be suspended.***

After receipt of initial regulatory approval, each of our products remains subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record-keeping. Furthermore, if we receive regulatory approval to market a particular product candidate, the product will also remain subject to the same extensive regulatory requirements. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or other conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could reduce our revenues, increase our expenses or render the approved product candidate not commercially viable.

If we or our partners fail to comply with the regulatory requirements of the FDA or other applicable regulatory authorities, or if previously unknown problems with any approved commercial products, manufacturers or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters and untitled letters;
- civil penalties and criminal prosecutions and penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or of supplements to approved applications.

***If we and our third-party suppliers do not maintain high standards of manufacturing in accordance with cGMP and other manufacturing regulations, our development and commercialization activities could suffer significant interruptions or delays.***

We and any third-party suppliers on which we may in the future rely will be required to comply with cGMP. In complying with these regulations, we and our third-party suppliers may be required to expend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that our products meet applicable specifications and other regulatory requirements. Failure to comply with these or other regulatory requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. Any of these third-party suppliers and we also may be subject to periodic inspections by the FDA and other regulatory agencies. If any of our third-party suppliers or we fail to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our products could suffer significant interruptions.



***We must comply with the laws, regulations and rules of many jurisdictions relating to the healthcare business, and if we are unable to fully comply with such laws, regulations and other rules, we could face substantial penalties.***

We are or will be, directly or indirectly through our customers, subject to extensive regulation by the various jurisdictions in which we may conduct our business. The laws that directly or indirectly affect our ability to operate our business include the following:

- the anti-kickback laws that prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid in the United States;
- other healthcare laws, including Medicare laws in the United States, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- laws and regulations, including the U.S. False Claims Act, which impose civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- laws and regulations, including the U.S. False Statements Act, which prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state law equivalents and comparable laws in countries outside of the United States, including laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of the laws, regulations, rules or policies described above or any other law or governmental regulation to which we or our customers are or will be subject, or if the interpretation of such laws, regulations, rules or policies change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found noncompliant with applicable laws, they may be subject to sanctions, which could negatively impact us. Any penalties, damages, fines, curtailment or restructuring of our operations would harm our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many such laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions may be open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management resources from the operation of our business and damage our reputation.

#### **Risks Related to this Offering and Our Common Stock**

***There is no established trading market for our common stock, and the price of our common stock may be highly volatile or may decline regardless of our operating performance.***

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which a trading market for our common stock will develop or be sustained after this offering. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters, based on factors that may not be indicative of future performance, and may not bear any relationship to the price at which our common stock will trade upon completion

of this offering. You may be unable to sell your shares of common stock at or above the initial public offering price.

The initial public offering price was determined based on several factors which are summarized in the "Underwriting" section of this prospectus. This price may vary from the market price of our common stock after this offering. You may be unable to sell your shares of common stock at or above the initial offering price. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, or, collectively, biopharmaceutical stocks. The volatility of biopharmaceutical stocks often does not relate to the operating performance of the companies represented by the shares.

The trading price of our common stock could be highly volatile in response to various factors, many of which are beyond our control, including:

- changes in the regulatory climate in the biopharmaceutical industry;
- developments concerning our products or any of our product candidates;
- the timing and results from our clinical trial programs or those of our competitors;
- failure of any of our product candidates, if approved, to achieve commercial success;
- new products introduced or announced by us or our competitors;
- announcements of technological innovations by us or our competitors;
- third-party reimbursement policies;
- developments concerning current or future strategic alliances;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- intellectual property, product liability or other litigation against us;
- market conditions in the biopharmaceutical sector;
- changes in the market valuations of similar companies;
- actual or anticipated variations in our operating results;
- deviations in our operating results from the estimates of securities analysts;
- additions or departures of key personnel; and
- sales of shares of our common stock, particularly sales by our officers, directors and significant stockholders.

In addition, equity markets in general, and the market for small pharmaceutical companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. Changes in economic conditions in the United States or globally could also impact our ability to grow profitably. These broad market and industry factors may materially affect the market price of our common stock, regardless of our business or operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***The ownership interests of our officers, directors and largest stockholders could conflict with the interests of our other stockholders.***

Following the completion of this offering, our directors, executive officers and holders of 5% or more of our outstanding common stock will beneficially own approximately % of our common stock. In particular, MRX Partners, LLC, MonoLine RX, L.P., MonoLine RX II, L.P. and Monosol RX Genpar, L.P., all of which are under common control and managed by Bratton Capital Management L.P., will own %, %, % and %, respectively, for a total of %. Douglas Bratton, the President of Bratton Capital Management L.P., makes decisions on behalf of Bratton Capital Management L.P. and also serves on our board of directors. Additionally, Halifax Monosol Investors, L.P. will own % of our common stock. As a result, our directors, executive officers and holders of 5% or more of our outstanding common stock, acting together, or MRX Partners, LLC, MonoLine RX, L.P., MonoLine RX II, L.P. and Halifax MonoSol Investors, L.P., may be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and approval of mergers or other significant corporate transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders. This concentration of ownership could also have the effect of delaying, deferring or preventing a change in our control or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

***We have broad discretion in the use of the proceeds from this offering and our use of the offering proceeds may not yield a favorable return on your investment.***

We expect to use proceeds from this offering for the development of prescription drug targets on thin film and other self-funded initiatives, including product development, clinical trials and submissions for new drug applications, or NDAs, 505(b)(2) applications, or 505(b)(2), supplemental new drug applications, or sNDAs, and abbreviated new drug applications, or ANDAs, operating expenditures and infrastructure, capital expenditures, and other general corporate purposes. However, our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. We may not invest the proceeds of this offering effectively or in a manner that yields a favorable or any return, and consequently, this could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates.

***We have never paid dividends on our common stock, and we do not anticipate paying dividends in the foreseeable future.***

We have paid no dividends to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any dividends in the foreseeable future. Any future payment of dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. Our common stock may not appreciate in value after the offering or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

***Investors in this offering will pay a much higher price than the book value of our common stock.***

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. The price per share you will pay will also substantially exceed the book value of our assets represented by your shares of common stock after subtracting related liabilities. You will incur immediate and substantial dilution of \$ per share,

representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price of \$ \_\_\_\_\_ per share. Upon completion of this initial public offering, the new public investors will have contributed \_\_\_\_\_ % of the total amount of capital used to fund us to date, and will own \_\_\_\_\_ % of the common stock outstanding after this offering.

***If an active, liquid trading market for our common stock does not develop, you may be unable to sell your shares quickly or at the market price.***

Prior to this offering, you could not buy or sell our common stock publicly. An active trading market for our common stock may not develop or be sustained after this offering. You may not be able to sell your shares quickly or at the market price if trading in our stock is not active.

***Certain provisions of Delaware law and our organizational documents could delay or discourage takeover attempts that stockholders may consider favorable.***

Certain provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware corporate law may make it more difficult for or prevent a third party from acquiring control of us or changing our board of directors and management. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- allow our board of directors to designate the terms of and issue, without stockholder approval, series of preferred stock with voting or other rights or preferences that could operate to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- limit stockholder action by written consent;
- limit who may call meetings of our stockholders; and
- require our stockholders to comply with advance notice procedures to nominate candidates for election to our board of directors or to place stockholders' proposals on the agenda for consideration at meetings of stockholders.

In addition, Section 203 of the Delaware General Corporation Law, or DGCL, generally prohibits us from engaging in any business combination with certain persons who own 15% or more of our outstanding voting stock without the approval of our board of directors. These provisions could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our stockholders. Any delay or prevention of a change in control transaction or changes in our board of directors or management could deter potential acquirers or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then-current market price for their shares.

***Future sales of our common stock may cause the market price of our common stock to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could reduce the market price of our common stock. After this offering, we will have outstanding \_\_\_\_\_ shares of common stock. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. The remaining approximately \_\_\_\_\_ shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold in the near future. Moreover, after the expiration of the lock-up period described in the section of this prospectus entitled "Shares Eligible for Future Sale — Lock-up Agreements"

approximately            shares of our common stock will be eligible for resale. We intend to register all shares of common stock that we may issue under our 2007 Stock Incentive Plan. See "Shares eligible for future sale" contained elsewhere in this prospectus.

***We have never operated as a public company and fulfilling our obligations as a public company will be expensive and time consuming.***

As a private company with limited resources, we have maintained a small finance and accounting staff. As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the U.S. Securities and Exchange Commission, or SEC, as well as the rules of The Nasdaq Global Market, Inc. will require us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations will increase our legal and financial compliance costs and place significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management will be required to conduct an annual evaluation of our internal control over financial reporting and include a report of management on our internal control in our annual reports on Form 10-K. In addition, we will be required to have our independent registered public accounting firm attest to and report on management's assessment of the effectiveness of our internal control over financial reporting. Under current rules, we will be subject to these requirements beginning with our annual report on Form 10-K for our fiscal year ending December 31, 2008. If we are unable to conclude that we have effective internal control over financial reporting or, if our independent registered public accounting firm is unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal control over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We continue to evaluate our internal control over financial reporting. Given the status of our efforts, coupled with the fact that guidance from regulatory authorities in the area of internal control continues to evolve, uncertainty exists regarding our ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior 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 common stock.

## SPECIAL NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the sections entitled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Forward-looking statements provide our current expectations or forecasts of future events. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "will," "should," "could," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward looking.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" and elsewhere in this prospectus. Accordingly, you should not unduly rely on these forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in our forward-looking statements include, but are not limited to:

- our ability to achieve and maintain profitability;
- our ability to successfully develop, market, commercialize and achieve market acceptance for any of the product candidates that we are developing or may develop in the future;
- the performance of third parties, whose actions we cannot control, with which we contract for pre-clinical studies, clinical trials, commercialization and marketing;
- the expected timing, progress or success of our pre-clinical and clinical trials and development programs;
- the timing, costs and other limitations involved in obtaining regulatory approval for any of our product candidates;
- delays in obtaining, or a failure to obtain and maintain, regulatory approval for our product candidates;
- our reliance on suppliers to supply us with the raw materials and other components we use in manufacturing our products;
- a disruption at our sole manufacturing site that could significantly interrupt our production capacities;
- our plans to expand our manufacturing facility;
- our estimate of future performance, including achieving our projected development goals;
- our ability to obtain additional capital needed for growth and market penetration or to continue our operations;
- our ability to enter into agreements with new partners or to maintain any existing partner agreements with respect to our product candidates and products;
- our ability to effectively maintain existing relationships with our collaborators and establish new relationships;

- our ability to manage our growth;
- potential disputes involving contractual obligations of our partners to purchase our products or pay royalties on the sale of our products;
- the potential advantages of our products or product candidates over other existing or potential products;
- our competitors' ability to develop and market products faster than we do, or to develop and market products that are less expensive or more effective than our products;
- potential product liability lawsuits against us;
- the loss of any of our key management, scientific personnel or scientific collaborators;
- potential serious adverse events requiring us to withdraw our products from the market;
- potential liability arising from our operations, including injuries caused by hazardous materials;
- our customers potentially requiring that we obtain certain regulatory approvals before purchasing our products;
- the failure of us and our third party suppliers to maintain high standards of manufacturing in accordance with cGMP and other manufacturing regulations;
- our continued compliance with the laws, regulations and rules of many jurisdictions relating to the healthcare business;
- the validity, enforceability and commercial value of our intellectual property rights;
- our ability to protect our intellectual property and know how and operate our business without infringing the intellectual property rights or regulatory exclusivity of others; and
- potential costly litigation or other proceedings relating to our patent or other intellectual property rights.

Forward-looking statements speak only as of the date on which they are made and, except as required by law, we undertake no obligation to update or publicly revise any forward-looking statement to reflect circumstances or events after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

## USE OF PROCEEDS

We will receive approximately \$ \_\_\_\_\_ million in net proceeds from the sale of our common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses. If the underwriters exercise their overallotment option in full, we estimate that our net proceeds will be approximately \$ \_\_\_\_\_ million.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) the net proceeds to us from this offering by \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds of this offering as follows:

- approximately \$ \_\_\_\_\_ million for the development of thin film versions of existing drugs and other self-funded initiatives, including product development, clinical trials, and any necessary regulatory submissions;
- approximately \$ \_\_\_\_\_ million for capital expenditures, including retrofitting the newly leased Ameriplex facility to create a cGMP manufacturing facility for the development and manufacture of dissolving thin film. In addition, proceeds will be used to acquire equipment to create additional laboratory and manufacturing capacity as demand increases; and
- the remainder, approximately \$ \_\_\_\_\_ million, for working capital and other general corporate purposes, a portion of which may be used to acquire businesses, products or technologies that are complementary to our current or future business and product lines.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, as supplemented by our research and co-development fees, will be sufficient to complete the development and commercialization of the product candidates in process and support all planned capital expenditures related to our Ameriplex facility and new equipment acquisition as well as to meet our projected operating requirements for approximately the next 24 months. The amounts and timing of our use of proceeds will vary depending on a number of factors, including the amount of cash used by our operations, and the rate of growth, if any, of our business. The allocation of the net proceeds of this offering described above represents our best current estimate of our projected operating requirements. Our management will have broad discretion in the application of the net proceeds and we reserve the right to change the use of these proceeds in response to certain contingencies such as the results of our commercialization activities, competitive developments, opportunities to acquire or license products to others, technologies or businesses and other factors.

## DIVIDEND POLICY

We have not declared or paid any dividends to date. We currently intend to retain future earnings, if any, to fund the development and expansion of our business and do not anticipate paying dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on a number of factors, including our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and other factors that our board of directors may deem relevant.



## CAPITALIZATION

The following table sets forth our cash and cash equivalents, and capitalization as of March 31, 2007:

- on an actual basis;
- on a pro forma basis to give effect to the merger of Monosol Rx LLC into MonoSol Rx, Inc.; and
- on a pro forma as adjusted basis to give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of the shares of common stock in this offering at an initial public offering price of \$        per share, after deducting underwriting discounts and commissions and estimated offering expenses.

	As of March 31, 2007		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except per share data)		
Cash and cash equivalents	\$ 11,306	\$ 11,306	\$
Members' equity/stockholders' equity:			
Members' equity — Preferred A membership interests	16,887	—	
Members' equity — Preferred A-1 membership interests	21,883	—	
Members' equity — Common membership interests	11,088	—	
Common stock, par value \$.01 per share, 100,000,000 shares authorized, no shares issued and outstanding, actual;        shares issued and outstanding, pro forma;        shares issued and outstanding, pro forma as adjusted	—		
Preferred stock, par value \$.01 per share, 20,000,000 shares authorized, no shares issued and outstanding	—	—	
Additional paid-in capital	—		
Accumulated deficit	(28,581)		
Total members' equity/stockholders' equity	21,277		
Total capitalization	\$ 21,277	\$	\$

The table above should be read in conjunction with the "Use of Proceeds," "Selected Financial Data," "Unaudited Pro Forma Financial Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus. This table is based on 101,413,600 membership interests in Monosol Rx LLC outstanding as of March 31, 2007 and        shares of our common stock outstanding on a pro forma basis as of March 31, 2007 and excludes, as of that date        shares of our common stock available for future grant under our 2007 Stock Incentive Plan. See "Unaudited Pro Forma Financial Statements."

## DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share you pay in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of March 31, 2007 was approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share of our common stock on a pro forma basis. Net tangible book value per share is equal to our total tangible assets minus total liabilities, divided by the number of shares of common stock outstanding.

After giving effect to the sale of the \_\_\_\_\_ shares of our common stock in this offering and after deducting underwriting discounts and commissions and our estimated offering expenses, our pro forma as adjusted net tangible book value would have been approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of approximately \$ \_\_\_\_\_ per share to existing stockholders and an immediate dilution of approximately \$ \_\_\_\_\_ per share to new investors. The following table illustrates this calculation on a per share basis:

Assumed initial public offering price per share	\$ _____
Pro forma net tangible book value per share of common stock as of March 31, 2007	
Pro forma as adjusted increase per share attributable to the offering	_____
Pro forma as adjusted net tangible book value per share of common stock after this offering	_____
Pro forma as adjusted dilution per share to new investors	\$ _____

If the underwriters exercise their overallotment option in full, the pro forma as adjusted net tangible book value as of March 31, 2007 will increase to approximately \$ \_\_\_\_\_ per share, representing an increase to existing stockholders of approximately \$ \_\_\_\_\_ per share, and there will be an immediate dilution of approximately \$ \_\_\_\_\_ per share to new investors.

The following table summarizes, as of March 31, 2007 on a pro forma as adjusted basis, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Total shares		Total consideration		Average price per share
	Number	%	Amount	%	
Existing stockholders		%	\$ _____	%	\$ _____
New investors		%		%	
Total		%	\$ _____	%	\$ _____

If the underwriters exercise their overallotment option in full, the following will occur:

- the percentage of shares of our common stock held by existing stockholders will decrease to approximately \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares of our common stock held by new public investors will increase to \_\_\_\_\_, or approximately \_\_\_\_\_ of the total number of shares of our common stock outstanding after this offering.

The tables and calculations above are based on \_\_\_\_\_ shares outstanding as of March 31, 2007 on a pro forma basis and exclude \_\_\_\_\_ shares of our common stock available for future grant under our 2007 Stock Incentive Plan.

**SELECTED FINANCIAL DATA**

Prior to this offering, we conducted our business through Monosol Rx LLC. Immediately prior to this offering, Monosol Rx LLC will merge with and into MonoSol Rx, Inc., a newly formed Delaware corporation, the shares of which are being sold in this offering.

The following table sets forth certain historical financial data for Monosol Rx LLC as of the dates and for the periods indicated. We have derived the selected historical statement of operations data for the years ended December 31, 2006, 2005 and 2004, and the balance sheet data as of December 31, 2006 and 2005, from the audited financial statements of Monosol Rx LLC included elsewhere in this prospectus. Prior to the formation of Monosol Rx LLC, our activities were carried out as part of the research and development efforts of Monosol, LLC, a manufacturer of commercial soluble films (the Predecessor). We have derived the historical financial data as of December 31, 2004 and 2003 (Predecessor), and for the year ended December 31, 2003 (Predecessor), from audited financial statements of Monosol Rx LLC that are not included in this prospectus. We have derived the selected historical statement of operations data for the three months ended March 31, 2007 and 2006, and the balance sheet data as of March 31, 2007 and 2006 from the unaudited financial statements of Monosol Rx LLC, included elsewhere in this prospectus. Since neither us nor our Predecessor were operating prior to 2003, no financial data has been presented for fiscal years prior to December 31, 2003. The historical results set forth below do not necessarily indicate results expected for any future period. The selected consolidated historical financial data should be read in conjunction with the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the historical financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,				Three Months Ended March 31,	
	2006	2005	2004	Predecessor 2003	2007	2006
(in thousands, except per share data)						
<b>Statement of Operations Data:</b>						
Revenues:						
Manufacture and supply revenue	\$ 1,765	\$ 1,458	\$ 1,947	\$ 81	\$ 429	\$ 963
Co-development and research fees	950	665	100	—	80	190
<b>Total revenues</b>	<b>2,715</b>	<b>2,123</b>	<b>2,047</b>	<b>81</b>	<b>509</b>	<b>1,153</b>
Cost of goods sold:						
Manufacture and supply	1,623	1,282	1,388	52	251	644
<b>Gross profit</b>	<b>1,092</b>	<b>841</b>	<b>659</b>	<b>29</b>	<b>258</b>	<b>509</b>
Operating expenses:						
General and administrative	11,296	7,372	3,168	454	3,729	1,923
Research and development	1,993	1,258	1,010	794	685	379
<b>Operating expenses</b>	<b>13,289</b>	<b>8,630</b>	<b>4,178</b>	<b>1,248</b>	<b>4,414</b>	<b>2,302</b>
<b>Operating loss</b>	<b>(12,197)</b>	<b>(7,789)</b>	<b>(3,519)</b>	<b>(1,219)</b>	<b>(4,156)</b>	<b>(1,793)</b>
Other income, principally related-party	64	41	—	—	—	13
Interest income	226	46	—	—	170	3
Income expense	(845)	(581)	(41)	—	—	(188)
<b>Net loss</b>	<b>\$ (12,752)</b>	<b>\$ (8,283)</b>	<b>\$ (3,560)</b>	<b>\$ (1,219)</b>	<b>\$ (3,986)</b>	<b>\$ (1,965)</b>
Net loss applicable to common stockholders						
Net loss per share:						
Basic						
Diluted						
Weighted average number of shares outstanding:						
Basic						
Diluted						

As of December 31,

As of March 31,

	As of December 31,				As of March 31,	
	2006	2005	2004	Predecessor 2003	2007	2006
	(in thousands)					
<b>Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 15,256	\$ 1,332	\$ 266	\$ —	\$ 11,306	\$ 4,900
Working capital	14,830	580	127	69	9,990	4,725
Total assets	27,179	12,306	10,114	1,862	23,801	16,184
Total debt	—	6,203	626	—	—	9,513
Accumulated deficit	(24,595)	(11,843)	(3,560)	(1,219)	(28,581)	(13,808)
Members' equity	25,263	4,665	7,744	1,862	21,277	5,501

## UNAUDITED PRO FORMA FINANCIAL STATEMENTS

The following unaudited pro forma financial statements have been derived from the application of certain pro forma adjustments to the historical financial statements of Monosol Rx LLC included elsewhere in this prospectus, and give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of all of the shares of common stock in this offering at an initial public offering price of \$        per share after deducting underwriting discounts and commissions and estimated offering expenses.

The unaudited pro forma financial statements presented below are based on the assumptions and adjustments described in the accompanying notes. The unaudited pro forma adjustments are based on available information and assumptions that management believes are reasonable under the circumstances. Such unaudited pro forma financial statements are presented for illustrative purposes only and are not necessarily indicative of what our financial position or results of operations would have been had this offering or other transactions described in this prospectus been consummated, nor are they necessarily indicative of what our financial position or results of operations will be in future periods. The unaudited pro forma financial statements, and the accompanying notes, should be read in conjunction with "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited and unaudited financial statements and related notes of Monosol Rx LLC, included elsewhere in this prospectus.

The following table sets forth our unaudited pro forma balance sheet as of March 31, 2007:

- on an actual basis;
- on a pro forma basis to give effect to the merger of Monosol Rx LLC into MonoSol Rx, Inc.; and
- on a pro forma as adjusted basis to give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of all of the shares of common stock in this offering at an initial public offering price of \$ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

As of March 31, 2007

	Actual	Corporate Formation Adjustments	Pro Forma	Offering Adjustments	Pro Forma, as Adjusted
	(in thousands)				
<b>Balance Sheet Data:</b>					
<b>Assets:</b>					
Current assets:					
Cash and cash equivalents	\$ 11,306	—	11,306	(4)	
Trade receivables	204	—	204	—	204
Other receivables	3	—	3	—	3
Inventories	865	—	865	—	865
Prepaid expenses and other current assets	136	—	136	—	136
<b>Total current assets</b>	<b>12,514</b>	<b>—</b>	<b>12,514</b>		
Property and equipment, net	9,579	—	9,579	—	9,579
Other assets	103	—	103	—	103
Intangible assets, net	1,605	—	1,605	—	1,605
	<b>\$ 23,801</b>	<b>—</b>	<b>23,801</b>		
<b>Liabilities and Members Equity/Stockholders' Equity:</b>					
Current liabilities:					
Accounts payable	1,815	—	1,815	—	1,815
Asset retirement obligations	90	—	90	—	90
Accrued expenses	619	—	619	—	619
<b>Total current liabilities</b>	<b>2,524</b>	<b>—</b>	<b>2,524</b>	<b>—</b>	<b>2,524</b>
Deferred income taxes	—	(1)			
Members' equity/stockholders' equity:					
Preferred A interests, no par value, 100,000,000 units authorized; 16,886,750 issued and outstanding	16,887	(16,887)(2)	—	—	—
Preferred A-1 interests, no par value, 100,000,000 units authorized; 21,526,850 issued and outstanding	21,883	(21,883)(2)	—	—	—
Common interests, no par value, 500,000,000 units authorized; 63,000,000 issued and outstanding	11,088	(11,088)(2)	—	—	—
Common stock, par value \$.01 per share, 100,000,000 shares authorized, no shares issued and outstanding, actual; shares issued and outstanding, pro-forma; issued and outstanding, pro forma as adjusted	—	(1)(4)	(3)	(4)	
Additional paid-in capital	—	(4)	(2)	(4)	
Accumulated deficit	(28,581)	(3)			
<b>Total Members' equity</b>	<b>21,277</b>				
	<b>\$ 23,801</b>				

(1) Represents the estimated deferred tax liability (long-term) to be recorded on the opening balance sheet of MonoSol Rx, Inc. in connection with the merger of Monosol Rx LLC into MonoSol Rx, Inc.

(2) Reflects the exchange of Monosol Rx LLC membership interests (common and preferred) for shares of MonoSol Rx, Inc. common stock.

(3) Reflects \$ million of amounts (compensation expense) due under the Monosol Rx LLC Performance Unit Plan, offset by the exchange of these amounts for the common stock of MonoSol Rx, Inc.

(4) Represents an increase from the receipt of the estimated net proceeds of this offering of \$ million.

The following table sets forth our unaudited pro forma statement of operations for the year ended December 31, 2006:

- on an actual basis;
- on a pro forma basis to give effect to the merger of Monosol Rx LLC into MonoSol Rx, Inc.; and
- on a pro forma as adjusted basis to give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of all of the shares of common stock in this offering at an initial public offering price of \$ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

	Year-ended December 31, 2006				
	Actual	Corporate Formation Adjustments	Pro Forma	Offering Adjustments	Pro Forma, as Adjusted
	(in thousands)				
<b>Statement of Operations Data:</b>					
Revenues:					
Manufacture and supply revenue	\$ 1,765	\$ —	\$ 1,765	\$ —	\$ 1,765
Co-development and research fees	950	—	950	—	950
<b>Total revenues</b>	<b>2,715</b>	<b>—</b>	<b>2,715</b>	<b>—</b>	<b>2,715</b>
Cost of goods sold:					
Manufacture and supply	1,623	—	1,623	—	1,623
<b>Gross profit</b>	<b>1,092</b>	<b>—</b>	<b>1,092</b>	<b>—</b>	<b>1,092</b>
Operating expenses:					
General and administrative expenses	11,296	(1)	—	—	—
Research and development	1,993	—	1,993	—	1,993
<b>Operating expenses</b>	<b>13,289</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Operating loss</b>	<b>(12,197)</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Other income, principally related-party	64	—	64	—	64
Interest income	226	—	226	—	226
Interest expense	(845)	—	(845)	—	(845)
<b>Net loss before income taxes</b>	<b>(12,752)</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Income taxes	—	900(2)	900	—	900
<b>Net loss</b>	<b>\$ (12,752)</b>	<b>\$ —</b>	<b>\$ 900</b>	<b>\$ —</b>	<b>\$ 900</b>

(1) Represents the amounts due participants under the Monosol Rx LLC Performance Unit Plan to be converted to the common stock of MonoSol Rx, Inc.

(2) Represents the estimated deferred tax liability (long-term) to be recorded on the opening balance sheet of MonoSol Rx, Inc. in connection with the merger of Monosol Rx LLC into MonoSol Rx, Inc.

The following table sets forth our unaudited pro forma statement of operations for the three months ended March 31, 2007:

- on an actual basis;
- on a pro forma basis to give effect to the merger of Monosol Rx LLC into MonoSol Rx, Inc.; and
- on a pro forma as adjusted basis to give effect to (1) the merger of Monosol Rx LLC into MonoSol Rx, Inc. and (2) the sale of all of the shares of common stock in this offering at an initial public offering price of \$ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

Three months ended March 31, 2007					
	Actual	Corporate Formation Adjustments	Pro Forma	Offering Adjustments	Pro Forma, as Adjusted
	(in thousands)				
<b>Statement of Operations Data:</b>					
Revenues:					
Manufacture and supply revenue	\$ 429	\$ —	\$ 429	\$ —	\$ 429
Co-development and research fees	80	—	80	—	80
<b>Total revenues</b>	<b>509</b>	<b>—</b>	<b>509</b>	<b>—</b>	<b>509</b>
Cost of goods sold:					
Manufacture and supply	251	—	251	—	251
<b>Gross profit</b>	<b>258</b>	<b>—</b>	<b>258</b>	<b>—</b>	<b>258</b>
Operating expenses:					
General and administrative expenses	3,729	(1)	—	—	—
Research and development	685	—	685	—	685
<b>Operating expenses</b>	<b>4,414</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Operating loss</b>	<b>(4,156)</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Other income, principally related-party	—	—	—	—	—
Interest income	170	—	—	—	170
Interest expense	—	—	—	—	—
<b>Net loss before income taxes</b>	<b>(3,986)</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Income taxes	—	900(2)	900	—	900
<b>Net loss</b>	<b>\$ (3,986)</b>	<b>\$ —</b>	<b>\$ 900</b>	<b>\$ —</b>	<b>\$ 900</b>

(1) Represents the amounts due participants under the Monosol Rx LLC Performance Unit Plan to be converted to the common stock of MonoSol Rx, Inc.

(2) Represents the estimated deferred tax liability (long-term) to be recorded on the opening balance sheet of MonoSol Rx, Inc. in connection with the merger of Monosol Rx LLC into MonoSol Rx, Inc.



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

*You should read the following discussion and analysis of financial condition and results of operations in conjunction with the "Selected Financial Information" and the financial statements and the related notes included elsewhere in this prospectus. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements" included elsewhere in this prospectus.*

### Overview

We are a drug delivery company specializing in proprietary dissolving thin film pharmaceutical products. Since our inception in 2004, we have developed a significant portfolio of intellectual property and know how in thin film drug delivery, including formulation manufacturing, encapsulation and packaging. We are working with partners to develop thin film versions of their products for use in the prescription pharmaceutical, over-the-counter, or OTC, and consumer markets. Additionally, we began our self-funded initiatives by selecting prescription pharmaceutical products for development in our thin film technology based upon factors such as technical suitability, market opportunity, approved indications, patent expiration and other factors. We intend to further develop these products on our own before seeking a partner with the goal of maximizing our potential revenue.

Both with partners and through our self-funded initiatives we are currently developing a number of prescription products. This is a multi-phase process which includes regulatory filings for approval of our formulations prior to them being sold in the marketplace. We are vertically integrated in all critical phases of development and manufacture of our thin film.

We have incurred significant net losses since our inception in January 2004. As of December 31, 2006, we had accumulated net losses of \$24.6 million, and our annual net loss has grown in size each year. Our losses have resulted principally from general and administrative expenses associated with developing our business and costs incurred in the research and development of our technologies. We expect to continue to incur net losses for the next several years as we pursue the development and commercialization of our product candidates.

We have financed our early stage operations with revenue from co-development arrangements and manufacturing and supply arrangements, the proceeds of capital contributions from our members and various debt offerings to affiliates of our members. In addition to proceeds from this offering, we may require additional financing to execute our business strategy.

Since the beginning of January 2006, we have added 49 employees, doubling the total size of our workforce, including contract employees and temporary employees. The growth in the size of our workforce included the hiring of our Chief Executive Officer and our Chief Financial Officer, as well as our Senior Vice Presidents of Business Development and Operations. We also added and plan to continue to add analytical scientists, packaging engineers and other manufacturing specialists necessary to attract and fulfill key customer contracts. These additional employees have increased dramatically, and will continue to increase our expenses in the short term but will enable the continued improvement of our thin film technology and development of products that we expect will produce revenue in the future.

In October 2006, we leased the Ameriplex facility which will become our primary development and analytical laboratories and manufacturing facility when retrofitting is complete in 2008. This facility will give us a state of the art cGMP manufacturing facility with enough capacity to hold all of our operations and room to grow in the future. We expect to invest nearly \$14 million in improvements to

the facility over the next two years. This amount excludes investments in any additional equipment necessary to ensure we have the appropriate capabilities and capacity to support ongoing customers' needs.

In November 2006, we completed a private placement of equity and issued preferred membership interests in exchange for \$16.9 million in cash and the settlement of \$20.5 million principal amount of Tranche A and B notes, together with related accrued interest. This transaction allowed us to retire all of our outstanding debt and provided cash proceeds for product development and general corporate purposes, including capital expenditures and working capital.

Since January 2007, we have entered into a number of new customer agreements for the development and supply of various products in the prescription pharmaceutical, OTC pharmaceutical and non-pharmaceutical categories. Each of these contracts and the products they represent have different development timelines and, in some cases, regulatory requirements that will determine when the products will be commercially available and begin to produce revenue. In each case, we expect the development effort to generate milestone-based development revenue for us in the near term and ultimately supply and, potentially, royalty revenue in the long term.

## **Financial Operations Overview**

### ***Revenues and Cost of Goods Sold***

We derive our revenues from two sources: manufacture and supply agreements and co-development and research fees. We currently generate manufacture and supply revenue from the production of thin film under commercial supply agreements with our customers for OTC products and a specialty application film. Co-development and research fees result from arrangements with third parties to test the applicability of and to develop products in thin film. These arrangements are usually for a finite period of time and are directed at a certain defined result. The fees may be related to completion of defined milestones. These arrangements may or may not lead to future research and development arrangements or manufacture and supply agreements. The acceptance of thin film as a drug delivery technology by medical practitioners and consumers along with increased direct-to-consumer marketing featuring nationally recognized brand names has helped create increased interest in our technology among potential partners as evidenced by recently signed agreements to develop and supply products to Philip Morris USA Inc., or Philip Morris USA, Adams Respiratory Therapeutics and Prestige Brands Holdings, Inc., or Prestige. These are examples of companies who are interested in our technology and our company.

Additionally, we are also in substantive negotiations with several other potential drug customers for contractual development and supply agreements. We believe that these potential new relationships demonstrate the customer acceptance of our technology and will contribute to the revenue growth we expect to realize.

With respect to our self-funded initiatives, we have continued to make progress with respect to the products we have identified and selected for development. We are in pilot bioavailability/bioequivalence clinical studies for the first product, Zolpidem Tartrate, and are preparing our second product, Ondansetron HCL, for clinical evaluation in the third quarter of 2007. We have also filed suitability petitions with the Food and Drug Administration, or FDA, for several other products in conjunction with the start of research and development activities.

Cost of goods sold is comprised of expenses related to manufacturing our thin film products, including raw materials, direct labor and fixed overhead. Our material costs include the costs of raw materials used in the production of our thin film drug delivery products and related packaging supplies. Direct labor costs consist of payroll costs (including benefits) of employees engaged in production activities. Fixed overhead principally consists of indirect payroll, facilities rent and depreciation for production machinery and equipment. As we commercialize more products and are able to

manufacture larger, contiguous batches of products while incorporating proprietary, patent pending, manufacturing processes utilizing our production facility, we expect our raw material, direct labor and overhead costs per strip to be reduced and our gross margins to increase. As we develop and commercialize more products and establish predictive reorder programs with our customers, we expect a greater utilization of annual strip production capacity and continued improvement of our cost of goods on a per strip basis.

Our revenues and cost of goods sold are impacted by the following factors:

- negotiated sales price with our partners for the products being manufactured;
- our customers' supply requirements; and
- costs of production, which includes:
  - raw materials, which we purchase at market prices; and
  - production efficiency (measured by the cost of a salable unit) which can increase or decrease based on the amount of direct labor and materials required to produce a product and the allocation of fixed overhead, which is dependent on the levels of production.

In the future, we expect to generate revenues from milestone payments for research and development activities and manufacture and supply agreements, which may include royalty payments.

Our development, supply and licensing agreements with Adams Respiratory Therapeutics, Inc., or Adams, provides for revenues for product development through commercial launch of a total of \$1.5 million. In addition, Adams agrees to pay \$167,000 on each of the second, third and fourth anniversaries of commercial launch. The development agreement is for a seven-year term, covers the United States, Canada and Mexico and may be extended at Adams' election for up to three three-year extension terms. In certain circumstances both we and Adams may cancel the development agreement before the term expires. We have agreed to develop the respiratory film product exclusively for Adams.

Our supply agreement with Adams contains standard terms and conditions, and is also for a seven-year term, which may be extended by Adams for up to three three-year extension terms. Our license agreement with Adams has the same term as the supply agreement, including the same right to extend by Adams, but will remain in effect for an additional seven years in the event Adams terminates the agreement for our breach. The license agreement only applies to the respiratory thin film product. Under the license agreement, Adams agrees to pay royalties for the respiratory product on annual net sales within the territory of 5% for the first \$15 million in net sales; 6% on net sales from \$15 to \$25 million; 7% on net sales from \$25 to \$35 million, and 7.5% on all net sales over \$35 million. In the event that a competitor obtains an approval for a competing, "AB"-rated product, our royalty rates are subject to reduction in accordance with a formula based upon the percentage decline in net sales of the product we make. Such a reduction could be material. Adams may terminate the license agreement upon 30 days' notice.

Our current manufacture and supply agreements for non-pharmaceutical products with Philip Morris USA and Dr. Katz provide revenue on a per strip or per case basis. The Philip Morris USA and Dr. Katz contracts are both exclusive arrangements and have five and four year terms, respectively. Our arrangements for the supply of OTC pharmaceuticals to Medtech Products Inc., or Medtech, a subsidiary of Prestige, GlaxoSmithKline plc, or GSK, Vita Health Products Inc., or Vita, and L. Perrigo Company, or Perrigo, whether via our contractual arrangements or on a purchase order basis, are all on a per strip, per packaged dose or per case basis and do not contemplate royalty payments based on sales. The agreement with Perrigo is a four year, nine month exclusive arrangement, and our agreement with Vita is a five year arrangement. Our relationships with Prestige and GSK are both purchase order supply arrangements until the formal manufacture and supply agreements are finalized.

Our current partner agreements with Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., or Angelini, and UMD Inc., or UMD, generate revenue for pharmaceutical development work. To date, UMD has paid us \$166,664 for formulation development and the manufacture of clinical supplies, contracted for on a purchase order basis. Angelini's initial work order is for \$40,000 in development work, of which \$20,000 has been paid to us.

In December 2006, we entered into a development agreement with a mid-sized global pharmaceutical manufacturer for a thin film that will buccally deliver certain controlled prescription actives. Under this agreement, we will receive payments upon meeting four different development milestones during the term of the agreement. This agreement has a term of nine months, which may be extended by the customer upon four weeks' notice. The customer is under no obligation to authorize all four development milestones, and may cancel the agreement at any time. Through May 2007, we have billed this customer \$250,000 under this agreement.

In August 2006, we entered into an agreement to develop a thin film that will sublingually deliver certain prescription actives. We have successfully completed preliminary formulation work and demonstrated our ability to achieve acceptable organoleptic performance and content uniformity at a very low drug loading level (i.e., micrograms). This product, should development continue, would entail the submission of a new drug application and will ultimately require dedicated manufacturing. This agreement may be terminated by either us or the customer upon 30 days' notice.

### **Research and Development Expenses**

Our research and development expenses reflect costs incurred in developing our thin film drug delivery technology, the development of our self-funded initiatives and external arrangements with third party partners. We expense research and development costs as incurred. Our partnered products generate co-development and research fees. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel;
- costs of laboratory supplies and materials;
- fees to professional service providers;
- depreciation of capital assets used in the research and development process; and
- allocated operating costs, such as the cost of facilities.

Our business is largely to identify presently marketed prescription pharmaceutical products that are suitable for thin film development. Our research and development cycle is shorter and less costly than the development of the pharmaceutical product itself. For each prescription thin film product we develop, we estimate that the research and development cycle will range between 24 to 30 months and total costs will be less than \$5 million. The time frame and cost can be affected by the regulatory path we select or are required to follow and the extent to which regulatory authorities require follow-on clinical studies.

Research and development costs incurred by us during the last three fiscal years for internal proprietary projects and arrangements with third parties are as follows:

Fiscal Year	Internal Proprietary Projects	Arrangements With Third Parties	Total
2006	\$ 1,194,000	\$ 799,000	\$ 1,993,000
2005	899,000	359,000	1,258,000
2004	941,000	69,000	1,010,000

We expect to incur increasing research and development expenses in future periods as we expand our internal research capabilities and increase the number of self-funded initiatives, or SFIs, we expect to enroll in pre-clinical studies and clinical trials. The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. We consider the development of our product candidates to be crucial to our long-term success. If we do not complete development of our product candidates and obtain regulatory approval to market one or more of these product candidates, we may not be successful. The probability of success for each product candidate may be impacted by numerous factors, including the timing and results of our pre-clinical research programs, the scope, rate of progress and cost of our clinical trials, future clinical trial results, the cost and timing of regulatory approvals, and the effects of competing technologies and market developments. We will make ongoing evaluations of our product candidates and determine which product candidates to advance and how much funding to direct to each based on an ongoing basis in response to their scientific and clinical success and market potential.

The total cost and length of the product development program largely depends on a number of factors:

- Whether or not we are developing a product with a partner under a development agreement and the extent to which we receive fees or milestone payments. Additionally, whether or not that partner has performed any critical development activities that may accelerate the overall development effort, meaning work under an existing approved NDA.
- Whether or not the development is for an existing approved active pharmaceutical ingredient, or API, and/or associated indication(s). New indication(s) or development of a thin film product for a potentially new chemical entity could significantly extend the development process.

In general, we believe the process from development to FDA approval should be up to 30 months based on the regulatory pathways, 505(j) or 505(b)(2), that we expect to undertake. For projects where we perform the development program prior to entering into a relationship with a partner, a self-funded initiative program, we believe development costs will be approximately \$2.5 to \$3.0 million. Given the uncertainty surrounding each stage of the development process, including regulatory approvals and the fact that we have not yet completed successful development of a prescription pharmaceutical product, we cannot be sure our estimates of the development costs of such products are accurate.

Research and development expense consists of expenses incurred in connection with developing and advancing our thin film technology and developing our product candidates. These expenses consist primarily of salaries and related expenses, facility costs and costs for pre-clinical and clinical trials including research, formulation and manufacturing, as well as estimated potential third party payments for materials and services such as APIs and other raw materials, testing, legal and consulting fees. We charge all research and development expenses to operations as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our research and development costs or our personnel and related costs on an individual product basis. The aggregate costs incurred during each period presented were calculated by combining costs directly associated with our operations as well as a costs allocation for shared resources supplied by Monosol, LLC. Furthermore, we use our research and development resources, including employees and our thin film technology, across multiple drug development and OTC and other programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our product candidates. Our total research and development expenses for the years ended December 31, 2006, 2005 and 2004 and the three months ended March 31, 2007 were \$2.0 million, \$1.3 million, \$1.0 million and \$0.7 million, respectively.

We expect our research and development costs to be substantial and to increase as we advance our portfolio of thin film product candidates through to commercialization as well as costs related with new

partnered agreements. Due to the fact that our product candidates are still in various stages of development, we cannot estimate anticipated completion dates and when we might receive material net cash inflows from our research and development projects.

There are many suitable candidates for development on thin film and the development time and cost for those opportunities is modest compared to that of developing a new API or demonstrating efficacy for a new indication. As such, the strength and viability of the company is not dependent upon any one project. If there is a failure to achieve the desired results in any one of the projects under development or the API is subject to adverse regulatory action prior to completion of our project, we believe there are enough alternate API candidates for development utilizing our thin film drug delivery technology to complete our business plan. In addition, this allows us the ability to continue a program of partnered and self-funded development initiatives to achieve the business growth and results that we seek.

### ***General and Administrative Expenses***

Our general and administrative expenses consist of salaries and benefits for executive and support personnel, professional fees for legal, accounting and other services, travel costs, facility-related costs such as rent, utilities for non-production activities and other general office expenses. These expenses include the following functions: corporate management, business development and licensing, finance, human resources, information systems and other administrative functions and unabsorbed manufacturing overhead costs. We expect our general and administrative expenses to increase as we continue to hire new employees, expand our infrastructure and incur additional costs related to the growth of our business and our operations as a public company.

### **Results of Operations**

#### ***Three Months Ended March 31, 2007 and March 31, 2006***

*Revenue.* Manufacture and supply revenue decreased \$0.6 million, or 60% to \$0.4 million for the three months ended March 31, 2007 from \$1.0 million for the three months ended March 31, 2006. This decrease is attributable to us receiving no orders in the first quarter of 2007 from a customer that accounted for \$0.9 million or 90% of manufacture and supply revenue in the first quarter of 2006. This was partially offset by increased revenues from recurring customers. Co-development and research fees decreased \$110,000, or 58% to \$80,000 for the three months ended March 31, 2007 from \$190,000 for the three months ended March 31, 2006. The decrease was attributable to customer movement from co-development projects to manufacture and supply orders.

*Customer Concentration.* Customers are considered major customers when sales exceed 10% of total net sales for the year or outstanding receivable balances exceed 10% of total receivables. For the three months ended March 31, 2007, we had two major customers with sales totaling \$465,000, or 91% of net sales, and an outstanding receivable balance of \$213,000, or 93% of total receivables at March 31, 2007. For the three months ended March 31, 2007, our major customers accounted for revenues of \$439,000 and \$27,000, respectively. For the three months ended March 31, 2006, we had two major customers, with sales totaling \$1,084,000, or 94% of net sales, and had outstanding receivables of \$439,000, or 92% of total receivables at March 31, 2006 from these customers. For the three months ending March 31, 2006 our major customers accounted for revenues of \$891,000 and \$193,000, respectively.

*Cost of Goods Sold.* Cost of goods sold decreased by \$393,000, or 61% to \$251,000 for the three months ended March 31, 2007 from \$644,000 for the three months ended March 31, 2006. This decrease was attributable to lower manufacture and supply revenue resulting from the decrease in order volume from a customer as we have described above.

*Research and Development Expenses.* Research and development expenses increased by \$306,000 or 81% to \$685,000 for the three months ended March 31, 2007 from \$379,000 for the three months ended March 31, 2006. The increased expenses for the three months ended March 31, 2007 were attributable to increased staffing and infrastructure to support our internal research efforts and the commencement of certain SFI projects.

*General and Administrative Expenses.* General and administrative expenses increased by \$1.8 million or 94% to \$3.7 million for the three months ended March 31, 2007, from \$1.9 million for the three months ended March 31, 2006. This increase was attributable to increased staffing levels across our business, higher legal and accounting expenses and the cost associated with our planned Initial Public Offering.

#### **Years Ended December 31, 2006, 2005 and 2004**

*Revenue.* Manufacture and supply revenue increased \$0.3 million, or 20% to \$1.8 million in 2006 from \$1.5 million in 2005. This increase is attributable to additional supply agreements we entered into with new customers and the initial demand generated by those contracts. Co-development and research fees increased \$285,000, or 43% to \$950,000 in 2006 from \$665,000 in 2005. The increase was attributable to additional development arrangements with new customers. Manufacture and supply revenue decreased \$0.4 million, or 21% to \$1.5 million in 2005 from \$1.9 million in 2004. This decrease is attributable to the discontinuation of business of one of our customers and the resulting termination of our relationship with that customer. Co-development and research fees increased \$565,000, or 565% to \$665,000 in 2005 from \$100,000 in 2004. The increase was attributable to us commencing operations in 2004 and the expansion of our customer base in 2005.

*Customer Concentration.* Customers are considered major customers when sales exceed 10% of total net sales for the year or outstanding receivable balances exceed 10% of total receivables. For 2006, we had four major customers with sales totaling \$2.5 million, or 93% of net sales, and outstanding receivables of \$563,000, or 97% of total receivables. We had no major customers in 2005. For 2004, we had one major customer, with sales totaling \$1.8 million, or 90% of net sales, and outstanding receivables of \$1.0 million, or 91% of total receivables.

*Cost of Goods Sold.* Cost of goods sold increased by \$0.3 million, or 23% to \$1.6 million in 2006 from \$1.3 million in 2005. This increase is attributable to the growth of revenue resulting from additional products sold as well as higher allocated overhead costs due to our adoption of Statement of Financial Accounting Standards, or SFAS, No. 151, Inventory Costs — an Amendment of Accounting Research Bulletin, or ARB, No. 43 effective January 1, 2006. Since our adoption of SFAS No. 151 was on a prospective basis, the higher levels of allocated overhead costs only affected our costs of goods sold and gross margins in 2006. In the future, as we utilize a greater percentage of our manufacturing capacity, we expect that the amount of our allocated overhead will decrease in relation to our revenue and gross margins which should correspondingly increase. These increases were partially offset by lower levels of excess and obsolete inventory in 2006. Cost of goods sold decreased by \$0.1 million, or 7% to \$1.3 million in 2005 from \$1.4 million in 2004. This decrease was attributable to a decrease in manufacture and supply revenue resulting from the terminated relationship with a significant customer as described above, offset by increased costs for excess and obsolete inventory in 2005.

*Research and Development Expenses.* Research and development expenses increased by \$0.7 million, or 54% to \$2.0 million in 2006 from \$1.3 million in 2005. Research and development expenses increased by \$0.3 million, or 30% to \$1.3 million in 2005 from \$1.0 million in 2004. The increased expenses in 2006 and 2005 were attributable to increased staffing and infrastructure to support our internal research efforts along with costs associated with the increase in partnered research and development arrangements for which we generate co-development and research fees.

*General and Administrative Expenses.* General and administrative expenses increased by \$3.9 million, or 53% to \$11.3 million in 2006 from \$7.4 million in 2005. General and administrative expenses increased by \$4.2 million, or 131% in 2005 from \$3.2 million in 2004. The increase of general and administrative expenses in 2006 and 2005 was attributable to the increase in the number of employees at our company from 11 full-time employees (inclusive of consultants and temporary workers) in 2004 to 36 and 63 full-time employees (inclusive of consultants and temporary workers) at the end of 2005 and 2006, respectively. In addition to increased staffing, we have incurred increased costs related to building our infrastructure and developing our business, including costs related to the recruitment of the current management team and other professionals, costs for additional facilities and related depreciation, as well as costs for outsourced formulation, and analytical and design work to support our development efforts.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

Since our inception in January 2004, we have never been profitable and as of March 31, 2007 we had accumulated net losses of approximately \$28.6 million. Through March 31, 2007, we received net proceeds from debt and equity issuances of approximately \$42.6 million as follows:

- at our formation in January 2004, we received a \$4.8 million contribution of net assets, including \$0.4 million in cash;
- later in 2004, we received an additional capital contribution of \$6.6 million, including \$4.8 million in cash;
- during 2005 and 2006, we issued \$20.5 million principal amount of Tranche A and B notes payable, along with stock purchase warrants. The notes had a ten year term and payment in kind interest at 4.33% and 4%, respectively; and
- in November 2006, we closed a private placement for \$38.4 million of preferred membership interests. A portion of the preferred interests were issued in settlement of amounts due under the Tranche A and B notes along with accrued interest. The net cash proceeds of \$16.9 million are available for general corporate purposes including product development, capital expenditures and working capital. The preferred membership interests will be converted into shares of our common stock pursuant to the merger to occur prior to the offering.

We had \$11.3 million in cash and cash equivalents as of March 31, 2007. Currently, our cash equivalents have a maturity of three months or less. The core of our strategy involves the development of our thin film drug delivery technology to targeted prescription pharmaceuticals. This area of product development is a multi-year process that requires significant expenditures prior to realizing any product revenue. We may need to raise additional funds through public or private debt or equity financings in order to develop or acquire new products or new product candidates, expand our manufacturing capacity, obtain FDA approval for our product candidates and continue our commercial growth. The proceeds from this offering will enable us to continue to execute our strategy, attract partners for co-development arrangements and ultimately develop products for commercial supply.

### *Cash Flows*

#### *Operating Activities*

*Three Months ended March 31, 2007 and 2006.* Cash used in operating activities was \$2.7 million for the three months ended March 31, 2007 and was primarily attributable to our \$4.0 million net loss, offset by \$0.7 million in non-cash charges, principally depreciation, and \$0.6 million from changes in operating assets and liabilities. Cash used in operating activities was \$1.9 million for the three months



ended March 31, 2006 and was primarily attributable to our \$2.0 million net loss, offset by \$0.6 million in non-cash charges principally depreciation and interest expense and changes in operating assets and liabilities.

*Years ended December 31, 2006, 2005 and 2004.* Cash used in operating activities was \$9.3 million for the year ended December 31, 2006 and was primarily attributed to our \$12.8 million net loss, offset by \$3.5 million in non-cash charges such as depreciation, amortization and non-cash interest expense, and changes in operating assets and liabilities. Cash used by operating activities was \$6.4 million for the year ended December 31, 2005 and was primarily attributed to our \$8.3 million net loss, offset by \$1.6 million in non-cash charges such as depreciation, amortization, non-cash interest expense and the write-off of accounts receivable, and changes in operating assets and liabilities. Cash used by operating activities was \$3.4 million for the year ended December 31, 2004 and was primarily attributed to our \$3.6 million net loss, offset by \$0.5 million in non-cash charges such as depreciation and amortization and changes in operating assets and liabilities.

#### ***Investing Activities***

*Three Months ended March 31, 2007 and 2006.* Cash used in investing activities was \$1.4 million and \$0.5 million for the three months ended March 31, 2007 and 2006, respectively, and was attributable to capital expenditures for property, plant and equipment.

*Years ended December 31, 2006, 2005 and 2004.* Cash used in investing activities was \$3.4 million, \$2.8 million and \$1.2 million for the years ended December 31, 2006, 2005 and 2004, respectively, and was attributable to capital expenditures for property, plant and equipment.

#### ***Financing Activities***

*Three Months ended March 31, 2007 and 2006.* Cash provided by financing activities was \$0.2 million for the three months ended March 31, 2007 and was solely provided by the proceeds of an asset transfer to the predecessor of Monosol Rx LLC. For the three months ended March 31, 2006 cash provided by financing activities was \$5.9 million primarily from \$6.0 million of proceeds from the issuance of debt and warrants.

*Years ended December 31, 2006, 2005 and 2004.* Cash provided by financing activities was \$26.5 million for the year ended December 31, 2006 and was primarily attributable to the \$16.9 million in net proceeds from the issuance of Series A Preferred Interests and \$10.0 million in net proceeds from the issuance of notes payable with warrants. Cash provided by financing activities was \$10.2 million for the year ended December 31, 2005 and was primarily attributable to \$10.5 million in net proceeds from the issuance of notes payable with warrants. Cash provided by financing activities was \$4.9 million for the year ended December 31, 2004 and was primarily attributable to \$5.1 million in capital contributions from members.

#### ***Funding Requirements***

Upon completion of this offering, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, as supplemented by our revenue, will be sufficient to meet our projected operating requirements for approximately the next 24 months. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts for thin film versions of existing drugs and other self-funded initiatives;
- the levels and timing of revenues from the commercialization of our product candidates;

- the capital expenditures required to support our increasing development and manufacturing capacity needs; and
- the infrastructure costs to support a public company.

We believe that research and development through FDA approval could take up to 30 months for each of the product candidates we choose to develop. In certain cases, depending on the partner and the regulatory path, that timeframe may be shorter. We expect the entire approval process, including clinical trials, to cost between \$2.5 and \$3.0 million for each product developed as a self-funded initiative. Generally, when we enter into a thin film drug development agreement with a partner, the partner will agree to pay for the development costs through development and/or milestone payments. We assume in our plans regarding funding requirements that we will undertake the development of a minimum of six product candidates as self-funded initiatives which, commence at different times over the next two years. We seek to develop as many partnered or self-funded product candidates as our resources will allow.

We currently expect the three non-pharmaceutical products we have developed with Philip Morris USA, GSK and Dr. Katz to contribute to our revenues during the next 24 months. Additionally, we expect that the OTC drug product we have developed with MedTech, a subsidiary of Prestige, will contribute to our revenues during the same timeframe. Due to the fact that our prescription product candidates are in various stages of development we cannot estimate anticipated completion dates, approval dates from the FDA or when we might receive material net cash inflows from these products. We also expect revenues from our co-development and research contracts to contribute revenues over the same timeframe.

With respect to capital expenditures, we expect to invest \$14 million through 2008 to retrofit the Ameriplex facility to a cGMP thin film manufacturing facility. Additionally, over the next 24 months we expect to invest an additional \$10 to \$12 million in laboratory facilities, manufacturing capacity and information technology assets.

We expect to incur significant additional costs to support the obligations of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations, such as the Sarbanes-Oxley Act of 2002. These expenditures will include the costs of additional employees with specific skills and experiences such as SEC reporting or internal controls, as well as, additional costs to outside service providers such as audit, tax and legal fees. We expect those additional costs to be in excess of \$1.5 million per year over the next two years.

We may raise additional capital through public or private equity offerings, debt financings, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our research, pre-clinical or clinical programs.

## Seasonality

To the extent we are producing OTC cough, cold and allergy pharmaceutical products, which by nature are seasonal, we could experience some seasonality in revenues in the second and third quarters of 2007 and 2008. In the long term, our strategy is to target selected prescription pharmaceuticals on thin film that are not cough, cold and allergy pharmaceutical products. As those products are brought to the market and they begin to represent a larger share of our product portfolio, the effects of seasonality caused by any cough, cold and allergy products will be diminished.

## Contractual Obligations

Our contractual obligations relate to operating leases for our facilities and purchases of production equipment.

The following table sets forth a summary of our contractual obligations as of December 31, 2006:

Contractual Obligations	Total	Less Than One Year	One to Three Years	Four to Five Years	After Five Years
Operating lease obligations	\$ 2,879,098	\$ 588,102	\$ 1,074,988	\$ 1,088,412	\$ 127,596
Equipment purchase obligations	3,690,000	3,690,000	—	—	—
<b>Total</b>	<b>\$ 6,569,098</b>	<b>\$ 4,278,102</b>	<b>\$ 1,074,988</b>	<b>\$ 1,088,412</b>	<b>\$ 127,596</b>

*Operating Lease Obligations.* We have various lease agreements for our production and research facilities and offices. Most leases contain renewal options, some contain purchase options and some require us to pay for taxes, maintenance and operating expenses. In October 2006, we entered into a lease for the AmeriPLEX facility. The lease expires in March 2012 with options to extend through March 2021, and a right of first refusal to purchase the facility. In July 2006, we entered into a lease for our headquarters located in Warren, New Jersey. The lease expires in 2011. We lease our current production facility in Portage, Indiana which houses our research and development, offices and manufacturing operations. This lease expires in March 2008, with an option to extend through March 2010. This lease also contains a purchase option at a fixed price. We also lease a small technology development laboratory in Kingsport, Tennessee. The lease related to the Kingsport, Tennessee laboratory expires in December 2009.

*Equipment Purchase Obligations.* In 2007, we intend to purchase a new film casting line to fulfill production requirements under a commercial supply agreement. The equipment will be purchased with cash and the customer that is a party to the supply agreement is obligated to make capacity commitment payments over two years that equal the cost of the equipment and any other capital expenditures related to its installation.

## Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

## Taxation

Our predecessor, Monosol Rx LLC, operated as a limited liability company which, for federal, state and local income tax purposes was treated as a partnership. As such, in lieu of company-level income taxes, its members were subject to tax on their respective pro rata shares of Monosol Rx LLC's income, deductions, gains, losses and credits, as allocated in accordance with the members' operating agreement. Because Monosol Rx LLC was treated as a partnership for federal, state and local income tax purposes, no income taxes have been recognized in the accompanying financial statements, except for certain state non-income taxes, which are immaterial and included in general and administrative

expenses. Effective on the merger of Monosol Rx LLC into MonoSol Rx, Inc., we will be subject to corporate-level income tax under subchapter C of the Internal Revenue Code for federal income tax purposes, as well as under state and local income tax laws. In accordance with U.S. generally accepted accounting principles, or GAAP, we are required to estimate the future tax consequences attributed to temporary differences between the financial statement and income tax bases of our assets and liabilities and record a deferred tax asset or liability. In the unaudited pro forma financial statements contained elsewhere in this prospectus, we recorded a \$900,000 one-time non-cash charge on the statement of operations to recognize the deferred tax liability related to existing taxable temporary differences that will reverse in future periods. The temporary differences resulted principally from depreciation of property and equipment, and amortization of intangibles.

### **Performance Unit Plans**

Our predecessor, Monosol Rx LLC, has maintained two Performance Unit Plans for the purpose of enhancing our long-term growth by providing incentives to key employees and other service providers. The performance units were granted with a base value equal to their estimated fair value at the date of grant, both of which were determined by our board of directors. The Performance Unit Plans call for accelerated vesting upon a change in control or an initial public offering. The vested units can be redeemed for cash or in the form of the same equity instruments received due to a change in control or an initial public offering, at the discretion of the board of directors. The payment to a participant is based on the spread between the fair value of the performance units at the time of the change in control or initial public offering and the base value of the performance units the participant was awarded. After the merger of Monosol Rx LLC with MonoSol Rx, Inc. and immediately prior to this offering, the performance units will be exchanged for common stock of MonoSol Rx, Inc. and we will incur compensation expense in the estimated amount of \$                      million, which has been reflected in the unaudited pro forma financial statements included elsewhere in this prospectus.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based on the financial statements, which have been prepared in accordance with GAAP. The preparation of the financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to the financial statements appearing elsewhere in this prospectus. We believe that the following accounting policies relating to revenue recognition, research and development expenses, inventory valuation, intangibles and impairment of long-lived assets are most critical to aid you in fully understanding and evaluating our reported financial results.

#### ***Revenue Recognition***

Our research and development agreements contain development milestones that we must meet in order to earn fees. In addition, these agreements often require that we achieve certain results in order to have the opportunity to earn additional fees and revenues. Product sales are generally a result of previous research and development efforts.

We recognize revenue in accordance with Staff Accounting Bulletin, or SAB, No. 101 *Revenue Recognition in Financial Statements*, as amended by SAB No. 104. For manufacture and supply

arrangements, we recognize revenue when products are shipped and the customer takes ownership and assumes risk of loss, collection of the relevant receivable is probable, pervasive evidence of an arrangement exists and the sales price is fixed or determinable. In instances where we utilize a third-party to complete the packaging process, revenue is recognized when the completed product is shipped from the third-party. Our products are made to order and manufactured only when a firm order is received from a particular partner. Once delivered to the partner, that partner takes and assumes all risk of inventory levels, returns from retailers, changes in the market, as well as risk from new product introductions by their competitors. Since our partners are selling to the consumer or retailer they bear the burden of rebates, return allowances and other revenue offsets. Our contracts with our partners do not anticipate nor make provision for returns of any type other than product defects or recalls. Accordingly, our financial statements do not depict any past or potential dilution of revenues for these items.

In the case of co-development and research fees, revenue is recognized when appropriate contractual milestones are realized, contractual amounts for those services are billed and collection of related receivables is probable. Absent significant historical data, the determination regarding the collectibility of revenues is based on management's judgments and are reviewed periodically. We currently reserve 2% of revenues for uncollectibility. We believe that given the customers we sell to and the nature of our agreements with them that this is a reasonable estimate. We believe it very unlikely that significant adjustments to revenue will be necessary due to the collectibility of our receivables. However, if our estimates of collectibility do not reflect our ability to collect revenues, our results of operations could be materially affected.

### ***Inventory Valuation***

Due to our continual change in customer mix, we evaluate the utility of our inventory frequently. Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Our inventories are evaluated for recoverability on a periodic basis and any non-usable inventory is written-off to expense. In addition, we establish a reserve for any inventory that may be stated in excess of its recoverable amount or potentially non-usable. Charges for such write-off and reserves are recorded as a component of cost of goods sold. Absent significant historical data, estimates regarding customer re-order cycles and inventory obsolescence are based on management's judgment and reviewed periodically. We manufacture to specific orders and do not generally manufacture for inventory or take inventory risk for finished goods and therefore believe it unlikely that significant adjustments for inventory obsolescence will take place. However, the FDA and other regulatory authorities may take action regarding certain active pharmaceutical ingredients that may cause raw material or packaging inventories to become non-usable. If our estimates for excess or obsolete inventory and its potential utility are less favorable than those projected, additional inventory reserves may be required.

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

Our property, plant and equipment are exposed to technological obsolescence. Management reviews the utility of these long-lived assets annually. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets*, long-lived assets such as property, plant and equipment, and purchased intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. In 2006, as a result of management's evaluation of our property, plant and equipment, we recorded an impairment charge of \$132,000. If these estimates or their related

assumptions change the fair value of these assets in the future, we may be required to record additional impairment charges.

### ***Intangible Asset***

Management evaluates the utility of our intellectual property underlying our principal production capabilities annually. Our intangible asset relates to composition and process technology used in thin film technology acquired as part of the Kosmos Pharma Limited, or Kosmos, acquisition in 2004 (see Note 2 in accompanying financial statements). We amortize these intangible assets on a straight-line basis over 10 years which is the expected useful life of the associated technology. The estimates are based on assumptions that we believe to be reasonable, but which are inherently uncertain. Changes in the assumptions regarding utility and useful life or the emergence of newer, more advantageous technologies could materially affect our estimates and could result in additional amortization or impairment.

### ***Research and Development Costs***

We expense costs associated with research and development activities as incurred. Research and development costs include costs incurred for our internal proprietary research and development projects as well as costs incurred under arrangements with third parties for which we generate co-development and research fees.

### **Quantitative and Qualitative Disclosures about Market Risk**

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. We attempt to increase the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in short-term investment grade debt instruments. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes. All of our investment choices are consistent with and driven by good cash management practices.

### **Changes In and Disagreements with Accountants on Accounting and Financial Disclosure**

In April 2006, our manager's general partner approved the engagement of KPMG LLP, or KPMG, to audit our financial statements for the fiscal years ended December 31, 2006, 2005, 2004 and 2003. Prior to our retention of KPMG, McGladrey & Pullen, LLP, or McGladrey, served as our certified independent accountants and reported on our financial statements for the fiscal year ended December 31, 2004. McGladrey was dismissed as our principal accountant on April 3, 2006.

McGladrey's report on our financial statements did not contain an adverse opinion or a disclaimer of opinion and the financial statements were not qualified or modified as to uncertainty, audit scope or accounting principles. During the fiscal years ended December 31, 2005 and 2004, and during the subsequent interim period between December 31, 2005 and McGladrey's dismissal, there were no disagreements with McGladrey on any matter of accounting principle or practice, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of McGladrey, would have caused it to make reference to the subject matter of the disagreement in connection with its report on our financial statements. In addition, during the fiscal years ended December 31, 2005 and 2004, and during the subsequent interim period between December 31, 2005 and McGladrey's dismissal, there were no reportable events pursuant to Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended December 31, 2005 and 2004, and during the subsequent interim period between December 31, 2005 and McGladrey's dismissal, we did not consult with KPMG regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our financial statements, or (ii) any matter that was either the subject of a disagreement or a reportable event with McGladrey.

#### **Recent Accounting Pronouncements**

In July 2006, the Financial Accounting Standards Board issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement 109, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a threshold of more-likely-than-not for recognition of tax benefits of uncertain tax positions taken or expected to be taken in a tax return. FIN 48 also provides related guidance on measurement, derecognition, classification, interest and penalties, and disclosure. The provisions of FIN 48 was effective for us on January 1, 2007, with any cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of FIN 48 did not have a material impact on our results of operations and financial condition.

### Overview

We are a drug delivery company specializing in proprietary dissolving thin film pharmaceutical products. Our thin film, which is similar in size, shape and thickness to a postage stamp, dissolves rapidly and utilizes a novel process and proprietary encapsulation compositions to mask the taste of the drug contained within the film. We believe these qualities render our thin film easy to use and consequently will improve patient compliance, providing a significant benefit to patients, their prescribing physicians and healthcare institutions. Our thin film drug delivery technology is currently used in the over-the-counter, or OTC, marketplace and we are developing thin film containing prescription drugs. By incorporating approved drugs with soon-to-expire or expired patents into our thin film, we believe we can extend their patent lives and protect the drug revenues important to our existing and future pharmaceutical partners. Furthermore, we are building the infrastructure required to produce our thin film rapidly and at scale.

We believe our thin film drug delivery technology has several material benefits over existing drug delivery forms and should enjoy strong physician, patient and consumer acceptance. Our thin film improves convenience and ease of use through discretion and portability and precludes the need for water or liquids. Our thin film may also improve dosing accuracy relative to liquid formulations thereby ensuring proper dosing for the pediatric, geriatric and mentally ill patients where proper administration is often difficult. In addition, our thin film provides ease of dosing for patients with conditions that make it difficult to swallow other solid dosage forms such as tablets or capsules.

Our proprietary thin film drug delivery technology is supported by a significant portfolio of intellectual property, which we believe differentiates us from our competitors. We believe this technology will enable pharmaceutical companies to better manage the life cycle of their products. By combining our thin film drug delivery technology with existing drugs, we believe our thin film can strategically differentiate existing or soon-to-be genericized drugs from potential generic competitors and can help protect branded prescription products against existing or new generic entries by providing additional patent protection or exclusivity in the marketplace. Additionally, we believe our thin film drug delivery technology can also be used to create new drug products with improved efficacy.

We believe we are the only company completely dedicated to thin film as a drug delivery dosage form and have created a vertically integrated infrastructure to ensure leadership capabilities in the critical activities of drug tastemasking, analytical development, global formulation development, manufacturing and packaging. We have invested significantly in this model of vertical integration to develop an operational infrastructure that we believe will position us to seamlessly commercialize products in concert with our partners' respective sales forces.

We have pursued and plan to continue to pursue four different strategic revenue paths to profitability. We plan to develop thin film versions of existing prescription products under partner-funded agreements. We also expect to self-fund the development of versions of existing prescription products which we intend to ultimately partner. We also plan to partner with pharmaceutical companies to develop and deliver new prescription products with improved efficacy and to continue to commercialize products in the OTC marketplace.

### Our Business Strategy

Our strategy is to develop and partner innovative thin film strip products in the prescription, generic and OTC pharmaceutical markets and to establish a leadership position in thin film drug delivery technology through continued development of our drug delivery technology and our intellectual property portfolio. We believe that pharmaceutical companies will want to partner with us to extend the life cycle of their products, defend against patent expiration, protect against generic encroachment and



differentiate their products in competitive categories. To achieve these goals, our strategy includes the following key elements:

- **Self-fund the development of thin film versions of existing prescription products.** We are currently developing a portfolio of thin film formulations of existing prescription drugs. We select our targets based upon technical suitability for our thin film drug delivery technology, patent expiration, approved indications, market size and other factors. We intend to maximize the commercial value of these drugs by seeking to partner with the drug innovators to enable them to extend the life cycle of their prescription drugs. We believe this strategy will result in superior economics for us as compared to initiatives where partners initially fund the product development program as we have taken on most of the development risk.
- **Develop thin film versions of existing prescription products with pharmaceutical partners.** In contrast to our self-funded initiatives, we are also currently developing a number of thin film formulations of existing prescription products under partner-funded agreements. Together with our development and marketing partners, we have selected targets based upon technical suitability for our thin film drug delivery technology, patent expiration, patient demographics approved indications and other factors. Similar to our self-funded initiatives, we believe these agreements will enable our partners to manage the life cycle of their prescription drugs. When compared to our self-funded initiatives, the development costs and risks associated with partnered products are significantly reduced.
- **Partner with pharmaceutical companies to deliver new prescription products with improved efficacy.** For certain drugs, we believe our thin film drug delivery technology, when utilized for sublingual (under the tongue), buccal (in the cheek) or vaginal delivery may improve efficacy. Improved efficacy can occur through faster onset of action or lower dosing which may also result in reduced side effects and improved safety. We believe that the potential to deliver prescription drugs with improved efficacy will make us a desirable partner for pharmaceutical companies.
- **Position ourselves to be a partner of choice for thin film drug delivery technology through vertical integration.** We will continue to maintain and control critical capabilities in tastemasking and analytical development, global formulation, manufacturing and packaging of thin film. We are dedicated to a model of vertical integration and have invested significantly to develop an operational infrastructure that we believe will position us to seamlessly commercialize products in concert with our partners' respective sales forces. We believe our vertical integration benefits our partners by allowing us to: (i) research, develop, manufacture and package more quickly and cost effectively than if we were dependent on others; (ii) better develop and protect our intellectual property and institutional expertise; (iii) reduce the risk of third-party performance and quality; and (iv) better manage compliance related to pharmaceutical manufacturing standards.
- **Continue to develop our intellectual property portfolio to position ourselves as a market leader in thin film drug delivery technology.** We believe our existing intellectual property portfolio in thin film drug delivery is a significant source of competitive advantage. We intend to continue to develop our thin film intellectual property portfolio in areas such as film composition, drug uniformity, tastemasking, methods of manufacture and packaging. We believe our intellectual property portfolio provides us with significant protection against competition.
- **Continue to commercialize products in the OTC marketplace.** In the near term, we intend to continue to develop and commercialize OTC pharmaceutical products utilizing our proprietary thin film drug delivery technology. The process for regulatory approval of most OTC pharmaceutical products, the monograph system, should enable us to leverage our existing research and development capabilities and operational infrastructure to generate near-term revenue and cash flow. We believe that continued commercialization of OTC products utilizing

## Industry Overview

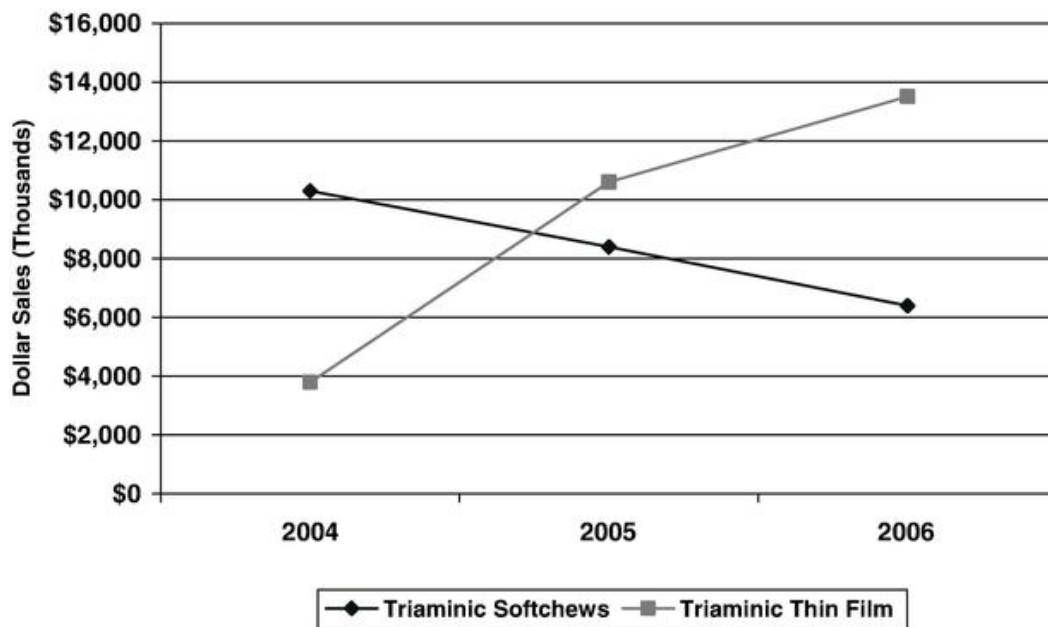
### Drug Delivery Methods

Drug delivery companies apply proprietary technologies to create pharmaceutical products that improve the administration, absorption, efficacy, differentiation or cost of marketed pharmaceutical products. Drug delivery and related technologies have facilitated the improved delivery of drugs through a variety of means including oral (through controlled release, quick dissolve and liquids), injection, transdermal (through the skin), transmucosal (through the mucous membranes of the nose and mouth), intranasal and pulmonary methods. According to Front Line Strategic Consulting, U.S. sales of advanced drug delivery systems was \$64.1 billion in 2005 and is projected to increase to approximately \$153.5 billion by 2011. Thin film drug delivery was first introduced into the market in late 2004, and sales as a percentage of the aggregate market for advanced drug delivery systems in 2005 were less than .02%. Based on this information, we believe the thin film drug delivery opportunity is substantial and untapped.

Drugs incorporating rapid-dissolve technology, like thin film, are particularly suitable for use by children, geriatric patients, and individuals with certain physiological conditions that create a difficulty in swallowing, or dysphagia. In addition, according to industry data, forty percent of people report problems swallowing tablets. Since rapid-dissolving dosage forms containing drugs are easier to swallow and often incorporate tastemasking technology, they have the potential to enhance patient compliance relative to conventional tablets. Furthermore, when compared to liquid formulations, rapid-dissolve technology may also improve dosing accuracy resulting in improved patient outcomes.

Thin film strips were first introduced in 2001 by Warner-Lambert Consumer Healthcare in the form of the Listerine PocketPak®. We believe the global success of the product demonstrates consumer acceptance of thin strips. Novartis Consumer Health was the first major pharmaceutical company to launch several thin strip OTC pharmaceutical drug products under its Triaminic® and TheraFlu® brands. As demonstrated in the chart below based on IRI Infoscan data, Triaminic® Thin Strips have significantly outsold Triaminic® Softchews, its rapid dissolve alternative, since its introduction into the market.

**Triaminic® Thin Strips and Triaminic® Softchews Sales Trends**



Other thin film products on the market today include Prestige's subsidiary's, Medtech Products Inc., or Medtech, Chloraseptic® strips for sore throat, Pfizer's Sudafed PE® phenylephrine strips, and Novartis' Gas-X® simethicone strips. Of these products, only Chloraseptic® employs our technology.

### ***Trends in the Pharmaceutical Industry***

Growth in the drug delivery industry is being driven by several significant trends in the healthcare industry. We believe pharmaceutical companies are becoming increasingly focused on life cycle product management. Life cycle product management is an issue due to expiring patents, generic encroachment and declining new drug pipelines. In addition to life cycle management, other trends in the pharmaceutical industry include an increase in direct-to-consumer marketing and the continued influence of managed care on reducing costs of treatment. The following is a more detailed discussion of these trends:

- **Drug patent expiration and increased generic competition.** We believe that pharmaceutical companies will adopt innovative drug delivery systems as a means of enhancing patient benefits and differentiating themselves from competition while preserving or increasing market share over the life cycle of a product. There are 83 major drugs, each with 2006 U.S. sales of \$100 million or greater, that are expected to lose patent or exclusivity protection through 2012. Collectively, these drugs represent 2006 U.S. sales of approximately \$95 billion, or 40% of the total U.S. retail pharmaceutical market. As a result, many pharmaceutical companies are increasingly focused on product life cycle management to protect the revenue from these products. One way that pharmaceutical companies are enhancing existing drug products is with innovative drug delivery technologies. These enhancements may include increased efficacy, improved compliance, reduced side effects and more convenient administration, any of which may provide a significant advantage over existing and future competition. We believe that pharmaceutical companies will continue to use drug delivery systems to preserve or increase market share, enhance efficacy, and extend product revenue life cycles. Generic competition occurs when a generic company markets a product that a pharmacist may substitute for the branded product in the event that the physician's prescription allows for substitution. In all states, except California, a pharmacist can substitute a generic product for a branded product solely where the FDA has confirmed therapeutic equivalence, also known as an "AB" rating, for the generic product. To obtain an "AB" rating, a generic company must demonstrate that its generic product contains the same drug, results in comparable drug blood levels to the branded product and is in the same dosage form. We believe our thin film will not be "AB" rated with either conventional tablets or capsules, or with orally dissolving tablets, or ODTs, since thin film is considered to be a different dosage form by the FDA.
- **Declining new drug pipelines.** In recent years, the development of new drugs has slowed dramatically while the cost of developing new drugs has increased. From 1996 to 2003, the number of new drug molecules approved annually by the FDA declined 60% and the number of new drug applications dropped by 45%. Also, according to industry data, by 2004 new drug research and development spending approached \$40 billion a year, but the number of new drugs approved per year had fallen. This slowdown in new drug approval is occurring at the same time that the pharmaceutical industry is facing patent expirations on major revenue producing drugs. As a result, we believe that pharmaceutical companies are motivated to find new ways of marketing existing drugs, in part through the use of advanced drug delivery technology such as thin film.
- **Increased direct-to-consumer marketing is raising consumer awareness and demand for alternative dosage forms.** In recent years, pharmaceutical companies have brought tremendous resources to bear on direct-to-consumer advertising and education efforts. According to a November 2006 U.S. Government Accountability Office study, the amount that drug companies

spent on direct-to-consumer advertising between 1997 and 2005 increased twice as fast as spending on promotion to physicians or on research and development. IMS Health estimated that, from 1997 through 2005, spending on direct-to-consumer advertising in the United States increased from \$1.1 billion to \$4.2 billion, an average annual increase of almost 20%. We believe this increased spending on direct-to-consumer marketing has raised consumer awareness of and demand for products that incorporate unique and innovative drug delivery technologies, such as film strip technology.

- **Influence of managed care.** The Centers for Medicare & Medicaid Services estimates that healthcare spending through 2016 will grow at an average annual growth rate of 6.9%, with total health spending in that period of about \$33.4 trillion. To address this issue, managed care providers and other insurers are keenly interested in products and technologies that help increase patient compliance thereby lowering the overall cost of treatment. Since the elderly, infant and juvenile patient populations typically have more frequent dosing requirements and a higher incidence of difficulty swallowing traditional oral solid dosage forms, we believe that physicians, patients, as well as managed care providers and other insurers, will seek out products incorporating advanced drug delivery systems to address the needs of these populations where compliance and accurate dosing are essential to proper treatment.

## **Our Solution**

We have developed a thin film drug delivery technology that we believe will be embraced by patients, prescribing physicians, healthcare providers, and pharmaceutical drug marketers. Our thin film, which is similar in size, shape and thickness to a postage stamp, dissolves quickly in the mouth and effectively hides the taste of the drug it contains. We believe these qualities render our thin film easy to use and consequently will improve patient compliance, providing a significant benefit to patients, their prescribing physicians and healthcare institutions. By incorporating approved drugs with soon to expire or expired patents into our thin film, we believe we can extend their patent lives and help protect the billions of dollars of drug revenues important to our existing and future pharmaceutical partners. Furthermore, we are building the infrastructure required to produce our thin film rapidly and at scale. We believe this combination creates a compelling partnering proposition for pharmaceutical companies who are in need of significant differentiation from branded competitors and generic drug manufacturers.

We believe that our thin film drug delivery technology will have strong physician, patient and consumer acceptance. Evidence of this acceptance can be seen in the OTC pharmaceutical market where thin film pharmaceutical products have increased brand share and provided consumers with a preferred alternative to conventional tablets, orally dissolving tablets and other dosage forms. We believe our thin film drug delivery technology possesses several key advantages over existing drug delivery forms such as convenience, ease of dosing, portability and absence of the need for water or liquids; improved dosing accuracy relative to liquid formulations; accurate administration of drugs for the pediatric, geriatric and mentally ill patients where proper dosing can be difficult; and provides an easy alternative to patients with swallowing disorders and those who dislike taking other solid dosage forms such as tablets or capsules.

For many of the same reasons we think our thin film delivery technology will appeal to physicians, patients, and consumers, we also believe our thin film drug delivery technology will appeal to healthcare providers. Compared to quick-dissolve tablet technologies, our strips disintegrate faster, are more durable, have excellent stability and are cost effective. In addition, our thin film accommodates unit dose packaging, is highly portable and is discreet. Because our thin film is easy to use, we believe our thin film technology may be a more effective means of drug delivery and may reduce the burden of repetitive daily dosing. Consequently, we believe our thin film will improve patient compliance with prescribed drug regimens reducing the need for repeat treatments.

We also believe our thin film drug delivery technology offers prescription pharmaceutical companies a compelling value proposition by enabling them to better manage the revenue life cycles of their products. Not only does our thin film drug delivery technology offer a unique ability to extend pharmaceutical product life through a non-"AB" rating but we also believe that our thin film drug delivery technology provides the essential characteristics necessary for product differentiation, performance and compliance with global drug standards. These characteristics include (i) limited clinical data requirements (505(b)(2) application, abbreviated new drug application, or ANDA, or European Union Mutual Recognition Procedure regulatory pathways), (ii) speed of dissolution, (iii) load capacity or ability to carry the drug, (iv) compatibility with tastemasking techniques, (v) manufacturing scalability, (vi) content uniformity, (vii) stability, (viii) an extensive and protective intellectual property portfolio and (ix) a highly differentiated patient friendly delivery form. Furthermore, we are dedicated to thin film as a drug delivery dosage form and have created a vertically integrated infrastructure to ensure leadership capabilities in drug tastemasking, analytical development, global formulation development, manufacturing and packaging.

We believe that our thin film technology is superior in its intellectual property portfolio position, ability to carry higher drug loads, better tastemasking performance, superior physical characteristics (reduced brittleness, increased pliability and resistance to tear), the ability to resist picking up water or moisture resulting in a more stable drug, shorter disintegration times at higher drug loads, excellent film casting efficiency, ease of packaging and greater final product yields.

## **Our Product Development**

We plan to develop and market our innovative thin film strip products in the prescription drug and OTC markets by pursuing four distinct revenue-generating strategies: (i) self-funded initiatives, or SFIs; (ii) partnered existing prescription products; (iii) partnered new prescription products; and (iv) partnered OTC pharmaceuticals and other products. We have identified and undertaken a number of self-funded initiatives, or SFIs, to develop thin film versions of existing products, which we ultimately intend to bring to market with a partner. We have also been engaged by pharmaceutical partners to develop thin film versions of existing prescription products. In the future, we expect to partner with pharmaceutical companies to deliver new prescription products with improved efficacy. We also expect to continue to develop and commercialize thin film products in the OTC and consumer marketplace.

We do not currently have any thin film versions of existing prescription products in commercial production; however, we expect to have thin film versions of existing prescription products available for commercialization in 2009, pending regulatory approval. The thin film OTC drug and other products that we currently have in commercial production are Dextromethorphan Hydrobromide; Benzocaine (Chloraseptic®), Pectin and Menthol (Breathe Right®), Specialty Flavor Application (Marlboro®) and Chlorine Dioxide (TheraBreath®).

### ***Self-Funded Initiatives***

We are developing thin film versions of a series of major revenue producing prescription drugs. We believe that these products can be approved on the basis of limited clinical data and on a development to approval timeline of 24 to 30 months. We plan to advance development of these initiatives until we realize certain product-specific development milestones, at which point we expect to attract partners with whom we will commercialize these film products. We have a large pool of drugs to choose from for thin film development because we believe our technology can be applied to over 400 drugs due to its load capacity. As a result, there are many candidates suitable for development utilizing our thin film drug delivery technology and we intend to carefully evaluate those candidates to determine their suitability for internal development.

The following chart summarizes potential SFI candidates by therapeutic category, number of candidates within each category and market opportunity based on 2005 worldwide sales:

### Potential Self-Funded Initiative Candidates

Category	Number of Candidates	2005 Global Category Market Value in U.S. \$ (Billions)
Anti-Psychotics	5+	\$ 11.0+
Pain	15+	6.0+
Neurodegenerative Disease Treatments	12+	4.5+
Urinary Incontinence	7	3.0+
Anxiety/Depression	20+	15.0+
Erectile Dysfunction	3	2.5+

We believe that these products can be approved on the basis of limited clinical data through the 505(b)(2) or ANDA regulatory pathways. For additional information, see the section of this prospectus entitled "Government Regulation." As thin film versions, these prescription drugs can strategically enter the global marketplace to minimize generic encroachment and in some cases allow sufficient marketing time to effectively replace the current dosage form with our non-generically substitutable film. In doing so, the drug's innovator can preempt generic introductions and retain the brand's sales and market share beyond ordinary patent expiration.

We are currently self-funding the development of the following pharmaceutical products:

### Self-Funded Initiatives

Brand Name	Drug	Patent Expiration	Category	U.S. Sales (Billion)*	Status
Ambien®	Zolpidem Tartrate	Expired	Sleep	\$ 2.3	In Pilot Bioavailability/Bioequivalence Clinical Trial; Suitability Petition Filed with FDA
Zofran®	Ondansetron HCl	Expired	Nausea/Vomiting	\$ 1.3	Pre-Clinical Work Complete; Pilot Bioavailability/Bioequivalence Clinical Trials Expected Third Quarter 2007; Suitability Petition Filed with FDA
Aricept®	Donepezil HCl	11/10	Alzheimer's Disease	\$ 1.1	In Pre-Clinical Development; Pilot Bioavailability/Bioequivalence Clinical Trials Expected First Half 2008; Suitability Petition Filed with FDA
Lexapro®	Escitalopram Oxalate	3/12	Anti-Depressant	\$ 2.0	In Pre-Clinical Development; Pilot Bioavailability/Bioequivalence Clinical Trials Expected First Half 2008; Suitability Petition Filed with FDA

\* The numbers presented represent the U.S. sales of the existing prescription drugs listed in the table for fiscal year 2006 and are only intended to represent the current size of the market for these prescription drugs. Additionally, these numbers are not meant to be representative of our future thin film product revenues, as we, as a potential thin film drug delivery partner, may only receive a portion of the available revenue at any point in time. The drug targets that we have identified may

### *Zolpidem Tartrate*

Zolpidem is a short-term insomnia medication and has a favorable side effect profile. Zolpidem is marketed by Sanofi-Aventis under the brand name Ambien® and generated sales of \$2.3 billion in 2006.

In April 2007, Ambien® lost patent protection and is presently subject to generic competition. Zolpidem's revenue, dose, patent expiration, compatibility with our dosage form and category competitive needs make it an ideal choice for development utilizing our thin film drug delivery technology. Our zolpidem thin film is currently in pilot bioavailability/bioequivalence clinical trial.

### *Ondansetron HCl*

Ondansetron is a selective 5-HT<sub>3</sub> receptor antagonist approved and commonly used to prevent nausea and vomiting due to chemotherapy, radiation treatments and following surgical procedures. Ondansetron is marketed by GlaxoSmithKline plc, or GSK, under the brand name Zofran® and generated sales of \$1.3 billion in 2006.

In December 2006, Zofran® lost patent protection and is presently subject to generic competition. Zofran's® revenue, dose, patent expiration, compatibility with our dosage form and category competitive needs make it an ideal choice for development utilizing our thin film drug delivery technology. Our dosage form makes it easier to administer ondansetron, especially for those patients who have difficulty swallowing after chemotherapy. Dosing with our thin film does not require water which may help to reduce further nausea due to the need for liquids in taking other dosage forms. Our ondansetron thin film is scheduled for pilot bioavailability/bioequivalence clinical trials in the third quarter of 2007.

### *Donepezil HCl*

Donepezil is an acetylcholinesterase inhibitor that is used as a treatment for Alzheimer's Disease. Donepezil is marketed by Eisai Inc. under the brand name Aricept® and generated sales of \$1.1 billion in 2006.

In November 2010, Aricept® is expected to lose its patent protection and be subject to generic competition. Aricept's® revenue, dose, future patent expiration, compatibility with our dosage form and category competitive needs make it an ideal choice for development using our thin film drug delivery technology. Our dosage form makes it easier to administer donepezil, especially to those elderly patients who have difficulty swallowing traditional dosage forms, such as tablets. We believe our thin film provides an immediate ease of use benefit for both the patient and the caregiver. Complete and swift dosing associated with thin film drug delivery also may reduce caregiver anxiety. Our donepezil thin film is currently in pre-clinical development and we expect to conduct pilot bioavailability/bioequivalence clinical trials during the first half of 2008.

### *Escitalopram Oxalate*

Escitalopram is in a class of drugs called selective serotonin reuptake inhibitors. It is approved for depression and generalized anxiety disorders. Escitalopram is marketed by Forest Laboratories, Inc. under the brand name Lexapro® and generated sales of \$2.0 billion in 2006.

In March 2012, Lexapro® is expected to lose its patent protection and be subject to generic competition. Escitalopram's revenue, dose, future patent expiration, compatibility with our dosage form and category competitive needs make it an ideal choice for development utilizing our thin

film drug delivery technology. Our escitalopram thin film is currently in pre-clinical development and we expect to conduct pilot bioavailability/bioequivalence clinical trials during the first half of 2008.

**Our Partnered Products**

We are currently engaged with pharmaceutical partners to develop thin film versions of existing prescription products. The following is a chart summarizing our disclosed partnered prescription products:

**Disclosed Partnered Prescription Products**

<b>Product</b>	<b>Category</b>	<b>Partner</b>	<b>Status</b>
Ketorolac	Menstrual Pain	UMD Inc.	Pre-Clinical Work Complete
Multiple Products	Respiratory	Adams Respiratory Therapeutics, Inc.	In Product Development(1)

(1) Our products are in various stages of the product development process including drug sourcing, tastemasking (if appropriate), film composition development and preliminary stability to support clinical investigation and potency requirements.

We have entered into pharmaceutical partner-funded agreements with companies to develop bioequivalent, thin film versions of existing drugs. We anticipate pursuing these products through either the 505(b)(2) or ANDA regulatory pathways. Under partnership agreements, our pharmaceutical partners fund the development program, regulatory submission and ultimately advertise, promote and market the new thin film product. One of the companies we have partnered with is Adams Respiratory Therapeutics, or Adams, for a thin film product for certain respiratory indications.

We also currently, and in the future, expect to partner with pharmaceutical companies to deliver new prescription products with improved efficacy. Such improved results may be achieved through, for example, sublingual delivery (under the tongue) for those drugs suitable for absorption in that manner. Over the life of our relationship with a partner we could potentially enter into separate agreements for development fees, milestone payments, manufacturing fees and royalties as a percentage of sales. We believe these products have the potential to offer maximum value but also involve longer development timelines and more rigorous clinical requirements compared to our bioequivalent thin film versions of existing pharmaceutical products. We anticipate pursuing approval of these products with our partners through the new drug application, or NDA 505(b)(1), or 505(b)(2) regulatory pathways. One of the improved products we are developing, in conjunction with UMD Inc., is a vaginal film to treat menstrual pain. To date, this thin film product has achieved successful proof of principle bioavailability studies.

We have had no proof of principle prototype development failures to date. We have also demonstrated the bioavailability of our initial zolpidem tartrate prototype in fasted patients and plan to perform additional pilot studies in the third quarter of 2007 to provide guidance as to bioequivalence.



## Our OTC Pharmaceuticals and Other Products

We are currently developing and expect to market a number of OTC and other products with our partners. The following is a chart summarizing our partnered OTC and other products:

### Partnered OTC Pharmaceuticals and Other Products

Product Brand Name	Category	Partner	Status
Dextromethorphan	Cough	Vita Health Products, Inc.	Commercialized(1)
Diphenhydramine HCl	Cough	L. Perrigo Company	Prototypes Complete
Benzocaine <i>Chloraseptic</i> ®	Sore Throat	Medtech Products Inc.	Commercialized(1)
Benzylamine	Sore Throat	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Prototypes Complete
Undisclosed	Undisclosed	CB Fleet Company, Inc.	Prototypes Complete
Pectin and Menthol <i>Breathe Right</i> ®	Anti-Snore	GlaxoSmithKline plc	Commercialized(1)
Specialty Application <i>Marlboro</i> ®	Tobacco	Philip Morris USA Inc.	Commercialized(1)
Chlorine Dioxide <i>TheraBreath</i> ®	Halitosis	Dr. Harold Katz LLC	Commercialized(1)

(1) Commercialized products are being manufactured when ordered by the partner and sold for revenue in accordance with a supply agreement or other arrangement with that partner.

We have entered into an agreement with Prestige's subsidiary, Medtech, to develop and supply thin film containing benzocaine for the Chloraseptic® brand. We have also entered into agreements with L. Perrigo Company, or Perrigo, (for a store brand, diphenhydramine product), and CNS, Inc. (now owned by GSK) to develop and commercialize an anti-snore strip for the Breathe Right® franchise. In addition, we have partnered with Philip Morris USA Inc., or Philip Morris USA, to supply a long lasting specialty application film. We also have a development program in place with Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., or Angelini, for an anti-inflammatory thin film product. The appropriate regulatory pathways will be followed to commercialize these products.

## Competition

We compete with drug delivery companies utilizing advanced technologies involving oral, injectable, patch-based, pulmonary and intranasal administration of pharmaceutical products. We also may compete with pharmaceutical companies seeking to develop and produce their own thin film products. However, some pharmaceutical companies have opted to partner with third-party technology providers rather than develop and manufacture their own delivery technologies in-house. However, such a trend may not continue in the future.

While there are several competitors in the thin film drug delivery market, we believe there are two primary competitors, Adhesives Research and Lohmann Therapie Systems. We compete against these companies to attract and retain partner relationships for the development and manufacture of thin film pharmaceuticals.

We differentiate ourselves through our vertically integrated business model which we believe increases our speed to market, reduces third-party performance risk and increases control from a regulatory perspective. We believe our proprietary composition, tastemasking and manufacturing process provides us with a competitive advantage in thin film.

## **Our Inventors**

We believe our proprietary thin film drug delivery technology is supported by our portfolio of intellectual property. Our senior management and consultants are named inventors on many of our pending patent applications. We believe that we have a strong team of inventors with particular experience in drug delivery and medical sciences. We believe that our portfolio of intellectual property is a source of competitive strength for us.

Our primary inventor to date is Richard C. Fuisz, M.D., one of our consultants. Dr. Fuisz founded Kosmos, the assets of which we substantially acquired in 2004. Dr. Fuisz is a named inventor for our issued Irish patent and on 65 of our pending worldwide patent applications.

Garry Myers, is our senior director of product development. Mr. Myers is a named inventor on 60 of our pending worldwide patent applications.

Dr. Pradeep Sanghvi, is our vice president for pharmaceutical development. Dr. Sanghvi is a named inventor on seven of our pending worldwide patent applications.

A. Mark Schobel is our chief executive officer. Prior to joining us, he was a named inventor on 12 issued patents ranging from controlled release methods to diagnostic devices.

Joseph Fuisz, the son of Dr. Fuisz, is a named inventor on 41 of our pending worldwide patent applications.

## **Intellectual Property**

Developing and protecting our global thin film intellectual property portfolio is a key component of our business strategy. Through our intellectual property we seek to attract partners for our products, deter new entrants from developing competing thin film drug delivery technologies and protect our products from competition. As of June 25, 2007, we had 13 published pending U.S. patent applications, 15 unpublished pending U.S. patent applications, two published pending Patent Cooperation Treaty, or PCT, applications, four unpublished pending PCT Applications, 40 published pending foreign applications, nine unpublished pending foreign applications and one issued Irish patent covering our thin film drug delivery technology. Our total number of patents and pending patent applications, including unpublished applications from all categories, exceeds 84.

Prior to partnering with us, our pharmaceutical company partners perform due diligence on our intellectual property portfolio. This due diligence typically consists of establishing our "freedom to operate." The process of establishing "freedom to operate" consists of determining whether a product using our thin film drug delivery technology can be marketed without infringing the valid rights of third parties, and a qualitative assessment of our future ability to create intellectual property-based barriers to competition from third parties.

A "freedom to operate" analysis generally includes a review of all known issued patents, as well as a review of known published pending art in the field. We believe our partners have reached favorable conclusions with respect to our "freedom to operate." We do not believe that our existing products and product candidates infringe upon the valid thin film intellectual property rights of others.

We believe our global portfolio of patent applications is a significant source of competitive advantage. Our applications seek to cover our product compositions, our use of encapsulation for tastemasking, our manufacturing process, and certain novel packaging embodiments. We believe our most critical patent applications are those that relate to our ability to effectively mask the taste of the drug formulations incorporated into our thin film and to manufacture film in which the drug is uniformly dispersed.

Adoption of our thin film technology depends on our ability to successfully mask the often bitter and poor taste of drug formulations. To achieve this end, we are seeking certain patent claims covering the use of drug encapsulation for tastemasking in thin film products. Encapsulation refers to the coating of drug particles with a polymeric covering sufficient to help mask the taste of the drug particle while maintaining the ability to release the drug for absorption in the stomach. Encapsulation is an efficient method for combining a high ratio of drug to non-drug elements in the tastemasked particle. In fact, we have been able to incorporate as much as 60% drug by mass in our encapsulations. This allows us to deliver high drug loads in a single film. We believe we are the first and only company to commercially apply encapsulation technology in thin film.

We believe the only commercially available alternative to encapsulation for tastemasking is the use of an ion exchange resin to bind the drug, forming a resinate that is less bitter than the drug alone, which then releases the drug in the stomach. The use of ion exchange resins for tastemasking has four significant challenges for its application to thin film. First, ion exchange resins are limited in their application to tastemask drugs due to the specificity of their chemistry. Second, the percentage of drug to non-drug elements in an ion exchange resinate tends to be fairly low, approximately 15-40% and is highly dependent on the drug. This means that the thin film needs to deliver a fairly large amount of resinate relative to the amount of drug that is delivered, thereby reducing the amount of drug which can be delivered by a single thin film dose. Third, ion exchange drug resinates form a new ionic drug complex which may necessitate more extensive safety and clinical investigations to obtain marketing approval from global regulatory authorities. Fourth, a patent covering the use of certain ranges of ion exchange resins for tastemasking in thin film was issued in June 2006 to Pfizer Consumer Health (US Patent 7,067,116). Unless Pfizer Consumer Health is willing to license its technology, it will be difficult for parties other than Pfizer Consumer Health to use ion exchange technology for thin film.

We are also seeking patent protection for our "mother daughter" mixing system technology. In this system, a main batch of water-based coating solution is prepared in the "mother" tank. This solution is then pumped into a "daughter" tank where the tastemasked (encapsulated) active drug is mixed in, and then applied onto a backing paper on which it is dried into film. While one fully mixed daughter tank is being used to feed the coating system, the second daughter tank is charged with drug and polymer and fully mixed. The system is designed to provide a continuous batch coating process of a uniform dispersion thereby minimizing the residence time of the drug active (or encapsulated drug active where encapsulation is used) in the water-based coating solution prior to making film thus maintaining the integrity of the encapsulation. We believe this mixing technology is critically important to enable the use of tastemasked drug encapsulations in thin film, the capability to process some sensitive drugs that may tend to degrade over time in an aqueous environment and the ability to maintain uniform film performance at large batch scales. This translates into film with better and more consistent tastemasking. It also allows us to be more efficient in our manufacturing process and ensures consistent drug release as compared to films containing encapsulated drug manufactured without this system.

Content uniformity is a requirement for all solid dosage forms. We need to maintain uniform dispersion of drug in our coating solution, during the application of the coating solution to the substrate, and during the ensuing drying process. We also have certain patent applications relating to our controlled film drying process, and the use of bottom drying in the initial stages of the film drying process. We believe that our process of controlled drying is critical to maintaining content uniformity of the drug during the drying process.

Collectively, we believe our extensive global portfolio of patent applications covering our compositions, methods of manufacture, particularly as they relate to tastemasking and uniformity, and other critical aspects of our thin film drug delivery technology have the potential to create significant barriers to entry for potential competitors.

We own, through assignment to us by our inventors, all of our pending thin film patent applications as well as our issued thin film patent in Ireland. We have not licensed any thin film patents from third parties. Our rights to practice and enforce our patent, and patents resulting from our

portfolio of pending applications, are thus unrestricted except to the extent we have agreed to license these applications to third parties.

We have entered into license obligations with our customers in two contexts: funded development agreements whereby customers pay us to develop new thin film products, and commercial supply agreements whereby we have agreed to supply customers with thin film products. Because our agreements are individually negotiated, the terms of each agreement may vary.

*Development Agreements.* As a general matter, we seek to retain intellectual property rights as much as possible at the development agreement stage, in part because our development partners are typically not contractually bound to move from successful development into commercial distribution. In our OTC development agreements, we have not licensed intellectual property rights in connection with such development. It is however possible that we may do so in the future, particularly for high value OTC targets.

In our development agreements for prescription drugs, we have entered into certain contingent licenses with our partners. In certain instances, we have agreed that, with respect to new intellectual property that we create, if any, in connection with the funded development work, we will license such new intellectual property exclusively to our customer for a defined field of use (which can be active pharmaceutical ingredient and/or based on a therapeutic category). If no new intellectual property arises, then we do not license anything. Additionally, we have retained exclusive intellectual property rights outside of the field. We have also entered into a funded development agreement for prescription candidates under which we have no license obligation at the development stage, like our OTC development agreements.

*Commercial Supply Agreements.* In our commercial supply agreements, we have licensed our intellectual property in a number of different ways. In a number of our OTC supply agreements, we have created an implied license to our thin film intellectual property by agreeing to supply a product, and by agreeing to exclusively sell certain products to such customers for a defined territory. However, we do not charge a royalty or grant explicit license rights. In other agreements, we charge a royalty based on level of sales. This royalty does not expire so long as we are supplying the product but does terminate on a country-by-country basis upon the market introduction of a competing thin film strip with the same active ingredient.

To date, we have entered into one commercial supply agreement for prescription drugs. Under the license terms of this agreement, our partner must pay a royalty on net sales of the product for so long as the agreement is in effect. The royalty rate is tiered based on the level of sales, and is subject to reduction solely in the event that an "AB" ratable competing thin film is approved, in which case the royalty will be reduced by the annual sales decrease in our partner's sales, if any.

A practice in the pharmaceutical industry is to refrain from investing resources where the potential for intellectual property obstacles is high. Since we have a number of patent applications pending this may serve as a deterrent to potential entrants. The uncertainty of the type and breadth of coverage that we may obtain may deter companies from making a substantial investment.

In addition, our ability to avoid infringing the patents of third parties is also a source of competitive strength in intellectual property.

Of course, when additional patents issue, such patents may be enforced where third parties infringe such patents. We have several very important patent applications relating to certain polyethelene oxide based compositions which are unique to the industry and provide significant advantages over conventional film-forming compositions. These advantages include relatively high drug loading, and a very flexible film which can be reliably packaged and does not require the use of a plasticizer (which may be important for freedom to operate in certain markets).

In addition to our patent strategy, we use trade secrets, know how and continuing technological innovation to develop and maintain our competitive position. The development of our technology and many of our processes are dependent upon the knowledge, experience and skills of key scientific and

technical personnel. We have employment and/or consulting agreements in place with all of our principal inventors. We require all employees, consultants and advisors to enter into confidentiality agreements that prohibit the disclosure to or use of confidential information by any third party and which assign any invention rights to us. Further, as a matter of company policy, all scientific and technical employees have executed agreements that generally require disclosure and assignment to us of discoveries and inventions made by these individuals while devoted to our activities.

## **Manufacturing and Production**

We currently manufacture film strip products in our current good manufacturing practices, or cGMP, manufacturing facility in Portage, Indiana. Our Portage facility has a bulk film production capacity of approximately 750 million strips per year. Our Portage facility has successfully passed pharmaceutical and governmental audits, including a food inspection by the FDA and a pharmaceutical inspection by the Australian Therapeutic Goods Administration, or the Australian TGA. Our Portage facility is registered with the Drug Enforcement Administration, or DEA, for Class III-V drugs. We also have a research and development laboratory in Kingsport, Tennessee. The Kingsport facility is registered with the DEA for Class II-V drugs. We believe that our current production capacity is sufficient to meet our present output requirements.

In October 2006, we entered into an agreement to lease the Ameriplex facility, a cGMP facility also in Portage, Indiana. Once retrofitted and approved, the Ameriplex facility will become our primary research, development, manufacturing and warehouse location. The Ameriplex facility provides us with the needed space for additional coating lines to meet future expected demand. The new facility and equipment give us greater control and operating efficiency for the products we produce.

In January 2007, we engineered and placed an order for a new second film manufacturing line to fulfill a long term customer supply agreement. The new line will have a maximum capacity of nearly 2.2 billion strips per year. Additionally, we own another smaller film manufacturing line that we intend to upgrade and validate for pharmaceutical products in 2008. We expect that the existing facility, the Ameriplex facility, the additional production capacity and the outsourcing relationships we presently have will allow us to meet our supply requirements for at least the next three years.

The various regulatory requirements to which we are subject, such as the regulations of the FDA, the DEA and the TGA, require us to adhere to cGMP. This standard requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. Our facility has undergone a food inspection by the FDA, a DEA inspection, a TGA drug inspection, and a number of quality and assurance inspections by pharmaceutical companies for cGMP compliance. In each case, our facility has passed inspection. At some point in the future, we will undergo a pharmaceutical inspection by the FDA as well. We are also subject to periodic re-inspection of our facilities.

We purchase our raw materials from qualified, approved vendors both domestically and internationally. We only have one "sole supplier" agreement and typically source raw materials from the lowest cost provider whenever possible. We expect that we will enter into more formal and predictive supply agreements in the future as production volumes increase and are more predictive. Additionally, we purchase active pharmaceutical ingredients, or APIs, from various suppliers in cases where such ingredients are not supplied by our pharmaceutical company partners.

## **Government Regulation**

Our operations are subject to regulation by the federal government, state governments, and certain foreign governments. The Federal Food, Drug, and Cosmetic Act, or FDCA, other federal statutes and regulations, various state statutes and regulations, and laws and regulations of foreign governments govern to varying degrees the testing, approval, production, labeling, distribution, post-market surveillance, advertising, dissemination of information, and promotion of our products. The lengthy process of laboratory, animal and clinical testing, data analysis, manufacturing development, and

regulatory review necessary for required governmental approvals is costly and uncertain, and can delay or prevent product introductions in a given market. Promotion, marketing, manufacturing, and distribution of pharmaceutical products are regulated in all major world markets.

The FDA's regulatory control of product approval directly affects our ability to launch our products in the United States market even though some OTC pharmaceutical products can be launched without the need for FDA product approval. These products are a subset of OTC products, which may be marketed without a specific FDA approval if they conform to a special published regulation of the FDA referred to as an OTC monograph.

### ***OTC Products***

OTC products are those that are available to consumers without a prescription. They are available to consumers without a prescription because they can be labeled for safe and effective use without the supervision of a physician or other professional healthcare provider. In the United States, the FDA establishes OTC drug monographs for particular product classes, such as cough and cold products. The monographs specify permissible active ingredients, labeling and indications. Products that conform to a monograph may be marketed without a specific FDA approval. OTC products that do not conform to an OTC monograph generally require review and approval through a new drug application, or NDA, abbreviated new drug application, or ANDA, or 505(b)(2) application.

### ***Prescription Drugs***

Most prescription drugs marketed in the United States must be approved by the FDA before they can be lawfully marketed. In the case of an existing prescription drug that has already been approved by the FDA, the FDA will likely need to grant a separate and additional approval if the drug is to be marketed in a new film dosage form. Comparable requirements exist in other countries.

### ***NDA Process***

For innovative, or non-generic, new drugs, an FDA approved NDA is generally required before the drugs may be marketed in the United States. The NDA must contain data to demonstrate that the drug is safe and effective for its labeled uses, and that it will be manufactured to appropriate quality standards. In order to demonstrate safety and effectiveness, an NDA typically must include or reference pre-clinical data from animal and laboratory testing and clinical data from controlled trials in humans. For a new chemical entity, this generally means that lengthy, uncertain and rigorous pre-clinical and clinical testing must be conducted. For compounds that have a record of prior or current use, it may be possible to utilize existing data or medical literature and limited new testing to support an NDA.

Any pre-clinical laboratory and animal testing must comply with the FDA's good laboratory practice and other requirements. In order to initiate a clinical trial, the sponsor must submit an investigational new drug application, or IND, to the FDA or meet one of the narrow exemptions that exist from the IND requirement. Clinical testing in human subjects must be conducted in accordance with the FDA's good clinical practice and other requirements.

The process leading up to the filing of the NDA presents a number of challenges. The FDA may refuse to accept the IND for review if applicable regulatory requirements are not met. Moreover, the FDA may delay or prevent the start of clinical trials if the manufacturing of the test drugs fails to meet cGMP requirements or the clinical trials are not adequately designed. Such government regulation may delay or prevent the study and marketing of potential products for a considerable period of time and may impose costly procedures upon a manufacturer's activities. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot continue without FDA authorization and then only under terms authorized by the FDA.

Success in early-stage clinical trials does not assure success in later-stage clinical trials. Results obtained from clinical activities are not always conclusive and may be susceptible 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 withdrawal of the marketing approval for the product.

Clinical trials involve the administration of the investigational drug to people under the supervision of qualified investigators. Clinical trials must be conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. These protocols are submitted to the FDA as part of the IND.

An independent institutional review board, or IRB, must review and approve each trial before it can begin, and these trials must be deemed adequate and well controlled to determine the safety and efficacy of the drug for each indication. Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Phase I includes the initial introduction of an IND into a small number of humans. These trials are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These trials are designed to determine the metabolic and pharmacologic actions of the drug in humans and the side effects associated with increasing doses as well as, if possible, to gain early evidence on effectiveness. Phase II usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and preliminarily evaluate the efficacy of the drug for specific indications. Phase III trials are large trials used to further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that we will successfully complete Phase I, Phase II or Phase III testing within any specified period of time, if at all. Furthermore, clinical trials may be suspended at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDA can, and does, reject new drug applications, require additional clinical trials, or grant approvals on only a restricted basis even when product candidates performed well in clinical trials. The FDA regulates and typically inspects manufacturing facilities, equipment and processes used in the manufacturing of pharmaceutical products before granting approval to market any drug. Each NDA submission requires a substantial user fee payment, unless a waiver or exemption applies. The FDA has committed generally to review and make a decision concerning approval on an NDA within 10 months, and on a new priority drug within six months. However, final FDA action on the NDA can take substantially longer, and where novel issues are presented there may be review and recommendation by an independent FDA advisory committee. The FDA can also refuse to file and review an NDA it deems incomplete or not properly reviewable.

### ***ANDA Process***

In the United States, generic drugs are approved through an abbreviated process based on the submission to the FDA of an ANDA. The ANDA must seek approval of a drug product that has the same active ingredient(s), dosage form, strength, route of administration, and labeling as a so-called "reference listed drug" approved under an NDA, although some limited exceptions may be permitted. For example, an applicant may file a suitability petition with the FDA seeking the agency's approval to file an ANDA for a different dosage form of a drug than the dosage form in the existing reference listed drug. Under the FDA's regulations, the agency will not grant a suitability petition for a change in dosage form if clinical testing would be needed to establish the safety and efficacy of the change. The FDA has previously determined that an applicant could submit an ANDA for famotidine 10 mg (marketed under the brand name Pepcid AC®) in an orally dissolving strip formulation where the reference listed drug is a chewable tablet. In the case of a prescription drug that is currently marketed in a quick dissolve dosage form, management believes, based upon informal discussions with the FDA's

Office of Generic Drugs, that it will be able to file an ANDA for approval of a film dosage form. We can give no assurance, however, that the FDA will make similar determination for our products.

An ANDA generally must contain limited clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at the same rate and to the same extent as the reference listed drug. This is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the reference listed drug. An ANDA may not be approved if the reference listed product is subject to applicable periods of market exclusivity, or if there are valid patents other than manufacturing (process) patents covering the reference listed drug for the ANDA. Special procedures apply when an ANDA contains certifications stating that a listed patent is invalid or not infringed, known as a Paragraph IV certification. If the owner of the patent or the NDA for the reference listed drug brings a patent infringement suit within a specified time after receiving notice of a paragraph IV certification, an automatic stay bars FDA approval of the ANDA for a specified period of time pending resolution of the suit or other action by the court.

The amount of testing and effort that is required to prepare and submit an ANDA is generally substantially less than that required for an NDA. ANDAs typically go through two review cycles at the FDA. The median time to approval can vary, but is likely to approximate 15-18 months.

The first applicant to have an ANDA accepted for filing by the FDA that includes a Paragraph IV certification is awarded a 180-day period of marketing exclusivity. This means that the FDA may not approve another ANDA for that product until the first developer's 180-day period of marketing exclusivity has expired or has been waived. Under current law, the 180-day marketing exclusivity period generally begins with the first commercial marketing of the product, although the exclusivity can be forfeited by failure to market within specified timelines and certain other events, and some products are subject to prior rules under which the 180-day period is triggered by a court determination that the relevant patents are invalid, unenforceable or not infringed.

### ***505(b)(2) Applications***

We currently intend to seek approval of our film versions of drugs that are currently approved in non-rapid dissolve dosage forms by using a type of an NDA referred to as a "505(b)(2) application." Under section 505(b)(2) of the FDCA, 505(b)(2) applications may rely, in whole or in part, on safety or efficacy data that the applicant does not have a right to reference. For example, the applicant can cite published medical literature without a right to reference the underlying study data involved. Under current FDA regulations and policies, 505(b)(2) applications can also be used where the applicant is relying on prior FDA findings of safety or effectiveness regarding another company's NDA but does not qualify for the ANDA process because of some change being made for the new product relative to the existing products. For example, an applicant may seek FDA approval under section 505(b)(2) of a controlled-release formulation of an approved immediate-release formulation of another company. The 505(b)(2) applicant would reference in its application the immediate-release formulation, and submit new data to support the change to a controlled-release formulation. The 505(b)(2) application process may significantly reduce the time and expense of new drug development by eliminating the need for certain duplicative testing.

505(b)(2) applicants must make patent certifications with respect to any reference listed drug in the same manner as ANDA applicants, and the 505(b)(2) applications are also subject to any market exclusivity periods covering a reference listed drug. These patent and market exclusivity protections on products referenced in a 505(b)(2) application may result in the lengthy and uncertain delays of approvals similar to those described above for ANDAs. In addition, there is ongoing debate around the legality of the FDA's interpretation of section 505(b)(2) to permit an applicant to rely upon prior FDA findings with respect to another company's application. If there is a legal challenge to the FDA's



interpretation and the agency's view is invalidated, there would be new limitations on an applicant's ability to use the 505(b)(2) application process rather than conducting its own substantial clinical testing.

### ***Post-Marketing Requirements***

The FDA continues to review marketed products after approval or issuance of an OTC monograph. If previously unknown problems are discovered or if there is a failure to comply with applicable regulatory requirements, the FDA may restrict the marketing of a product, cause the withdrawal of the product from the market, or under certain circumstances seek recalls, seizures, injunctions or criminal sanctions. For example, the FDA may require labeling changes or additional studies for any marketed pharmaceutical product if new information reveals questions about a drug's safety or effectiveness. In addition, in the case of a product subject to an NDA, ANDA, or 505(b)(2) application, changes to the product, the manufacturing methods or locations, or labeling are subject to additional FDA approval, which may or may not be received, and which may be subject to a lengthy FDA review process.

Whether marketed under an approved application or an OTC monograph, all drugs must be manufactured in conformity with cGMP and other FDA regulations and requirements, and pharmaceutical products subject to an approved application must be manufactured, processed, packaged, labeled and promoted in accordance with the approved application. Certain products must also be packaged with child-resistant and senior friendly packaging under the Poison Prevention Packaging Act and Consumer Product Safety Commission regulations. Products that do not comply with these requirements can be considered misbranded and subject to seizure, recall, monetary fines, and other penalties. We must comply with cGMP and product specific regulations enforced by the FDA, and are continually subject to inspection by the FDA and other governmental agencies. Manufacturing operations could be interrupted or halted in any of those facilities if a government or regulatory authority determines that our contract manufacturers do not comply with applicable regulations or as a result of an unsatisfactory inspection.

The distribution of prescription pharmaceutical products is also subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. States require the registration of manufacturers and distributors who provide pharmaceuticals, including in certain states even if these manufacturers or distributors have no place of business within the state but satisfy other nexus requirements, for example, the shipment of products into such state. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples to licensed practitioners and impose other requirements to ensure accountability in the distribution of samples.

Other reporting and recordkeeping requirements also apply for marketed drugs, including for most products requirements to review and report cases of adverse events. Product advertising and promotion are subject to FDA and state regulation, including requirements that promotional claims conform to any applicable FDA approval, and be appropriately balanced and substantiated. OTC drug advertising is also regulated by the Federal Trade Commission. Sales, marketing and scientific/educational programs must comply with applicable requirements of the anti-kickback provisions of the Social Security Act, the False Claims Act, the Veterans Healthcare Act, and the implementing regulations and policies of the United States Health and Human Services Office of Inspector General and United States Department of Justice, as well as similar state laws. Pricing and rebate programs must comply with applicable pricing and reimbursement rules, including the Medicaid drug rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

### **Other Regulatory Requirements**

In addition to the statutes and regulations described above, we are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. We believe that we have complied with these laws and regulations in all material respects, and we have not been required to take any action to correct any material noncompliance. We are unable to predict, however, the impact on our business of any changes that may be made in these laws or of any new laws or regulations that may be imposed in the future. We cannot be sure that we will not be required to incur significant compliance costs or be held liable for damages resulting from any violation of these laws and regulations.

### **Sales And Marketing**

We market directly to leading pharmaceutical companies for products that we believe would benefit from our thin film drug delivery technology. Our strategy has been to leverage the brand equity, clinical, regulatory, marketing and sales capabilities of these pharmaceutical companies to maximize the value of our thin film drug delivery technologies. We will continue to build our credibility with major pharmaceutical companies by speaking at technical seminars, publishing in technical journals and exhibiting at pharmaceutical and drug delivery conferences.

We pursue feasibility or pilot agreements with leading pharmaceutical companies who fund the development of new products incorporating our drug delivery technologies. If the new product development is successful, we generally enter into licensing and supply agreements.

### **Partner Agreements**

We have a number of partner agreements for the development of prescription and OTC thin film drug targets and the commercial supply of products including certain specialty non-pharmaceutical thin film applications. We have generally structured our partner agreements in the framework that is common to the rapid dissolve drug delivery market. Typically, a partner engages us to develop a particular product using specific active ingredients and, where appropriate, apply tastemasking and incorporate flavors. These arrangements are milestone-based and require payment by the partner as each particular milestone is achieved. Once development is underway, we negotiate a long-term commercial supply and licensing agreement with the partner. Revenue is realized under those agreements through the amount paid to us for product supply as well as through royalties. The royalties are calculated as a percentage of product sales. For the years ended December 31, 2006, 2005 and 2004 most of our partners were principally located in the Northeastern and Southeastern parts of the United States.

We believe that the financial terms we have agreed upon with partners are in line with comparable transactions in the rapid dissolve drug delivery market. We believe we are able to attract certain higher value partnerships than traditional rapid dissolve transactions in certain cases because some of our partnerships involve new therapeutic products or total product replacements (i.e. moving an entire product into thin film). In contrast, rapid dissolve technologies have traditionally been limited to line extensions where a company sells a rapid dissolve tablet at the same time it offers a traditional tablet version (e.g. Schering Plough's Claritin® is sold as both a conventional tablet and as a rapidly dissolving Reditab). In 2006, Philip Morris USA, King Pharmaceuticals, Leiner Health Products and Warner Chilcott each accounted for more than 10% of our revenues.

*Adams Respiratory Therapeutics, Inc.* In March 2007, we entered into development, supply and licensing agreements with Adams Respiratory Therapeutics, Inc., or Adams, for a prescription respiratory product. The development agreement includes a work plan for the initial product, which is a thin film containing a respiratory product, and contemplates that the parties may agree on additional products to be developed under the terms of the development agreement. The development milestones

for the respiratory product from development through commercial launch total \$1.5 million. In addition, Adams agrees to pay \$167,000 on each of the second, third and fourth anniversaries of commercial launch. The development agreement also contains rights of first refusal for certain drugs that we or Adams may develop in the future. Pursuant to this right of first refusal, if we develop one of these pharmaceutical products, Adams will have the first right to exclusively market them in the United States. Likewise, if Adams desires to develop one of these drug products, we will have a right of first refusal to develop and manufacture them in the United States. These rights of first refusal are conditioned upon the development of a second thin film product, on terms to be negotiated, within 180 days following the proof of concept bio-study for the respiratory product, but in any case not before the calendar year 2008. In addition to other representations and warranties, we represent in the development agreement that our performance will not, to the best of our knowledge, infringe or otherwise conflict with the intellectual property rights of third parties. The development agreement is for a seven-year term, covers the United States, Canada and Mexico and may be extended at Adams' election for up to three three-year extension terms. In certain circumstances both we and Adams may cancel the development agreement before the term expires. We have agreed to develop the respiratory film product exclusively for Adams.

Our supply agreement with Adams contains standard terms and conditions, and is also for a seven-year term, which may be extended by Adams for up to three three-year extension terms.

Our license agreement with Adams has the same term as the supply agreement, including the same right to extend by Adams, but will remain in effect for an additional seven years in the event Adams terminates the agreement for our breach. The license agreement only applies to the respiratory thin film product. Adams agrees to pay royalties for the respiratory product on annual net sales within the territory of: 5% for the first \$15 million in net sales; 6% on net sales from \$15 to \$25 million; 7% on net sales from \$25 to \$35 million, and 7.5% on all net sales over \$35 million. In the event that a competitor obtains an approval for a competing, "AB"-rated product, our royalty rates are subject to reduction in accordance with a formula based upon the percentage decline in net sales of the product we make. Such a reduction could be material. Adams may terminate the license agreement upon 30 days' notice. Through May 31, 2007, we have not received any revenues from our agreements with Adams.

*UMD Inc.* UMD Inc., or UMD, has engaged us on a purchase order basis to develop a dual film system to vaginally deliver an active ingredient. To date, UMD has paid us \$166,664 for formulation development and the manufacture of clinical supplies, contracted for on a purchase order basis. This product has undergone in vivo testing with favorable results. We are currently negotiating follow-on development work with UMD.

*Philip Morris USA Inc.* In February 2007, we entered into a five-year strategic exclusive supply agreement with Philip Morris USA for the supply of specialty application film strips for use in certain tobacco products. Subject to the agreement terms, Philip Morris USA has agreed to purchase all of its requirements for specialty application film strips for those tobacco products from us. In return, we agree to supply all of Philip Morris USA's requirements up to the amount of the capacity for our new production line which we have agreed to deploy in connection with our entry into this agreement. Philip Morris USA can terminate the agreement if we fail to meet certain service levels. Philip Morris USA may also terminate our strategic supply agreement without penalty if a change in control, including certain changes in the composition of our board of directors occurs as well as under certain conditions. We have made certain representations and warranties to Philip Morris USA, including that the specialty application film strips we provide will not infringe upon the intellectual property rights of third parties. Through May 31, 2007, we have recognized \$558,531 of revenue from this customer and its affiliates under our agreement. We have also recognized \$1,580,721 from Philip Morris USA and its affiliates under previous agreements in prior years.

*Medtech Products Inc.* In October 2006, we entered into a development agreement with Medtech Products Inc., or Medtech, a subsidiary of Prestige. Pursuant to this agreement, we will develop three thin film product prototypes. During this development phase the agreement requires Medtech and us to negotiate a five-year commercial supply agreement, pursuant to which we will agree to supply all of Medtech's requirements for a benzocaine sore throat product, which Medtech will agree to exclusively purchase from us. Our development agreement with Medtech terminates if Medtech does not accept product validation and stability data within 180 days of the end of the development phase. This acceptance may not be unreasonably withheld by Medtech.

*L. Perrigo Company.* In March 2007, we entered into a development and supply agreement with Perrigo. Under this agreement, we are to develop and supply a thin film product containing Diphenhydramine HCl, a cough medication, and will receive payments upon reaching preformulation, pilot stability, and scale-up milestones. This product will be a national brand equivalent to an existing, branded thin film product, and will be exclusive to Perrigo for store brand marketing in the United States and Canada. The initial term of the agreement extends through December 31, 2011. Through May 31, 2007, we have recognized revenues of \$150,000 from our agreement with Perrigo.

*CNS, Inc.—GlaxoSmithKline plc.* We developed an anti-snore thin film product for CNS, Inc. prior to its acquisition by GlaxoSmithKline plc, on a purchase order basis, and have received payments of \$290,870 to date for such development. We have received a purchase order for product launch quantities and are currently negotiating a global supply agreement for the product.

*Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.* In April 2006, we entered into a development agreement with Angelini to develop a thin film product containing benzydamine, a sore throat medication. The initial work order is for \$40,000 in development work, of which \$20,000 has been paid to us.

*Dr. Harold Katz LLC.* In June 2004, we entered into a four-year exclusive agreement with Dr. Harold Katz LLC to supply breath strips to Dr. Harold Katz LLC and its affiliates, together, TheraBreath. This agreement has an initial term of four years, with automatic one year extensions unless one party notifies the other of its intent to cancel within three months of the extension. We also supply TheraBreath with a vitamin product on a purchase order basis. Through May 31, we have recognized revenues of \$277,000 from this agreement.

*Vita Health Products, Inc.* In June 2006, we entered into a development and supply agreement with Vita Health Products, Inc. of Canada, or Vita. Under this agreement, we have agreed to supply two OTC thin film products to Vita for sale in the Canadian market. Vita is responsible for registering the products in Canada. In 2007, we received initial purchase orders from Vita for the two products. The initial term of the agreement is five years.

*C.B. Fleet Company, Inc.* We are developing a thin film OTC product for C.B. Fleet Company, Inc., or Fleet, on a purchase order basis. We also entered into a non-binding term sheet with Fleet in April 2007 which includes terms for the supply and license of this thin film product. Under these terms, we will receive a royalty of 3% to 6% of net sales, our royalty percentage increasing as certain sales volumes are reached, and we will sell the product exclusively to Fleet on a global basis, except for the Middle East and North Africa. Under the non-binding term sheet, Fleet also has the exclusive right to develop a second thin film product for a limited time period. We are working with Fleet on a definitive agreement based upon the non-binding term sheet. The initial work order is for \$153,170. Through May 31, 2007, we have not recognized any revenue under this contract.

*Certain Undisclosed Pharmaceutical Partners.* In December 2006, we entered into a development agreement with a mid-sized global pharmaceutical manufacturer for a thin film that will buccally deliver certain controlled prescription actives. Under this agreement, we will potentially receive payments upon

meeting four different development milestones during the term of the agreement. This agreement has a term of 9 months, unless extended by the customer upon four weeks' notice. The customer is under no obligation to authorize all four development milestones, and may cancel the agreement at any time. Through May 2007, we have billed this customer \$250,000.

In August 2006, we entered into an agreement to develop a thin film that will sublingually deliver certain prescription actives. We have successfully completed preliminary formulation work and demonstrated our ability to achieve acceptable organoleptic performance and content uniformity at a very low drug loading level (i.e., micrograms). This product, should development continue, would entail the submission of a new drug application and will ultimately require dedicated manufacturing. This agreement may be terminated by either us or the customer upon 30 days' notice.

## **Employees**

As of April 23, 2007, we had 63 employees (not including contract and temporary workers). Of these employees, four hold Ph.D. degrees. With the exception of one employee, all of our employees are full-time; 20 of these are directly involved in research and development, and approximately 31 are involved in manufacturing operations, including regulatory affairs.

We are subject to local labor laws and regulations with respect to our employees in those jurisdictions. These laws principally concern matters such as paid annual vacation, paid sick days, length of the workday and work week, minimum wages, pay for overtime, and insurance for workers' compensation.

Our employees are not represented by a labor union. We do not have written employment contracts with most of our employees, and we believe that our relations with our employees are satisfactory.

## **Facilities**

We currently lease an approximately 10,000 square foot facility, including offices, in Portage, Indiana, which houses our research and development, analytical labs and cGMP manufacturing operations. This facility currently has the capacity to produce approximately 1 billion thin film strips per year. Our lease on the Portage facility was entered into in February 2002 and expires (including renewals) in 2010, at which time we have the right to purchase the facility for approximately \$1.3 million. Our current monthly rent for this facility is \$14,304.

We also lease a 400 square foot technology development laboratory in a multi-tenant facility in Kingsport, Tennessee, which is registered with the DEA for Class II-V drugs. The lease was entered into in January 2003 and expires December 31, 2009. Our monthly rent for this facility is currently \$1,300.

We currently lease our 4,140 square-foot headquarters office in Warren, New Jersey. The office is located in a large, multi-tenant technology center. We plan to upfit 600 square feet of this space for laboratory use in 2007. The lease for this facility commenced in July 2006 and expires in 2011. Our monthly rent for this facility is currently \$7,859.

We also are guarantor of a lease for approximately 1,000 square feet of office space in Washington, D.C. The underlying lease was entered into by one of our consultants and expires in May 2007. This space is used as our business development office. We have agreed to extend the lease on a month to month basis.

We also entered into an agreement to lease the 73,000 square foot Ameriplex facility. The lease and renewal options expire in 2021 and also contain a "right of first refusal" option on any potential sale of the property. The rent for the first 18 months of the lease is approximately \$33,500 per month.

## **Legal Proceedings**

We are not currently a party to any material legal proceedings. We may, from time to time, become involved in litigation or other adversarial proceedings based on commercial claims, product liability or other claims.

## MANAGEMENT

### Executive Officers And Directors

Set forth below is the name, age, position and a brief account of the business experience of each of our executive officers and directors as of March 30, 2007:

Name	Age	Position(s)
A. Mark Schobel	51	President, Chief Executive Officer and Director
Keith J. Kendall	49	Executive Vice President, Chief Financial Officer, Treasurer and Secretary
Joseph Fuisz	36	Senior Vice President, Business Development and Licensing
Larry Kranking	60	Senior Vice President, Manufacturing and Operations
Dr. Pradeep Sanghvi	42	Vice President of Pharmaceutical Development
Douglas Bratton	48	Chairman of the Board and Director
Dr. Gregory Brown	53	Director
John Cochran	41	Director
Robert Flanagan	51	Director
Frank Tanki	66	Director

**A. Mark Schobel** has served as our President, Chief Executive Officer and a member of our Board of Directors since November 2005. From March 2001 to November 2005, Mr. Schobel was the Global Head of New Technology and Product Innovation for the Consumer Health Business Unit at Novartis. Prior to Novartis, Mr. Schobel held various general management positions with Reed & Carnrick Pharmaceuticals, Warner-Lambert, and Pharmaceutical Formulations Inc.

**Keith J. Kendall** has served as our Senior Vice President and Chief Financial Officer since July 2006. From February 1999 to June 2006, Mr. Kendall was the Vice President and Managing Director of the Americas for Hewlett Packard Financial Services. Mr. Kendall held a number of positions with AT&T Capital Corporation including President of AT&T Credit Corporation and NCR Credit Corporation from 1985 to 1998.

**Joseph Fuisz** has served as Senior Vice President of Business Development and Licensing since September 2006. From January 2004 to September 2006, Mr. Fuisz served as a business development consultant for Monosol Rx LLC. Mr. Fuisz was a member of the board of Monosol Rx LLC from January 2004 to May 2007. From February 2000 to January 2004, Mr. Fuisz, who co-founded Kosmos Pharma, the assets of which were acquired in January 2004, served as Vice President and General Counsel of Kosmos Pharma. Mr. Fuisz practiced corporate law with the firm of Sullivan & Cromwell LLP from 1996 to 1999.

**Larry Kranking** has served as our Senior Vice President of Manufacturing and Operations since March 2007. Prior to joining us, Mr. Kranking was President of Lang Medikaments, Inc. from January 2005 to May 2006, a contract manufacturing company focused on the production of sterile ophthalmic and parenteral products. From 1996 through 2004, Mr. Kranking was Vice President and General Manager of Eisai Inc., RTP, NC where he managed the design, construction, qualification and FDA approval of its parenteral and solid dose drug development and commercial operations facility.

Mr. Kranking was a board member of the International Society of Pharmaceutical Engineering, or ISPE, from 1989 to 1998 and held the position of President from 1996 to 1997.

**Dr. Pradeep Sanghvi** has served as our Vice President of Pharmaceutical Development since 2004, and is responsible for the technical and regulatory aspects of pharmaceutical formulation. Dr. Sanghvi was previously Director of Pharmaceutical Development at Penwest Pharmaceuticals, an oral drug development company, from October 2000 to February 2004. He also served as Director of Formulations and Process Development at Fuisz Technologies, a fast dissolve company that was acquired by Biovail Technologies, from December 1994 to September 2000.

**Douglas Bratton** has served on our board of directors since 2004. He manages the investment operations of the Edward P. Bass Group of Fort Worth, Texas, or the Bass Group. Since 1983, Mr. Bratton has served as an investment professional with various organizations utilizing alternative asset strategies. Since 1997, Mr. Bratton has been President of Bratton Capital Management L.P., a firm that provides investment management services to the Bass Group.

**Dr. Gregory Brown** joined our board in March 2007. He is currently an independent consultant with over 20 years of combined clinical, operating and healthcare investment experience. From 2003 through 2006, Dr. Brown was a partner at Paul Capital Partners, a global private equity firm. From 1997 through 2002, Dr. Brown was a healthcare investment banker and co-head of investment banking at Adams, Harkness & Hill, Inc. (now Canaccord Adams). Dr. Brown is a member of the board of directors of Oscent Pharmaceuticals Corporation. Dr. Brown was a practicing thoracic and vascular surgeon.

**John Cochran** has served on our board of directors since 2004. He has been a partner of Bratton Capital Management L.P. since October 1998, and is responsible for directing its day-to-day operations. Mr. Cochran is also responsible for the operations of the Crestline Fund of Funds products. Prior to joining Bratton Capital Management L.P., from December 1989 to October 1998 he was employed with KPMG Peat Marwick, L.L.P.

**Robert Flanagan** joined our board in January 2007. Since September 1989, Mr. Flanagan has been Executive Vice President of Clark Enterprises, Inc., a Bethesda, Maryland-based holding company that is the ownership, investment and asset management arm of the various Clark entities. Mr. Flanagan is a member of the board of directors of The Clark Construction Group, Inc., ILD Telecommunications, Martek BioSciences, Eagle Oil & Gas and Castle Brands, Inc.

**Frank Tanki** joined our board in January 2007. He is a certified public accountant and retired in 1998 as a Senior Partner of Coopers & Lybrand, the predecessor of PricewaterhouseCoopers. Mr. Tanki was a member of the Coopers & Lybrand Executive Management Committee from 1994 to 1995 and the Firm Council from 1982 to 1994. He served as the Director of Accounting and SEC Technical Services as well as the Business Assurance Partner In Charge of the New York Practice. He served on the Auditing Standards Board of the American Institute of Certified Public Accountants. Mr. Tanki has been a member of the board of directors of Computer Horizons Inc. since November 2005 and the Nasdaq company, Media Sciences International, Inc. since December 2006.

#### **Board Composition**

We have a board of directors comprised of six (6) members, which we believe will be compliant with the independence criteria for boards of directors under applicable law. We will continue to evaluate our compliance with these criteria over time. To the extent we deem necessary, we will seek to appoint additional independent directors.

## **Board Committees**

### ***Audit Committee***

Our audit committee is comprised of Frank Tanki (chairman), Robert Flanagan and Dr. Gregory Brown. All three members of the audit committee are independent as defined under the applicable listing standards of The Nasdaq Global Market. The board of directors has determined that Mr. Tanki is an "audit committee financial expert" as defined under SEC rules and regulations by virtue of his business background and experience described under "Executive Officers and Directors" above.

Our audit committee is responsible for, among other things:

- overseeing the accounting and financial reporting processes and audits of our financial statements;
- appointing an independent registered public accounting firm to audit our financial statements;
- overseeing and monitoring:
  - the integrity of our financial statements;
  - our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
  - our independent auditor's independence and performance; and
  - our internal accounting and financial controls;
- preparing the audit committee report that SEC rules require be included in our annual proxy statement or annual report on Form 10-K; and
- providing management with the results of its monitoring and recommendations.

### ***Compensation Committee***

Our compensation committee is comprised of John Cochran (chairman), Douglas Bratton and Robert Flanagan. Our compensation committee is responsible for, among other things:

- reviewing and approving executive compensation plans for our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors regarding the compensation policy for such other officers as directed by the board;
- reviewing and making recommendations to the board of directors regarding general compensation goals and guidelines for employees;
- reviewing and making recommendations to the board of directors regarding general guidelines for the issuance of options and other forms of equity based compensation to all employees and consultants;
- preparing a compensation committee report to be included in our annual proxy statement or annual report on Form 10-K; and
- acting as administrator of our current benefit plans, including making recommendations for amendments to the plans.



### ***Governance and Nominating Committee***

Our governance and nominating committee is comprised of Douglas Bratton (chairman), John Cochran and Dr. Gregory Brown. Our governance and nominating committee is responsible for, among other things:

- reviewing board composition, procedures and committees, and making recommendations on these matters to the board of directors;
- reviewing, soliciting and making recommendations to the board of directors and stockholders with respect to candidates for election to the board; and
- overseeing compliance by the board of directors and management with our corporate governance principles and ethics standards and code of conduct.

### **Compensation Committee Interlocks And Insider Participation**

None of the members of our compensation committee was at any time during 2006 one of our officers or employees. No member of our compensation committee and none of our executive officers serve 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.

*Compensation Objectives*

The primary objective of the compensation committee of our board of directors with respect to executive compensation is to attract, motivate and retain the best possible executive talent. Further, we believe that compensation should support our business goals and encourage increased stockholder value. These objectives govern the decision making process with respect to the amount and type of compensation payable to our executive officers. We expect to further implement and maintain, compensation plans that link executive compensation to the achievement of key strategic goals such as the level of earnings and new product commercialization. We believe that this will better align compensation with stockholder value. The compensation program is designed to reward the attainment of both company goals and individual goals.

*Compensation Setting Process*

Total compensation levels for each of our named executive officers are evaluated on an annual basis. In the past, our predecessor company, Monosol Rx LLC and its manager's general partner set compensation levels for each of our named executive officers. In the future, our compensation committee will set compensation with input from our chief executive officer.

During 2006, our manager's general partner relied on publicly available compensation data to establish compensation for our executive officers. As a startup company with significant operating losses, in order for us to attract highly skilled and experienced executive officers and managers, we aggressively bid for candidates in certain situations. In these cases, compensation was determined by industry norms, an individual's current compensation and a compensation premium that would be sufficient enough to attract that individual to work for us. In each of these cases, the manager's general partner and members of our advisory board were an integral part of setting each individual's executive compensation.

Each of our named executive officers is a party to an employment agreement with us that sets forth certain elements of their respective compensation, including base salary. Please see the narrative discussion following the Grants of Plan-Based Awards table for additional information on the employment agreements with our named executive officers.

During 2006, our manager's general partner took into account company performance and individual performance when determining annual bonuses. In setting and assessing company and individual performance, we have not used a predetermined formula or weighted factors. Our company achievement objectives generally relate to the growth of our business and the development of a company infrastructure to support the activities related to that growth. In 2006, our corporate focus was on revenues, customer development, product development and employee skill development. In 2006, the individual objectives generally related to either financial factors such as cash management and capital raising or strategic factors such as pre-clinical and clinical development, regulatory approval of our product candidates and management of our manufacturing operations in meeting cost targets and demand levels for our product and product candidates. The amount of emphasis put on each individual achievement depends on the individual's role within our company. Our manager's general partner also took into account an individual's tenure, position, performance and responsibilities in approving the 2006 bonuses. For the chief executive officer, overall company performance is used to evaluate his individual performance. Please refer to "Discretionary Annual Bonus Opportunity" below for additional information.

Following the completion of our initial public offering, our compensation committee expects to establish a benchmark group of companies in the life sciences and pharmaceutical industries that are

similar to us in terms of stage of development, size, locations and/or job type. The benchmark group would also be representative of the types of companies we would compete with for executives and other employees.

### ***Compensation Components***

Our executive compensation program includes the following five components:

- Base Salary
- Discretionary Annual Bonus
- Long-Term Incentives
- Employee Benefits and Perquisites
- Severance and Change in Control Benefits

We do not have any formal policies for allocating compensation among these components. We consider market pay practices in determining the amounts to be paid, what components should be paid in cash versus equity and what portion of compensation should be short-term versus long-term.

### ***Base Salary***

Base salaries for each of our named executive officers, including our chief executive officer, are determined pursuant to the terms of their individual employment agreements. Base salaries are based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions to ensure that we are able to attract and retain quality candidates. The general partner of our manager has in the past and our compensation committee may in the future have the discretion to increase the base salary of the chief executive officer from time to time, based upon such factors that include, but are not limited to, performance and market levels. Generally, the chief executive officer may increase base salaries of the other named executive officers from time to time in his discretion, based upon such factors that include, but are not limited to, performance and market levels. Please see the narrative discussion following the Grants of Plan-Based Awards Table for additional information on the employment agreements.

### ***Discretionary Annual Bonus Opportunity***

Our executive officers are eligible for annual discretionary bonuses designed to reward the achievement of corporate financial and operational goals, as well as individual performance objectives. Bonus targets are expressed as a percentage of the executive's base salary, as provided in our named executive officers' respective employment agreements. Like our base salaries, the bonus targets set forth in the employment agreements were based on the scope of a named executive officer's responsibilities, taking into account competitive market compensation paid by other companies for similar positions to ensure that we are able to attract and retain quality candidates. Our manager's general partner has in the past and our compensation committee will in the future have the discretion to increase or decrease the bonus above the target percentage of an executive officer's bonus based on the performance of the individual against company and individual goals.

The manager's general partner has in the past and our compensation committee will in the future approve the annual bonus award for the chief executive officer, and for each officer below the chief executive officer level, the bonus award is based on the chief executive officer's performance assessment of each officer. Typically, the bonus is paid in a single installment in the first quarter following the completion of a given fiscal year. Depending on the terms of the executive officer's

employment agreement, a portion of a named executive officer's bonus may be granted in performance units of the company. Please see the narrative discussion following the Grants of Plan-Based Awards Table for additional information on the employment agreements.

Generally, the employment agreements with our named executive officers provide that eligibility for discretionary bonuses is tied to the achievement of company performance targets. In practice, we have taken both company and individual achievement into account. In the past, in setting and assessing company and individual performance, we have not used a predetermined formula or weighted factors. Our company achievement objectives generally relate to the growth of our business and the development of a company infrastructure to support the activities related to that growth. In 2006, our corporate focus was on revenues, customer development, product development and employee skill development. In 2006, the individual objectives generally related to either financial factors such as cash management and capital raising or strategic factors such as pre-clinical and clinical development, regulatory approval of our product candidates and management of our manufacturing operations in meeting cost targets and demand levels for our product and product candidates. The amount of emphasis put on each individual achievement depends on the individual's role within our company. The manager's general partner of our predecessor also took into account an individual's tenure, position, performance and responsibilities in approving the 2006 bonuses. For the chief executive officer, overall company performance is used to evaluate his individual performance.

The level of company and individual achievement is monitored by the chief executive officer and other executive officers on an ongoing basis throughout the year. At the end of the year, as part of each executive officer's evaluation and compensation review, each executive officer's achievement, as well as the executive's contribution to corporate performance, is assessed. The manager's general partner has in the past and our compensation committee will in the future assess the performance of the chief executive officer.

From time to time, special bonuses may be granted in order to attract highly qualified and talented executives. In 2006, Mr. Kendall received a one-time signing bonus when he joined us.

In 2006, the following discretionary bonuses were earned by our named executive officers.

Executive Officer	Position	Actual Bonus Amount Paid	Target Bonus (% of Base Salary)
A. Mark Schobel	President, Chief Executive Officer	\$ 227,500	50%
Keith Kendall*	Executive Vice President, Chief Financial Officer	\$ 158,438	75%
Joseph Fuisz*	Senior Vice President, Business Development and Licensing	\$ 44,660	50%
Dr. Pradeep Sanghvi**	Vice President of Pharmaceutical Development	\$ 64,064	50%
Carl Fischer	(former Chief Financial Officer) current Senior Director, Finance	\$ 32,813	25%

\* These officers joined the company during 2006 and their bonus amounts are pro rated based upon their date of hire.

\*\* Dr. Sanghvi received a pro-rated bonus based upon his eligibility and base salary change under the terms of his employment agreement.

Please refer to the Summary Compensation Table set forth herein for additional information.

For 2007, the manager's general partner of our predecessor determined that discretionary annual bonus awards for each executive officer should be contingent upon the achievement of company and individual performance targets and established our 2007 goals. We intend to rely more heavily on such

company and individual goals and objectives and the measurement of achievement against those goals. We have established a performance management system that outlines the process for setting performance objectives and assessing performance against those objectives. As in the past, these goals continue to generally relate to our growth and continue to emphasize revenues, customer development, product development and employee skill development. Additionally, our individual goals for each executive are in the process of being determined by the chief executive officer and the individual executive, with the oversight and approval of our board of directors. For the chief executive officer, the overall company goals are his individual goals. The individual goals will continue to generally relate to either financial factors such as cash management and capital raising or strategic factors such as pre-clinical and clinical development, regulatory approval of our product candidates and management of our manufacturing operations in meeting cost targets and demand levels for our product and product candidates.

### ***Long-Term Incentives***

We believe that long-term performance is achieved through an ownership culture that encourages long-term participation by our executive officers in equity-based awards. Our incentive plans have been established to provide our current and future directors, officers, consultants and advisors, including our executive officers, with incentives to help align their interests with the interests of our stockholders. We believe that the use of equity-based awards offers the best approach to achieve our compensation goals.

In 2006, equity awards were granted under our performance units plan either upon the commencement of employment or due to antidilution measures with respect to previously granted awards. Equity awards have been negotiated on an individual basis with our named executive officers as part of their overall compensation packages. Equity awards have been made to support our compensation objectives of attracting, motivating and retaining executive talent and have been based upon the scope of a named executive officer's responsibilities, taking into account competitive market compensation paid by other companies for similar positions to ensure that we are able to attract and retain quality candidates.

### ***Performance Unit Plans***

Our predecessor, Monosol Rx LLC, maintained and we have assumed two performance unit plans, or Plan A and Plan B. The performance unit plans provide for distribution of equity interests, subject to repurchase rights, upon certain terminations of employment or change in control transactions, subject to the satisfaction of applicable vesting conditions. The performance units do not have any value until there is a triggering event, such as a termination or change in control, including an initial public offering. At the time of such a triggering event, all outstanding performance units vest automatically and each participant is entitled to a payment in cash or in the same consideration received by us upon the triggering event. Each participant's awards have been for a specific number of units at our predecessor's then current value, or Base Value. An executive officer with multiple awards often has multiple Base Values. The value of the performance units to a participant is based on the spread between our fair value at the time of a change in control and the Base Value of the performance units the participant has been awarded.

Plan A and Plan B are substantially similar. Mr. Fuisz received a grant of performance units in 2004 which is covered by Plan A. All of his subsequent antidilution grants are covered by Plan B, along with the grants made to each of our other named executive officers.

In 2006, several awards were made under Plan B to each of our named executive officers. Mr. Kendall received a grant of awards at the start of his employment pursuant to the terms of his employment agreement. All other awards to our named executive officers were granted as a result of

antidilution measures. We hold their respective equity equivalent interests in the fair market value growth of the company stable at the respective percentages to prevent any dilution of those interests prior to this offering. Those percentages are for Mr. Schobel: 4%; Mr. Kendall: 3%; Mr. Fuisz: 4.5%; Dr. Sanghvi: 1% and Mr. Fischer: 0.5%.

During 2006, there were several potentially dilutive events that necessitated grants to each of the executives. These grants were made consistent with the terms of the performance unit plan and at the then current Base Value. Vesting for these units was consistent with the vesting schedule in the performance unit plan or, if applicable, the executive's employment agreement where vesting terms were specifically negotiated. The performance unit plan vesting schedule is as follows:

	<u>Vesting Percentage</u>	<u>Cumulative Vested Percentage</u>
After Year 1	25%	25%
After Year 2	25%	50%
After Year 3	50%	100%

Messrs. Schobel, Kendall and Fuisz have negotiated vesting schedules that vary from the performance unit plan vesting schedule. Mr. Schobel's performance units vest ratably over three years on the anniversary of his hire in November 2005. Mr. Kendall's units vest ratably every six months over three years from the date of his hire in June 2006. Upon the conclusion of the term of Mr. Fuisz's consulting agreement which is anticipated to be in effect upon the expiration of his amended and restated employment agreement, the vesting of his remaining units will accelerate. If Mr. Fuisz's amended and restated employment agreement is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in his amended and restated employment agreement), then the vesting schedule of his remaining units will not be affected and will bridge any such break in service. We have entered into a letter agreement with Mr. Fuisz which provides for similar continued vesting in the event his employment with, or his engagement as a consultant by, us is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in Plan A).

In addition, the performance units vest automatically upon a change in control.

In 2006, the following performance units were granted:

*Mr. Schobel*

- 02/13/2006—947,203 units at a base value of \$39,473,349
- 03/22/2006—58,820 units at a base value of \$39,473,349
- 06/16/2006—74,032 units at a base value of \$87,500,000
- 09/21/2006—1,583,067 units at a base value of \$100,000,000

*Mr. Kendall*

- 06/16/2006—3,042,408 units at a base value of \$87,500,000

*Mr. Fuisz*

- 03/22/2006—752,590 units at a base value of \$39,473,349
- 06/16/2006—83,869 units at a base value of \$87,500,000
- 09/21/2006—1,767,537 units at a base value of \$100,000,000

- 03/22/2006—194,004 units at a base value of \$39,473,349
- 06/16/2006—18,660 units at a base value of \$87,500,000
- 09/21/2006—392,775 units at a base value of \$100,000,000

*Mr. Fischer*

- 02/13/2006—118,654 units at a base value of \$39,473,349
- 03/22/2006—7,099 units at a base value of \$39,473,349
- 06/16/2006—9,127 units at a base value of \$87,500,000
- 09/21/2006—197,757 units at a base value of \$100,000,000

No awards have been made in 2007 and we do not expect to make further grants pending the completion of our initial public offering. After the merger of Monosol Rx LLC with MonoSol Rx, Inc. and immediately prior to this offering, the outstanding performance units will be exchanged for the common stock of MonoSol Rx, Inc. We intend to discontinue the performance units plans upon the completion of our initial public offering.

If the value per share of our common stock at the time of the initial public offering is assumed to be \$ , we estimate that, immediately before the initial public offering, the aggregate dollar value of the outstanding awards under our performance unit plans will be \$ . All unvested performance units shall vest in an amount equal to the Base Value of the grant and the proportional unit value at the time of the initial public offering. The estimated dollar value of the performance unit awards held by each of our named executive officers at the time of the initial public offering are set forth in the following table:

Executive Officer	Value of Performance Plan Units
A. Mark Schobel	
Keith Kendall	
Joseph Fuisz	
Dr. Pradeep Sanghvi	
Carl Fischer	

**Stock Incentive Plan**

We anticipate that, before the completion of the initial public offering, our board of directors will adopt and our stockholders will approve a new stock incentive plan. Approval of our new stock incentive plan by our stockholders before the initial public offering would satisfy the Nasdaq requirement that equity compensation plans receive stockholder approval and consequently, awards that we make under the stock incentive plan after the completion of the initial public offering will not be subject to further vote by our stockholders. We intend to submit the performance criteria under the long-term incentive plan to our stockholders at or before our first annual meeting of stockholders occurring more than 36 months after the completion of the initial public offering in order to meet certain deductibility conditions of the Internal Revenue Code.

The plan is intended to help us (1) optimize our profitability and growth through long-term incentives that are consistent with our goals and that link the interests of participants to those of our stockholders, (2) provide participants with an incentive for excellence in individual and organizational performance, and (3) provide flexibility to help us attract, motivate and retain the services of participants who make significant contributions to our success.

In general, the plan will be administered by our compensation committee. The compensation committee may delegate its authority to persons other than its members, subject to such limitations as may be imposed by the plan or applicable law or stock exchange rules. In general, our compensation committee will decide who will receive awards under the plan and the terms and conditions of those awards, and will have broad discretion regarding the administration and interpretation of the plan and individual awards made under the plan. Our board of directors has the authority to grant awards and to make other determinations under the plan with respect to non-employee directors.

Our compensation committee or the board of directors, as the case may be, will have the authority to grant various types of awards to employees under the plan, including:

- *Stock Options.* Each stock option represents the right to purchase a specified number of shares of our common stock at a fixed grant price that cannot be less than the fair market value of the shares on the grant date. The plan does not permit re-pricing of any previously granted stock options. The maximum term of a stock option is 10 years from the date of grant. Any option will be exercisable, if at all, in accordance with terms established by our compensation committee. The purchase price of an option may be payable in cash, shares of our common stock (valued at fair market on the day of exercise), or a combination of both. The plan authorizes our compensation committee to grant non-qualified stock options as well as incentive stock options that comply with the requirements of Section 422(b) of the Code.
- *Stock Appreciation Rights.* A stock appreciation right, or SAR, represents the right to receive an increase in the value of a share of our common stock above the value on the date of grant. The maximum term of a SAR is 10 years. A SAR will be exercisable, if at all, in accordance with terms established by our compensation committee. A SAR may be settled in the form of cash or shares of our common stock, as determined by our compensation committee.
- *Restricted Stock and Restricted Stock Units.* Restricted stock and restricted stock units represent grants of our common stock or stock units (consisting of the right to receive shares of our common stock in the future) that are subject to a risk of forfeiture or other restrictions that lapse if and when specified service, performance or other objectives prescribed by our compensation committee are achieved. Any awards will be subject to such conditions, restrictions, and contingencies as our compensation committee determines. Restricted stock units are payable in cash, common stock, or a combination of both, as determined by our compensation committee.
- *Other Awards.* Our compensation committee will have authority to grant other types of share-based incentive awards that are payable in shares of our common stock or their cash equivalent, including, for example, performance shares, performance units and dividend equivalent rights. In addition, our compensation committee may grant cash incentive awards that are conditioned upon attaining prescribed performance objectives. The compensation committee has the discretion to determine the terms and conditions of any such awards.

Our compensation committee will determine the date on which awards are payable and may permit or require a participant to defer payment of all or a portion of an award subject to conditions established by our compensation committee. If awards are paid in shares of our common stock, our compensation committee will determine whether the shares will be subject to transfer restrictions and/or vesting conditions.

We will be authorized to issue up to \_\_\_\_\_ shares of our common stock (adjusted for certain capital changes) under the plan. In applying this limitation, we do not count as issued (and thus add back to the plan's share pool): (a) shares covered by awards that expire or are canceled, forfeited, settled in cash or otherwise terminated, and (b) shares delivered to us and shares withheld by us for the payment or satisfaction of purchase price or tax withholding obligations associated with the exercise or settlement of an award. Also, shares covered by stock-based awards assumed by us in connection with the acquisition of another company or business are not taken into account in determining the number of shares that are or may be issued under the plan.



No awards have been granted under the plan. The exact number of future stock options and other awards that may be allocated to any one individual or group of individuals under the plan is not presently determinable.

Unless it is terminated earlier, the plan will remain in effect until all shares subject to the plan have been purchased, acquired, or forfeited, and all cash awards have been paid or forfeited, pursuant to the plan's provisions. However, in no event may an award be granted after 10 years from the effective date of the plan. During the term of the plan, our board of directors may amend or terminate the plan. Any amendment that would cause the plan to fail to comply with any requirement of applicable law, regulation, or rule if it were not approved by stockholders will not be effective unless our stockholders approve the amendment.

### ***Employee Benefits and Perquisites***

Consistent with our compensation philosophy to attract and retain talent, we intend to continue to maintain competitive employee benefits and perquisites for all employees, including executive officers.

We currently offer the following employee benefits and perquisites to our named executive officers to remain competitive in the marketplace:

- *Healthcare contribution*—We contribute to each named executive officer's health, vision and dental insurance premiums.
- *Moving expenses*—We reimburse our named executive officers for normal moving expenses associated with employment.
- *Life and disability insurance premiums*—We contribute to each named executive officer's life insurance premiums, short-term and long-term disability premiums and accidental death & dismemberment premiums.
- *401(k) Plan and Matching Contributions*—Each of our named executive officers is eligible to participate in the 401(k) plan which allows for a 100% company match on employee contributions up to 6%. The plan provides for immediate participation upon hire and includes a five year vesting period.

For a further description of these benefits, please refer to the Summary Compensation Table set forth herein.

In the future, the compensation committee, in its discretion, may revise, amend or add to the officers' executive benefits and perquisites if it deems advisable. We believe these benefits and perquisites are currently at competitive levels for comparable companies.

### ***Severance and Change in Control Benefits***

The employment agreements with our named executive officers as well as our incentive plans will require us to provide compensation or other benefits to our named executive officers in connection with certain events related to a termination of employment or change in control. For a description of the terms of these arrangements see "Termination of Employment and Change-in-Control Arrangements."

We have established these arrangements because we believe providing executive officers compensation and benefits arrangements upon a change in control is necessary in order for us to be competitive with compensation packages of other similarly situated companies and assists us in recruiting and retaining talented executives. In addition, formalizing our termination and change in control benefits provides us with certainty in terms of our obligations to an eligible executive in the event that our relationship with any such executive is terminated.

### Impact of Tax Treatment on Compensation

In general, a federal income tax deduction is not allowed for annual compensation in excess of \$1,000,000 paid to the chief executive officer or any of the four other most highly compensated officers of a public company. However, qualifying "performance-based" compensation is not counted against this limit. We anticipate that stock options and SARs awarded under our long-term incentive plan will be deemed to be "performance-based" compensation that is not subject to the deduction limit. In addition, certain other awards that may be conditioned by our compensation committee on the attainment of prescribed performance goals may also qualify as "performance-based" compensation that is not subject to the deduction limit. To satisfy the requirements that apply to "performance-based" compensation, the performance measures must be approved by our stockholders, subject to transition relief that would apply generally to grants made before the 2011 annual stockholder meeting. It is expected that the performance measures to be used under a plan will be submitted for stockholder approval at the 2011 annual stockholder meeting (if not sooner).

While we seek to take advantage of favorable tax treatment for executive compensation where appropriate, the primary drivers for determining the amount and form of executive compensation must be the retention and motivation of superior executive talent rather than tax-based considerations.

### Summary Compensation Table

The following table sets forth the compensation for our chief executive officer, our chief financial officer, our former chief financial officer and our two other most highly compensated executive officers for the fiscal year ended December 31, 2006. We have no other executive officers. We refer to these officers collectively herein as our named executive officers.

Name and Principal Position	Salary (\$)	Bonus (\$)	Option Awards(8) (\$)	All Other Compensation (\$)	Total (\$)
A. Mark Schobel President and Chief Executive Officer	\$ 350,000	\$ 227,500	—	\$ 20,983(9)	\$ 598,483
Keith Kendall Executive Vice President, Chief Financial Officer	\$ 156,250(1)	\$ 358,438(5)	—	\$ 1,136(9)	\$ 515,824
Joseph Fuisz Senior Vice President—Business Development and Licensing	\$ 204,889(2)	\$ 44,660(6)	—	\$ 3,900(9)	\$ 253,449
Dr. Pradeep Sanghvi Vice President of Pharmaceutical Development	\$ 242,885(3)	\$ 64,064(7)	—	\$ 12,434(9)	\$ 319,383
Carl Fischer (former Chief Financial Officer)(4)	\$ 172,408	\$ 32,813	—	\$ 14,443(9)	\$ 219,664

(1) Mr. Kendall joined the company on June 16, 2006. Information presented is from June 16, 2006 through December 31, 2006.

(2) Mr. Fuisz worked as a consultant for the period of January 1, 2006 through September 13, 2006 and \$127,500 of his base salary listed above reflects his compensation earned as a consultant. Mr. Fuisz was hired as an employee on September 14, 2006 and \$77,389 of his base salary listed above reflects his compensation earned as an employee.

(3) Under the terms of his employment arrangement in effect during the initial part of 2006, Dr. Sanghvi received an annual base salary ranging from \$176,775 to \$187,500. Effective upon entry into his employment agreement on August 1, 2006, Dr. Sanghvi's annual base salary was increased to \$280,000.

- (4) Mr. Fischer ceased his duties as our chief financial officer on June 16, 2006. He has remained an employee of the company and is currently our senior director, finance, which we do not consider to be an executive officer position. The compensation amounts reflected in the table were based upon his previous employment agreement. His current employment agreement reflecting his role as our senior director, finance was entered into as of January 1, 2007.
- (5) Consists of a signing bonus in the amount of \$200,000 that Mr. Kendall received upon the commencement of his employment and an annual bonus in the amount of \$158,438, pro-rated to his date of hire.
- (6) Mr. Fuisz received a pro-rated bonus in the amount of \$44,660, based on his date of hire.
- (7) Dr. Sanghvi received a pro-rated bonus in the amount of \$64,064, based on the date of his employment agreement.
- (8) In 2006, awards of performance units were made under our performance unit Plan B to each of our named executive officers as follows: Mr. Kendall received a grant of awards at the start of his employment pursuant to the terms of his employment agreement. All other awards to our named executive officers were granted as a result of anti-dilution measures.

These awards of performance units represent a percentage of our ownership in the equity value in excess of a base value equal to our estimated fair value on the date of grant. The performance units do not have any value until there is a triggering event, such as a termination or change in control, including an initial public offering. Accordingly, no equity was recorded for the performance units at the time of their grant. Please see note 14 to our audited financial statements contained elsewhere in this prospectus.

- (9) Includes (i) matching contributions to our 401(k) plan in the following amounts with respect to each named executive officer: for Mr. Schobel: \$17,577, Mr. Fuisz: \$3,237, Dr. Sanghvi; \$9,657 and Mr. Fischer: \$11,631, (ii) premiums paid by us with respect to the medical insurance premiums (health, vision and dental) in the following amounts with respect to each named executive officer: for Mr. Schobel: \$1,408, Mr. Kendall: \$632, Mr. Fuisz: \$210, Dr. Sanghvi: \$1,408, and Mr. Fischer: \$1,408, and (iii) premiums paid by us with respect to the life insurance policies in the following amounts with respect to each named executive officer: for Mr. Schobel: \$1,998, Mr. Kendall: \$504, Mr. Fuisz: \$453, Dr. Sanghvi; \$1,369 and Mr. Fischer: \$ 1,404.

## Grants of Plan-Based Awards

The following table provides information regarding plan-based awards granted during fiscal year 2006 to our named executive officers.

Name	Grant Date(1)	Estimated Future Payouts Under Stock Incentive Plan Awards(2)			All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards(3) (\$/Sh)	Grant Date Fair Value of Stock and Option Awards(4)
		Threshold (#)	Target (#)	Maximum (#)			
A. Mark Schobel	2/13/2006	0	947,203	947,203	0	\$ 0	—
	3/22/2006	0	58,820	58,820	\$	0	—
	6/16/2006	0	74,032	74,032	\$	0	—
	9/21/2006	0	1,583,067	1,583,067	\$	0	—
Keith Kendall	6/16/2006	0	3,042,408	3,042,408	0	\$ 0	—
Joseph Fuisz	3/22/2006	0	752,590	752,590	0	\$ 0	—
	6/16/2006	0	83,869	83,869	\$	0	—
	9/21/2006	0	1,767,537	1,767,537	\$	0	—
Dr. Pradeep Sanghvi	3/22/2006	0	194,004	194,004	0	\$ 0	—
	6/16/2006	0	18,660	18,660	\$	0	—
	9/21/2006	0	392,775	392,775	\$	0	—
Carl Fischer	2/13/2006	0	118,654	118,654	0	\$ 0	—
	3/22/2006	0	7,099	7,099	\$	0	—
	6/16/2006	0	9,127	9,127	\$	0	—
	9/21/2006	0	197,757	197,757	\$	0	—

(1) Consists of performance units granted during 2006 as follows: Mr. Kendall received a grant of awards at the start of his employment pursuant to the terms of his employment agreement. All other awards to our named executive officers were granted as a result of anti-dilution measures. We hold their respective equity equivalent interests in our fair market value growth stable at the respective percentages to prevent any dilution of those interests prior to this offering. During 2006, there were several potentially dilutive events that necessitated grants to each of the executives. These grants were made consistent with the terms of the performance unit plan and at the then current base value.

These awards represent a percentage of ownership in the equity value of the company in excess of a base value equal to our estimated fair value on the date of grant. The equity percentages are as follows: Mr. Schobel: 4%; Mr. Kendall: 3%; Mr. Fuisz: 4.5%; Dr. Sanghvi: 1% and Mr. Fischer: 0.5%.

### Mr. Schobel

- 02/13/2006—947,203 units at a base value of \$39,473,349
- 03/22/2006—58,820 units at a base value of \$39,473,349
- 06/16/2006—74,032 units at a base value of \$87,500,000
- 09/21/2006—1,583,067 units at a base value of \$100,000,000

### Mr. Kendall

- 06/16/2006—3,042,408 units at a base value of \$87,500,000

### Mr. Fuisz

- 03/22/2006—752,590 units at a base value of \$39,473,349
- 06/16/2006—83,869 units at a base value of \$87,500,000
- 09/21/2006—1,767,537 units at a base value of \$100,000,000

### Dr. Sanghvi

- 03/22/2006—194,004 units at a base value of \$39,473,349
- 06/16/2006—18,660 units at a base value of \$87,500,000
- 9/21/2006—392,775 units at a base value of \$100,000,000

- 02/13/2006—118,654 units at a base value of \$39,473,349
- 03/22/2006—7,099 units at a base value of \$39,473,349
- 06/16/2006—9,127 units at a base value of \$87,500,000
- 09/21/2006—197,757 units at a base value of \$100,000,000

- (2) Vested performance units can be redeemed for cash or in the form of the same equity instruments received due to a change in control or an initial public offering, at the discretion of the board of directors. If there is no such triggering event, a participant would receive no amounts payable on the performance units. The target and maximum amounts assume a one-for-one redemption upon a triggering event.
- (3) There is no per unit exercise price for the performance units under the performance unit plans.
- (4) Performance units are only valued at the time of a change in control or other triggering event, including an initial public offering. The performance units do not have any value until such a triggering event occurs. Accordingly, no equity was recorded for the performance units at the time of their grant.

### ***Annual Base Salary and Bonus Overview***

Base salary paid to the named executive officers in 2006 constituted approximately the following percentages of their total compensation as set forth in the Summary Compensation Table: Mr. Schobel: 58.5%; Mr. Kendall: 30.3%; Mr. Fuisz: 80.8%; Dr. Sanghvi: 76.0%; and Mr. Fischer: 78.5%. Discretionary annual bonuses paid to named executive officers in 2006 constituted approximately the following percentages of their total compensation as set forth in the Summary Compensation Table: Mr. Schobel: 38%; Mr. Kendall: 69.5%; Mr. Fuisz: 17.6%; Dr. Sanghvi: 20%; and Mr. Fischer: 14.9%. The base salary and bonus amounts are pro rata based upon the dates of hire of Mr. Kendall and Mr. Fuisz and, for Dr. Sanghvi, reflect the change in his salary and bonus eligibility under his employment agreement.

### ***Employment Agreements***

We have entered into employment agreements with each of our named executive officers. Please see the discussion under "Termination of Employment and Change-in-Control Arrangements" for additional information on our employment agreements.

*A. Mark Schobel.* Mr. Schobel's employment agreement was entered into as of November 17, 2005. Mr. Schobel's employment agreement has a three-year term which automatically renews for additional one-year periods until terminated by us or Mr. Schobel. Pursuant to his employment agreement, Mr. Schobel received an annual base salary of \$350,000 for 2006, which is subject to increase according to the policies and practices we may adopt from time to time and at the discretion of our board of directors. In addition to receiving an annual base salary and standard employee benefits, Mr. Schobel is eligible for a discretionary annual incentive bonus of 50% of his base salary, based on our achievement of established performance targets. If we exceed our performance targets, we may increase the amount of Mr. Schobel's annual bonus. The bonus is to be paid 50% in cash and 50% in cash or in performance units, under the managing partner's discretion in the past and under the compensation committee's discretion in the future. The employment agreement also provides for a grant of performance units under the performance units plan that entitle him to 4% of the growth in the fair market value of the Company over and above the base value assigned to the units at the time they were granted. The base value of the units granted to Mr. Schobel at January 6, 2006 was \$20 million. Mr. Schobel is also entitled to certain anti-dilution rights in connection with his performance units under this agreement. The performance units vest ratably over the term of the employment agreement on the anniversary of his employment.

*Keith Kendall.* Mr. Kendall's employment agreement was entered into as of June 16, 2006. Mr. Kendall's employment agreement has a three-year term which automatically renews for additional one-year periods until terminated by us or Mr. Kendall. Mr. Kendall's annual base salary is set at \$325,000, which is subject to increase based upon performance and other considerations as appropriately determined by our chief executive officer. In addition to receiving an annual base salary and standard employee benefits, Mr. Kendall is eligible for a discretionary annual incentive bonus of a target of 75% of his base salary, based on our achievement of established performance targets. If we exceed our performance targets, we may increase the amount of Mr. Kendall's annual bonus. The bonus is to be paid 66% in cash and 34% in cash or performance units in the chief executive officer's discretion. The employment agreement also provides for a grant of performance units under the performance unit plan that entitle him to 3% of the growth in the fair market value of the company over and above the base value assigned to the units at the time they were granted. The base value of the units granted to Mr. Kendall at June 16, 2006 was \$87.5 million. These performance units vest ratably in six month periods over the term of the employment agreement. Mr. Kendall is also entitled to certain anti-dilution rights in connection with his performance units under this agreement.

*Joseph Fuisz.* Mr. Fuisz's previous employment agreement was entered into on September 14, 2006 and provided for a term of two years and four months, concluding on December 31, 2008. Under the agreement, Mr. Fuisz's base salary is set at \$280,000, which is subject to increase based upon performance and other considerations as appropriately determined by our chief executive officer. In addition to receiving an annual base salary and standard employee benefits, Mr. Fuisz is eligible for a discretionary annual incentive bonus of a target of 50% of his base salary, based on our achievement of established performance targets. If we exceed our performance targets, we may increase the amount of this annual bonus. The bonus may be paid in cash or performance units as determined by the company. Prior to entering into this employment agreement, Mr. Fuisz served as a consultant for business development and legal matters.

On May 12, 2007, we entered into an amended and restated employment agreement with Mr. Fuisz on terms similar to his previous employment agreement. His base salary and bonus structure remain the same. The amended and restated employment agreement, however, provides for a term of 8 months and will conclude on December 31, 2007. There is no automatic renewal provision. Upon the conclusion of the term of the amended and restated employment agreement, and assuming that Mr. Fuisz neither resigns voluntarily nor is terminated for "cause" (as defined in his amended and restated employment agreement), Mr. Fuisz shall return to providing services to us as a consultant on the terms set forth in the form of consulting agreement attached as an exhibit to the amended and restated employment agreement.

*Dr. Pradeep Sanghvi.* Dr. Sanghvi's employment agreement was entered into on August 1, 2006 for a period of three years and automatically extends for additional one year periods unless terminated by us or Dr. Sanghvi. Under the agreement, Dr. Sanghvi's annual salary is set at \$280,000, which is subject to increase based upon performance and other considerations as appropriately determined by our chief executive officer. In addition to receiving an annual base salary and standard employee benefits, Dr. Sanghvi is eligible for a discretionary annual incentive bonus of a target of 50% of his base salary, based upon achievement by us and Dr. Sanghvi of established performance goals. The actual bonus amount may increase if such performance targets are exceeded. Prior to entering his employment agreement with us, Dr. Sanghvi was an at-will employee.

*Carl Fischer.* Mr. Fischer's employment agreement in his capacity of chief financial officer was in effect during 2006. The employment agreement was entered into on December 13, 2005 for a one-year term. Mr. Fischer received an annual base salary of \$175,000 for 2006. In addition to receiving an annual base salary and employee benefits, Mr. Fischer was eligible for a discretionary annual incentive bonus of 25% of his base salary, based on our achievement of established performance targets. The

employment agreement also provides for a grant of performance units under the performance unit plan that entitle him to 0.5% of the growth in the fair market value of the company over and above the base value assigned to the units at the time they were granted. The base value of the units granted to Mr. Fisher at January 6, 2006 was \$20 million. Mr. Fisher was entitled to certain anti-dilution rights in connection with his performance units.

Mr. Fisher's new employment agreement, reflecting his capacity as senior director, finance, was entered into on January 1, 2007 for a period of six months, expiring on June 29, 2007. Mr. Fisher's employment agreement will not automatically extend or renew unless we and Mr. Fisher mutually agree on new terms prior to expiration of the agreement. Under the agreement, Mr. Fisher receives an annual base salary of \$135,000. In addition to receiving an annual base salary and standard employee benefits, Mr. Fisher is eligible for a bonus of 30% of his base salary, pro-rated to reflect the six-month employment term, based upon achievement by us and Mr. Fisher of established performance goals.

During the respective terms of their employment agreements and following the termination of their agreements for any reason as long as the information remains confidential, Messrs. Schobel, Kendall, Fuisz and Fischer and Dr. Sanghvi shall not make use, for his own benefit or for the benefit of a business or entity other than us, of any verbal or written secret or confidential information, so long as the information is confidential.

In addition, Messrs. Schobel, Kendall, Fuisz, Fischer and Dr. Sanghvi may not engage in competitive activities in the area of film based drug delivery systems during the terms of their respective employment agreements and for terms ranging from 12 to 24 months post-employment.

Each of Messrs. Schobel, Kendall, Fuisz and Fischer and Dr. Sanghvi may not solicit any of our employees or customers for terms ranging from 12 to 24 months post-employment.

## Outstanding Equity Awards at December 31, 2006

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2006.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable(1)	Number of Securities Underlying Unexercised Options (#) Unexercisable(1)	Stock Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (1)	Option Exercise Price(\$)(2)	Option Expiration Date(3)
A. Mark Schobel	—	1,393,423	—	—	—
	—	947,203	—	—	—
	—	58,820	—	—	—
	—	74,032	—	—	—
	—	1,583,067	—	—	—
Keith Kendall	—	3,042,408	—	—	—
Joseph Fuisz	—	1,570,795	—	—	—
	—	83,565	—	—	—
	—	305,255	—	—	—
	—	752,590	—	—	—
	—	83,869	—	—	—
	—	1,767,537	—	—	—
Dr. Pradeep Sanghvi	—	235,381	—	—	—
	—	173,316	—	—	—
	—	194,004	—	—	—
	—	18,660	—	—	—
	—	392,775	—	—	—
Carl Fischer	—	174,431	—	—	—
	—	118,654	—	—	—
	—	7,099	—	—	—
	—	9,127	—	—	—
	—	197,757	—	—	—

(1) Our performance units represent a percentage of ownership in the equity value of the company in excess of a base value equal to our estimated fair value on the date of grant. Until there is a triggering event, such as a change in control or an initial public offering, these performance units are not exercisable. The equity percentages are as follows: Mr. Schobel: 4%; Mr. Kendall: 3%; Mr. Fuisz: 4.5%; Dr. Sanghvi: 1% and Mr. Fischer: 0.5%.

Mr. Schobel has a total of 4,056,545 performance units which were granted as follows:

- 11/17/2005—1,393,423 units at a base value of \$20,000,000
- 02/13/2006—947,203 units at a base value of \$39,473,349
- 03/22/2006—58,820 units at a base value of \$39,473,349
- 06/16/2006—74,032 units at a base value of \$87,500,000
- 09/21/2006—1,583,067 units at a base value of \$100,000,000

Mr. Kendall has a total of 3,042,408 performance units which were granted as follows:

- 06/16/2006—3,042,408 units at a base value of \$87,500,000



Mr. Fuisz has a total of 4,563,611 performance units which were granted as follows:

- 01/22/2004—1,570,795 units at a base value of \$12,500,000
- 04/13/2005—83,565 units at a base value of \$17,857,143
- 07/31/2005—305,255 units at a base value of \$17,857,143
- 03/22/2006—752,590 units at a base value of \$39,473,349
- 06/16/2006—83,869 units at a base value of \$87,500,000
- 09/21/2006—1,767,537 units at a base value of \$100,000,000

Dr. Sanghvi has a total of 1,014,136 performance units which were granted as follows:

- 02/23/2004—235,381 units at a base value of \$13,750,000
- 04/13/2005—173,316 units at a base value of \$17,857,193
- 03/22/2006—194,004 units at a base value of \$39,473,349
- 06/16/2006—18,660 units at a base value of \$87,500,000
- 09/21/2006—392,775 units at a base value of \$100,000,000

Mr. Fischer has a total of 507,068 performance units which were granted as follows:

- 12/13/2005—174,431 units at a base value of \$20,000,000
- 02/13/2006—118,654 units at a base value of \$39,473,349
- 03/22/2006—7,099 units at a base value of \$39,473,349
- 06/16/2006—9,127 units at a base value of \$87,500,000
- 09/21/2006—197,757 units at a base value of \$100,000,000

The performance unit plan vesting schedule for Messrs. Fuisz, Sanghvi and Fischer is as follows:

	Vesting Percentage	Cumulative Vested Percentage
After Year 1	25%	25%
After Year 2	25%	50%
After Year 3	50%	100%

Messrs. Schobel, Kendall and Fuisz have negotiated vesting schedules that vary from the performance unit plan vesting schedule. Mr. Schobel's performance units vest ratably over three years on the anniversary of his hire in November 2005. Mr. Kendall's units vest ratably every six months over three years from the date of his hire in June 2006. Upon the conclusion of the term of Mr. Fuisz's consulting agreement, which is anticipated to be in effect upon the expiration of his amended and restated employment agreement, the vesting of his remaining units will accelerate. If Mr. Fuisz's amended and restated employment agreement is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in his amended and restated employment agreement), then the vesting schedule of his remaining units will not be affected and will bridge any such break in service. We have entered into a letter agreement with Mr. Fuisz which provides for similar continued vesting in the event his employment with, or his engagement as a consultant by us is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in Plan A).

- (2) There is no per unit exercise price for the performance units under the performance unit plans.
- (3) Performance units do not expire; they continue until the time of termination or other triggering event.

#### Director Compensation

None of the members of our predecessor Monosol Rx LLC board of directors received any compensation from us during 2006 or any preceding periods.

Upon the closing of this offering, we intend to provide cash compensation and stock options to non-employee members of our board of directors for serving on our board of directors. We will pay each of our non-employee directors \$25,000 per year for serving on our board of directors. In addition to compensation for board services, we will pay the members of our committees \$10,000 per year to each member of our audit committee and \$5,000 per year to each member of our compensation committee and governance and nominating committee. In addition to any payments for being a member of the various committees of our board of directors, we will also pay the chair of the audit committee \$10,000 and the chairs of each of the compensation committee and the governance and nominating committee \$5,000. We will also pay each member of the board of directors \$1,500 per meeting of the board of directors. Members of our board of directors are reimbursed for some expenses in connection with attendance of board and committee meetings.

We anticipate that, before the completion of the initial public offering, our board of directors will adopt and our stockholders will approve a new long-term incentive plan. Upon the completion of this offering, it is anticipated that each of our directors will receive an option to acquire 15,000 shares of our common stock. We expect that this initial grant will vest quarterly over three years. On the date a new director is first elected or appointed to the board of directors, we intend that he or she will automatically be granted an option to acquire 15,000 shares of our common stock on the date of the grant. In addition, upon election of directors each year, we intend that each director will receive an automatic grant of options to acquire 5,000 shares of common stock on a fully diluted basis on the date of the grant. We expect that these options will also vest quarterly over three years.

### **Termination of Employment and Change-in-Control Arrangements**

The types of arrangements that would trigger payments to our named executive officers upon a change in control of the company include employment agreements, our stock incentive plan and our performance unit plans. We have established these arrangements because we believe providing executive officers compensation and benefits arrangements upon a change in control is necessary in order for us to be competitive with compensation packages of other similarly-situated companies and assists us in recruiting and retaining talented executives.

#### ***Employment Agreements***

Please see the narrative discussion following the grants of plan-based awards table for additional information on the employment agreements.

*A. Mark Schobel.* Pursuant to the terms of Mr. Schobel's employment agreement, if Mr. Schobel's employment is terminated due to his disability or death, Mr. Schobel will be entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled under any of our plans;
- accrued, unpaid vacation days;
- a pro rata cash bonus based upon Mr. Schobel's bonus amount from the previous year; and
- any performance units held by Mr. Schobel will vest on a pro rata basis to the date of termination and, at his option, not be subject to repurchase.

If we terminate Mr. Schobel's employment for "cause" (as defined in his employment agreement), Mr. Schobel will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Schobel voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation).

If we terminate Mr. Schobel's employment without "cause" or Mr. Schobel terminates such employment for "good reason," Mr. Schobel will be entitled to receive:

- his base salary for the greater of 12 months or the remainder of his employment term at such intervals as the same would have been paid had Mr. Schobel's employment continued;
- any benefits to which he is entitled to under any of our plans; and
- reimbursement for his cost of purchasing medical benefits for himself under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, (provided COBRA is available and elected) for the greater of 12 months or the remainder of his employment term, but no longer than 18 months or until such time as Mr. Schobel is eligible to receive medical benefits from another person or entity comparable to those provided by us immediately prior to his termination.

In addition to the foregoing benefits, if Mr. Schobel terminates his employment for "good reason":

- he will be entitled to a pro rata cash bonus based upon Mr. Schobel's bonus amount from the previous year; and
- his performance units shall vest on a pro rata basis up to the date of termination and at his option, shall not be subject to repurchase.

If at any time during the initial two year period of Mr. Schobel's employment agreement, we are unable to fulfill our obligations as set forth therein, the managing general partner is required to guarantee payment of Mr. Schobel's base salary for a period of one year, payable in 12 equal monthly installments, less applicable deductions and withholdings.

*Keith Kendall.* Pursuant to the terms of Mr. Kendall's employment agreement, if Mr. Kendall's employment is terminated due to his disability or death, Mr. Kendall will be entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled under any of our plans;
- accrued, unpaid vacation days; and
- a pro rata cash bonus based upon Mr. Kendall's bonus amount from the previous year.

If we terminate Mr. Kendall's employment for "cause" (as defined in his employment agreement), Mr. Kendall will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Kendall voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination, any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation) and a pro rata bonus in cash calculated based upon Mr. Kendall's bonus amount from the previous year.

If we terminate Mr. Kendall's employment without "cause" or Mr. Kendall terminates such employment for "good reason," Mr. Kendall will be entitled to receive:

- his base salary for the greater of 18 months or the remainder of his employment term at such intervals as the same would have been paid had Mr. Kendall's employment continued;
- for the greater of 18 months or the remainder of his employment term, a monthly cash payment equal to one-twelfth of the bonus he received the previous year, pro-rated for any partial month; and
- any benefits to which he is entitled under any of our plans for a period of one year.

Regardless of the reason for Mr. Kendall's termination, within five days of his last day of employment with us, he shall receive a lump sum amount equal to the unvested portion of his 401(k) account.

*Joseph Fuisz.* Pursuant to the terms of the employment agreement that was in effect on December 29, 2006, if Mr. Fuisz's employment is terminated due to his disability or death, Mr. Fuisz will be entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled to under any of our plans;
- accrued, unpaid vacation days; and
- a pro rata cash bonus based upon Mr. Fuisz's bonus amount from the previous year.

If we terminate Mr. Fuisz's employment for "cause" (as defined in his employment agreement), Mr. Fuisz will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Fuisz voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation).

If we terminate Mr. Fuisz's employment without "cause" or Mr. Fuisz terminates such employment for "good reason," Mr. Fuisz will be entitled to receive:

- his base salary for the remainder of his employment term at such intervals as the same would have been paid had Mr. Fuisz's employment continued; and
- any benefits to which he is entitled under any of our plans for the remainder of his employment term.

Pursuant to the terms of Mr. Fuisz's amended and restated employment agreement, which became effective on May 12, 2007, if Mr. Fuisz's employment is terminated due to his disability or death, Mr. Fuisz will be entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled to under any of our plans;
- accrued, unpaid vacation days; and
- a pro rata cash bonus based upon Mr. Fuisz's bonus amount from the previous year.

If we terminate Mr. Fuisz's employment for "cause" (as defined in his amended and restated employment agreement), Mr. Fuisz will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Fuisz voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation).

If we terminate Mr. Fuisz's employment without "cause" or Mr. Fuisz terminates such employment for "good reason," Mr. Fuisz will be entitled to receive:

- his base salary for the remainder of his employment term at such intervals as the same would have been paid had Mr. Fuisz's employment continued; and
- any benefits to which he is entitled under any of our plans for the remainder of his employment term.

Upon the automatic termination of Mr. Fuisz's amended and restated employment agreement on December 31, 2007, we will enter into a one-year consulting agreement with Mr. Fuisz.

Further, if Mr. Fuisz resigns voluntarily or is terminated for "cause," Mr. Fuisz will lose all rights to and interests in the consulting agreement that is to become effective following the term of the amended and restated employment agreement.

*Dr. Pradeep Sanghvi.* Pursuant to the terms of his employment agreement, if Dr. Sanghvi's employment is terminated due to his disability or death, Dr. Sanghvi will be entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled under any of our plans;
- accrued, unpaid vacation days for the year in which the termination occurs; and
- a pro rata cash bonus based upon Dr. Sanghvi's bonus amount from the previous year.

If we terminate Dr. Sanghvi's employment for "cause" (as defined in his employment agreement), Dr. Sanghvi will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation). Likewise, if Dr. Sanghvi voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation).

If we terminate Dr. Sanghvi's employment without "cause," Dr. Sanghvi will be entitled to receive:

- his base salary for the remainder of his employment term at such intervals as the same would have been paid had Dr. Sanghvi's employment continued; and
- any benefits to which he is entitled under any of our plans (with the exception of any bonus and/or incentive compensation) for the remainder of his employment term.

*Carl Fischer.* Pursuant to the terms of Mr. Fischer's employment agreement that was in effect on December 29, 2006, if we terminated Mr. Fischer's employment due to his disability or death, Mr. Fischer was entitled to receive:

- unpaid but earned base salary through the date of termination;
- any benefits to which he is entitled under any of our plans;
- accrued, unpaid vacation days; and
- a pro rata cash bonus based upon Mr. Fischer's bonus amount from the previous year.

If we terminated Mr. Fischer's employment for "cause" (as defined in his employment agreement), Mr. Fischer will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Fischer voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he was entitled under any of our plans (with the exception of any bonus and/or incentive compensation).

If we terminated Mr. Fischer's employment without "cause" (as defined in the employment agreement) or Mr. Fischer terminates such employment for "good reason," Mr. Fischer was entitled to receive:

- his base salary for the greater of 12 months or the remainder of his employment term at such intervals as the same would have been paid had Mr. Fischer's employment continued;
- any benefits to which he is entitled to under any of our plans; and
- reimbursement for his cost of purchasing medical benefits for himself under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (provided COBRA is available and elected) during the "severance period" (as defined in the employment agreement) but no longer than 18 months or until such time as Mr. Fischer is eligible to receive medical benefits from another person or entity comparable to those provided by us immediately prior to his termination.

Under his employment agreement that is currently in effect, if Mr. Fischer's employment is terminated due to his disability or death, Mr. Fischer will be entitled to receive:

- unpaid but earned base salary through the date of termination;

- any benefits to which he is entitled under any of our plans;
- accrued, unpaid vacation days;
- a pro rata cash bonus calculated based upon Mr. Fischer's bonus amount from the previous year; and
- any performance units held by Mr. Fischer will vest on a pro rata basis to the date of termination and, at his option, not be subject to repurchase.

If we terminate Mr. Fischer's employment for "cause" (as defined in his employment agreement), Mr. Fischer will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans. Likewise, if Mr. Fischer voluntarily resigns, he will be entitled to receive his unpaid but earned base salary through the date of termination and any benefits to which he is entitled under any of our plans.

If we terminate Mr. Fischer's employment without "cause," Mr. Fischer will be entitled to receive:

- his base salary for the remainder of his employment term at such intervals as the same would have been paid had Mr. Fischer's employment continued;
- any benefits to which he is entitled to under any of our plans; and
- reimbursement for his cost of purchasing medical benefits for himself under COBRA (provided COBRA is available and elected) during the "severance period" (as defined in the employment agreement) or until such time as Mr. Fischer is eligible to receive medical benefits from another employer, whichever is shorter.

**Performance Unit Plans**

Within the context of the performance unit plans, a change in control is generally defined as an event or series of events (such as a merger, acquisition or reorganization) that result in our beneficial owners immediately preceding the change in control owning less than 20% of the company following the change of control event or an initial public offering as contemplated herein.

Upon a change in control each participant's unvested units immediately vest and we are obligated to make a payment, either in cash or in the same consideration received by us upon the change in control.

Each participant's distribution under the plan would be calculated in the following manner as defined in the plan:

$$\frac{\text{Number of participant's vested performance units}}{\text{Number of outstanding performance units}} \times (\text{fair market value } \textit{minus} \text{ base value}) = \text{total payment}$$

Fair market value is defined as the fair market of the company prior to the change in control. Base value is the base value assigned to each individual grant made to a participant.

**Long-Term Incentive Plan**

We anticipate that, before the completion of the initial public offering, our board of directors will adopt and our stockholders will approve a new long-term incentive plan. In order to protect the rights of participants, we expect that our stock incentive plan will provide that, in the event of a change in control, as defined in the plan, outstanding awards made under the plan will either (1) be converted into equivalent awards with respect to shares of stock of the acquiring or successor company, or (2) be fully vested and settled in cash or shares. In general, we expect that if an award is converted into an equivalent award, the award will continue to be subject to the vesting and other terms and conditions applicable to the original award; however, vesting may accelerate in the event of an involuntary termination of employment within two years after the date of the change in control. Our board of directors will be responsible for determining the disposition of awards in the event of a change in control. No awards have been made under the plan at this time.

## Potential Payments Upon Termination Without a Change in Control

The following table provides quantitative disclosure of the estimated payments and benefits that would be provided to our named executive officers assuming that each named executive officer's employment with us was terminated on December 29, 2006, the last business day of our fiscal 2006, and was not in connection with an event that constituted a "Change in Control" under any agreement or plan described above. We have also assumed that the base salary earned by each named executive officer for his services to us through December 29, 2006 was fully paid.

Name	Cash Severance Payment(\$)	Cash Payment for Performance Units(\$)	Other Benefits Under Any of Our Plans (present value) (\$)	Total Termination Benefits(\$)
<b>A. Mark Schobel</b>				
Termination by us due to Mr. Schobel's disability or death	\$ 0	\$ 366,400(1)(2)	\$ 0	\$ 366,400
Termination by us for "cause"	0	0	0	0
Mr. Schobel's voluntary resignation	0	0	0	0
Termination by us without "cause" or by Mr. Schobel for "good reason"	656,250	366,400(1)(2)	21,600	1,044,250
<b>Keith Kendall</b>				
Termination by us due to Mr. Kendall's disability or death	25,000	62,500(1)	0(3)	87,500
Termination by us for "cause"	0	0	0(3)	0
Mr. Kendall's voluntary resignation	0	0	0(3)	0
Termination by us without "cause" or by Mr. Kendall for "good reason"	798,958	62,500(1)	0(3)	861,458
<b>Joseph Fuisz(4)(5)</b>				
Termination by us due to Mr. Fuisz's disability or death	21,500	1,434,021(1)	0	1,455,521
Termination by us for "cause"	0	0	0	0
Mr. Fuisz's voluntary resignation	0	0	0	0
Termination by us without "cause" or by Mr. Fuisz for "good reason"	560,000	1,434,021(1)	0	1,994,021
<b>Dr. Pradeep Sanghvi</b>				
Termination by us due to Dr. Sanghvi's disability or death	24,308	135,189(1)	0	159,497
Termination by us for "cause"	0	0	0	0
Dr. Sanghvi's voluntary resignation	0	0	0	0
Termination by us without "cause"	723,333	0	0	723,333
<b>Carl Fischer(4)</b>				
Termination by us due to Mr. Fischer's disability or death	2,692	34,400(1)	0	37,092
Termination by us for "cause"	0	0	0	0
Mr. Fischer's voluntary resignation	0	0	0	0
Termination by us without "cause" or for "good reason"	\$ 0	\$ 34,400(1)	\$ 21,600	\$ 56,000

- (1) Under the terms of our performance unit Plan B, our advisory board may, in its sole discretion, elect to provide a participant in the plan with a cash payment in an amount equal to the number

of each such participant's vested performance units divided by the outstanding unit amount, multiplied by the fair market value minus the base value of the award. We may elect to make this cash payment within 12 months of an officer's termination. Historically, we have never exercised this discretion and do not intend to do so in the future. We have assumed a fair market value of \$100,000,000 as of December 29, 2006, which is based upon the most recent valuation by our board of advisors as of September 18, 2006, in anticipation of our private placement of preferred members interests. It is possible that our value could have been higher at December 29, 2006, if appraised at that time.

- Mr. Schobel: 464,474 vested performance units granted at a base value of \$20,000,000
- Mr. Kendall: 507,068 vested performance units granted at a base value of \$87,500,000
- Mr. Fuisz: 1,570,795 vested performance units granted at a base value of \$12,500,000 (granted under Plan A); and 97,205 vested performance units granted at a base value of \$17,857,143. We have assumed that, if the advisory board were to exercise its discretion as to Mr. Fuisz's performance units that were granted under Plan B, it would exercise similar discretion with respect to the 1,570,795 performance units granted under Plan A.
- Dr. Sanghvi: 117,691 vested performance units granted at a base value of \$13,750,000; and 43,329 vested performance units granted at a base value of \$17,857,143.
- Mr. Fischer: 43,608 vested performance units granted at a base value of \$20,000,000.

- (2) If we elect not to exercise our discretion with respect to a cash payment, Mr. Schobel's employment agreement provides for the pro rata vesting of Mr. Schobel's performance units up to the date of termination, and at his option, not be subject to repurchase. This consists of the vesting of 464,474 performance units. The performance units do not have any value until there is a triggering event, such as a termination or change in control, including an initial public offering. Accordingly, there is no value linked to the vesting of the performance units.
- (3) Mr. Kendall is entitled to an amount equal to the unvested portion of his 401(k) account, which as of December 29, 2006 was \$0.
- (4) Amounts are determined in accordance with the respective employment agreements that were in effect as of December 29, 2006 for Messrs. Fuisz and Fischer.
- (5) On May 12, 2007, we entered into an amended and restated employment agreement with Mr. Fuisz. If Mr. Fuisz's amended and restated employment agreement is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in his amended and restated employment agreement), then the vesting schedule of his remaining units will not be affected and will bridge any such break in service. We have entered into a letter agreement with Mr. Fuisz which provides for similar continued vesting in the event his employment with, or his engagement as a consultant by, us is terminated for a reason other than his voluntary resignation or his termination for "cause" (as defined in Plan A).

#### **Potential Payments Upon a Change in Control Without Termination**

The following table provides quantitative disclosure of the estimated payments and benefits that would be provided to our named executive officers assuming an event which constituted a "change in control" under any agreement or plan described above on December 29, 2006, the last business day of our fiscal 2006, in connection with which none of the named executive officers' employment with us was terminated.

Upon a change in control, all performance units held by each of our named executive officers will automatically vest. The vested performance units may be redeemed for cash or in the form of the same



equity instruments received due to a change in control or an initial public offering, at our discretion. The value of the performance units is calculated as follows

$$\frac{\text{Number of participant's vested performance units}}{\text{Number of outstanding performance units}} \times (\text{fair market value } \textit{minus} \text{ base value})$$

Fair market value is defined as the fair market of the company at the change in control. Base value is the base value assigned to each individual grant of performance units made to a participant. We have assumed a fair market value of \$100,000,000 as of December 29, 2006, which is based upon the most recent valuation by our board of advisors as of September 18, 2006, in anticipation of our private placement of preferred members interests. It is possible that our value could have been higher at December 29, 2006, if appraised at that time. In accordance with the foregoing assumptions, the following table provides the potential realizable value of the performance units held by our named executive officers.

Name	Potential Realizable Value(\$)
A. Mark Schobel	\$ 1,708,643(1)
Keith Kendall	\$ 375,000(2)
Joseph Fuisz	\$ 2,129,786(3)
Dr. Pradeep Sanghvi	\$ 458,664(4)
Carl Fischer	\$ 213,580(5)

(1) Mr. Schobel has a total of 4,056,545 performance units which were granted as follows:

- 11/17/2005—1,393,423 units at a base value of \$20,000,000
- 02/13/2006—947,203 units at a base value of \$39,473,349
- 03/22/2006—58,820 units at a base value of \$39,473,349
- 06/16/2006—74,032 units at a base value of \$87,500,000
- 09/21/2006—1,583,067 units at a base value of \$100,000,000

(2) Mr. Kendall has a total of 3,042,408 performance units which were granted as follows:

- 06/16/2006—3,042,408 units at a base value of \$87,500,000

(3) Mr. Fuisz has a total of 4,563,611 performance units which were granted as follows:

- 01/22/2004—1,570,795 units at a base value of \$12,500,000
- 04/13/2005—83,565 units at a base value of \$17,857,143
- 07/31/2005—305,255 units at a base value of \$17,857,143
- 03/22/2006—752,590 units at a base value of \$39,473,349
- 06/16/2006—83,869 units at a base value of \$87,500,000
- 09/21/2006—1,767,537 units at a base value of \$100,000,000

(4) Dr. Sanghvi has a total of 1,014,136 performance units which were granted as follows:

- 02/23/2004—235,381 units at a base value of \$13,750,000
- 04/13/2005—173,316 units at a base value of \$17,857,143
- 03/22/2006—194,004 units at a base value of \$39,473,349
- 06/16/2006—18,660 units at a base value of \$87,500,000
- 09/21/2006—392,775 units at a base value of \$100,000,000

(5) Mr. Fischer has a total of 507,068 performance units which were granted as follows:

- 12/13/2005—174,431 units at a base value of \$20,000,000
- 02/13/2006—118,654 units at a base value of \$39,473,349
- 03/22/2006—7,099 units at a base value of \$39,473,349
- 06/16/2006—9,127 units at a base value of \$87,500,000
- 09/21/2006—197,757 units at a base value of \$100,000,000

#### **Limitations On Liability And Indemnification Of Directors And Officers**

We have adopted provisions in our certificate of incorporation that limit or eliminate the personal liability of its directors to the maximum extent permitted by the Delaware General Corporation Law, or DGCL. The DGCL expressly permits a corporation to provide that its directors will not be liable for monetary damages for a breach of their fiduciary duties as directors, except for liability:

- for or any breach of the director's duty of loyalty to us or our stockholders;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for any unlawful payments of dividends or unlawful stock purchases or redemptions; or
- for any transaction from which the director derived an improper personal benefit.

These limitations of liability do not generally affect the availability of equitable remedies such as injunctive relief or rescission. Our certificate of incorporation and bylaws also authorize us to indemnify our officers, directors, employees and other agents to the fullest extent permitted under the DGCL and we may advance expenses to our directors, officers, employees and other agents in connection with a legal proceeding, subject to limited exceptions. In addition, we maintain directors' and officers' liability insurance for our officers and directors.

As permitted by the DGCL, our certificate of incorporation and bylaws provide that:

- we must indemnify our board members and officers to the fullest extent permitted by the DGCL and advance expenses to our board members and officers in connection with a legal proceeding, subject to limited exceptions; and
- we may purchase and maintain insurance on behalf of our current or former board members, officers, employees or agents against any liability asserted against them and incurred by them in any such capacity, or arising out of their status as such.

In March 2007, we entered into separate indemnification agreements with each of our directors. Prior to the completion of this offering, we will enter into separate indemnification agreements with each of our board members and certain of our officers that will require us to indemnify them to the fullest extent permitted by the DGCL. These indemnification agreements will also require us to advance any expenses incurred by the board members and certain officers as a result of any proceeding against them as to which they could be indemnified.

The limited liability and indemnification provisions in our certificate of incorporation and bylaws and in any indemnification agreements we enter into may discourage stockholders from bringing a lawsuit against our board members for breach of their fiduciary duties and may reduce the likelihood of derivative litigation against our board members and officers, even though a derivative action, if successful, may otherwise benefit us and our stockholders. A stockholder's investment in us may be adversely affected to the extent we pay the costs of settlement or damage awards against our directors and officers under these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification by us is sought, nor are we aware of any threatened litigation or proceeding that may result in a claim for indemnification.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of the common stock of MonoSol Rx, Inc. before and after the completion of this offering (on a pro forma basis, after giving effect to the conversion of the membership interest for common stock as described under "Corporate Formation Transactions") and shows the number and percentage owned by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person or group of affiliated persons whom we know to beneficially own more than 5% of our common stock.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock underlying options or warrants held by that person that are currently exercisable or will become exercisable within 60 days are deemed outstanding and are included in the number of shares beneficially owned, while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. There are currently no options or warrants outstanding. To our knowledge, except as indicated in the footnotes to this table and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The address for those individuals for which an address is not otherwise indicated is: c/o MonoSol Rx, Inc., 30 Technology Drive, Warren, New Jersey 07059.

	Shares Beneficially Owned			
	Prior to the Offering		After the Offering	
	Number	%	Number	%
<b>Director and executive officers:</b>				
A. Mark Schobel	—			
Keith J. Kendall	—			
Dr. Pradeep Sanghvi	—			
Carl Fischer	—			
Joseph Fuisz	—			
Douglas Bratton	—			
Dr. Gregory Brown	—			
John Cochran	—			
Robert Flanagan	—			
Frank Tanki	—			
<b>All directors and executive officers as a group</b>	—	%		%
<b>Five percent stockholders:</b>				
MRX Partners, LLC(1)	—	15.9%		%
MonoLine RX, L.P.(1)	—	15.6%		%
MonoLine RX II, L.P.(1)	—	28.4%		%
Halifax Monosol Investors, L.P.(2)	—	12.1%		%

\* Represents beneficial ownership of less than 1%.

(1) Sole voting and dispositive power is held by Douglas Bratton, the President of Bratton Capital Management L.P.

(2) Sole voting and dispositive power is held by David Dupree, the Managing Director and Chief Executive Officer of The Halifax Group.

**Corporate Transaction**

In accordance with the agreement and plan of merger, after the merger our equity will continue to be owned by the same entities in the same proportions as before the merger. After completion of this offering, our existing equity owners, which include the direct and indirect holders of membership interests in Monosol Rx LLC will own \_\_\_\_\_ shares of our common stock representing approximately \_\_\_\_\_ % of the voting power of our outstanding capital stock. See "Principal Stockholders" for more information regarding the ownership of our common stock.

**Unsecured Note—Dr. Richard Fuisz**

In conjunction with Monosol Rx LLC's formation in January 2004 we assumed an unsecured note payable to Dr. Richard Fuisz with a principal amount of approximately \$904,000. At December 31, 2006 the note was repaid and \$347,650 was outstanding at December 31, 2005. Interest expense on the note was \$21,890, \$38,386 and \$41,324 for the years ended December 31, 2006, 2005 and 2004, respectively.

**Monosol, LLC Asset Purchase**

In December 2006, we sold an asset consisting of a small film casting machine to Monosol, LLC for \$200,000. The asset was part of the original capital contribution to Monosol Rx LLC by Monosol, LLC made in 2004 at the time the company was formed. The machine was found to be unsuitable for pharmaceutical applications and as such not used in our operations. Prior to the transaction, in order to determine an appropriate sales price we obtained independent estimates from dealers in the secondary market. The sales price was in excess of the estimates obtained. In addition, during 2006 we received \$54,000 in rent from Monosol, LLC for use of the asset.

**Melton Road Lease Amendment and Guarantee**

In September 2006, Monosol Rx LLC, with the landlord's agreement and acceptance, assigned to us all rights and obligations of the existing lease. As part of the agreement Monosol, LLC agreed to guarantee lease payments in an aggregate amount of \$218,423 through March 2008. In January 2007, the landlord released Monosol, LLC from its guarantee in consideration for us providing a security deposit in the amount of three months rent and amending the date we need to provide notice to the landlord that we do not intend to renew our lease from six months to nine months prior to the end of the current lease term.

**Monosol, LLC Cost Allocation**

The statements of operations include certain shared costs allocated to us by Monosol, LLC. Charges for rent, insurance, employee fringe benefits, and other overhead costs are based on the ratio of payroll expense of our employees to aggregate payroll expense for Monosol, LLC employees. In the opinion of management, the costs charged have been allocated on a basis that is believed to be reasonable within the structure of Monosol, LLC. However, the costs charged are not necessarily indicative of the level of expenses that may have been incurred if we and the Predecessor had operated as a stand alone entity. The total amount of costs allocated to us was \$250,000, \$696,000 and \$727,000 for 2006, 2005 and 2004, respectively. As of October 2006 the cost allocation arrangement with Monosol, LLC was terminated.

## Consulting Agreements

In conjunction with our purchase of all of the assets of Kosmos, Dr. Richard Fuisz and his son, Mr. Joseph Fuisz, significant shareholders in Kosmos, entered into consulting agreements with the Company. These consulting agreements were each for a three year term and provided for a monthly and annual fee of \$13,333 and \$160,000, respectively, plus the reimbursement of certain expenses. Including reimbursed fees, we paid Dr. Fuisz \$163,301, \$179,806 and \$148,925 for 2006, 2005, and 2004 respectively, and Joseph Fuisz \$224,117, \$281,010 and \$197,319 for 2006, 2005, and 2004, respectively, under the agreements. The consulting agreement between us and Joseph Fuisz, was terminated in September 2006, when Mr. Fuisz entered into an employment agreement with us. This employment agreement was amended and restated in May 2007, and will automatically terminate on December 31, 2007. At this time, we will enter into a new one-year consulting agreement with Joseph Fuisz, the terms of which are set forth in an exhibit to his amended and restated employment agreement.

In September 2006, the consulting agreement between us and Dr. Fuisz was extended through September 2009 with substantially the same terms. We have agreed to provide Dr. Fuisz with a one-time fee of \$100,000 under his consulting agreement within 15 days after the date that the registration statement becomes effective. We will have no obligation to pay this fee in the event that the registration statement becomes effective after December 31, 2007.

We agreed to transfer the assets and properties relating to certain technology and intellectual property unrelated to thin film to a new Delaware limited liability company, 55% of the interests of which will be owned by Dr. Fuisz and 45% of the interests of which will be owned by our members as of the date of such transfer. We have also agreed to release Dr. Fuisz from all claims that we may have now or in the future against him, with the exception of claims arising under certain agreements between us and Dr. Fuisz or his affiliates. We have also agreed to indemnify Dr. Fuisz to the same extent we have agreed to indemnify our officers and directors.

We also are a guarantor through May 2007 of a lease for office space in Washington, D.C. that is used by Dr. Fuisz and Joseph Fuisz. The aggregate remaining lease payments through May 2007 are \$12,153. We made payments to Dr. Fuisz in connection with the lease of \$28,386, \$29,893 and \$41,133 for 2006, 2005 and 2004 respectively. We have agreed to extend this lease on a month to month basis.

## DESCRIPTION OF CAPITAL STOCK

### General

Upon completion of this offering, the total amount of our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$.01 per share, and 20,000,000 shares of preferred stock, par value \$.01 per share. As of June 15, 2007, there were no shares of common stock outstanding and no shares of preferred stock outstanding. As of June 15, 2007, we had no record holders of our common stock. In addition, as of \_\_\_\_\_, 2007 \_\_\_\_\_ shares of our common stock were reserved for grants under our stock incentive plan, and options to purchase a total of zero shares of our common stock were outstanding. As of April 1, 2007, pursuant to our predecessor's performance unit plans there were 21,418,125 units outstanding which will be converted to \_\_\_\_\_ shares of our common stock.

Immediately after this offering, there will be \_\_\_\_\_ shares of our common stock and no shares of preferred stock outstanding.

The following description of our capital stock does not purport to be complete and is subject to, and is qualified by, our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, and by the applicable provisions of Delaware law.

### Common Stock

#### *Voting*

The holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders, including the election of directors, and do not have any right to cumulative votes in the election of directors.

#### *Dividends*

Subject to the rights and preferences of the holders of any series of preferred stock which may at the time be outstanding, holders of our common stock are entitled to such dividends as our board of directors may declare from time to time out of legally available funds. Dividends on the common stock are not cumulative.

#### *Liquidation rights*

In the event of any liquidation, dissolution or winding-up of our affairs, after payment of all of its debts and liabilities, and subject to the rights and preferences of the holders of any outstanding shares of any series of its preferred stock, the holders of our common stock will be entitled to receive their pro rata distribution of any of our remaining assets.

#### *Other matters*

Holders of our common stock have no conversion, preemptive or other subscription rights and there are no redemption rights or sinking fund provisions with respect to the common stock. The shares of our common stock to be sold in this offering when issued and paid for will be validly issued, fully paid and non-assessable.

### Preferred Stock

We are authorized to issue up to 20,000,000 shares of preferred stock. Our certificate of incorporation authorizes our board, from time to time, without any further stockholder action or approval: to issue these shares in one or more classes or series; to establish from time to time the number of shares to be included in each class or series; and to fix the designation, powers, preferences,

and rights of the shares of each wholly unissued class or series and any of its qualifications, limitations or restrictions. In some circumstances, the issuance of shares of preferred stock may render more difficult or tend to discourage a merger, tender offer or proxy contest, the assumption of control by a holder of a large block of our securities or the removal of incumbent management. Our board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. We currently have no plans to issue any shares of preferred stock.

### **Certain Provisions of Our Certificate of Incorporation, Bylaws and Delaware Law**

Provisions of our certificate of incorporation, bylaws and Delaware law, which are summarized below, may be deemed to have an anti-takeover effect and may delay, defer or prevent a tender offer or takeover attempt that a stockholder may consider in such stockholder's best interest, including those attempts that may result in a premium over the market price for our common stock. These provisions include restrictions on stockholder's ability to take action by written consents, elimination of the ability of stockholders to call special meetings, advance notice procedures for stockholder proposals and director nominations, and certain Delaware law provisions.

#### ***Number of Directors; Removal for Cause; Filling Vacancies***

Our certificate of incorporation provides that our board of directors will consist of one or more directors, the exact number of which will be fixed from time to time by the board. Our board of directors will consist of six directors.

Our bylaws provide that any newly created directorships on our board, or any other vacancy on the board, may be filled by a majority of the board then in office, even if a quorum is not present, or by a plurality of votes cast at a meeting of the stockholders. Any director elected in accordance with the preceding sentence will hold office for the remainder of the full term of office of the director whom he or she replaced or until such director's successor shall have been elected and qualified.

#### ***Special Meetings of Stockholders***

Our bylaws deny stockholders the right to call a special meeting of stockholders. Our bylaws provide that a special meeting of stockholders may be called only by our board.

#### ***Stockholder Action by Written Consent***

Our certificate of incorporation and bylaws deny stockholders the ability to act by written consent without a meeting, unless the holders of 66<sup>2</sup>/<sub>3</sub>% of our issued and outstanding stock act by such a written consent. All other stockholder action must take place at a meeting of stockholders.

#### ***Stockholder Proposals***

At an annual meeting of stockholders, only business that is properly brought before the meeting will be conducted or considered. To be properly brought before an annual meeting of stockholders, business must be specified in the notice of the meeting (or any supplement to that notice), brought before the meeting by or at the direction of the board (or any duly authorized committee of the board) or properly brought before the meeting by a stockholder. For business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely written notice of the business in proper written form to our secretary.

To be timely, a stockholder's notice must be delivered to or mailed and received at our principal executive offices not less than 60 days nor more than 180 days prior to the anniversary date of the last annual meeting; provided, however, that in the event that the annual meeting is called for a date that is

not within 45 days before or after the anniversary date, notice by the stockholder must be received not later than the close of business on the 10th day following the day on which notice of the date of the annual meeting was mailed or public disclosure of the date of the annual meeting was made, whichever first occurs.

To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter the stockholder proposes to bring before the annual meeting:

- a brief description of the business desired to be brought before the annual meeting and the reasons for conducting the business at the annual meeting;
- the name and address, as they appear on our books, of the stockholder proposing such business;
- the class or series and number of our shares which are owned beneficially or of record by the stockholder proposing the business; and
- any material interest of the stockholder in such business.

Similarly, at a special meeting of stockholders, only such business as is properly brought before the meeting will be conducted or considered. To be properly brought before a special meeting, business must be specified in the notice of the meeting (or any supplement to that notice).

#### ***Nomination of Candidates for Election to Our Board***

Under our bylaws, only persons who are properly nominated will be eligible for election to be members of our board. To be properly nominated, a director candidate must be nominated at an annual meeting of the stockholders or any special meeting called for the purpose of electing directors by or at the direction of our board (or any duly authorized committee of the board) or properly nominated by a stockholder. To properly nominate a director, a stockholder must:

- be entitled to vote at the meeting; and
- have given timely written notice in proper written form to our secretary.

To be timely, a stockholder's notice must be delivered to or mailed and received at our executive offices:

- in the case of an annual meeting, not less than 90 days prior to the anniversary date of the last annual meeting of our stockholders; and
- in the case of a special meeting of stockholders called for the purpose of electing directors, not later than the close of business on the 10th day following the day on which notice of the date of such meeting was mailed or public disclosure of the date of the special meeting was made, provided that such statement is mailed no earlier than 120 days prior to the date of such meeting.

To be in proper written form, a stockholder's notice to the secretary must be accompanied by a written consent of each proposed nominee to being named as a nominee and to serve as a director if elected and must set forth:

- as to each person whom the stockholder proposes to nominate for election as a director:
  - the name, age, business address and residence address of the person;
  - the principal occupation or employment of the person;
  - the class or series and number of shares of our capital stock that are owned beneficially or of record by the person; and



- any other information relating to the person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors pursuant to Section 14 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations promulgated thereunder; and
- as to the stockholder giving the notice:
- the name and record address of such stockholder;
- the class or series and number of shares of our capital stock that are owned beneficially or of record by such stockholder;
- a description of all arrangements or understandings between such stockholder and each proposed nominee and any other person or persons (including their names) under which the nomination(s) are to be made by such stockholder; and
- a representation that the stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice.

***Amendment of Certificate of Incorporation and Bylaws***

Our certificate of incorporation can only be amended by the approval of a majority of the stockholders. Our bylaws provide that the board of directors or the stockholders have the right to alter, amend or repeal the bylaws. In addition, our certificate of incorporation grants our board of directors the authority to amend and repeal our bylaws without a stockholder vote in any manner not inconsistent with the laws of the State of Delaware or our certificate of incorporation.

***Delaware Law***

We will be subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, those provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding those shares owned by directors and officers and shares issued under employee stock plans under which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after the date the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines "business combination" to include the following:

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

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation 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.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling, controlled by, or under common control with the entity or person.

#### **Nasdaq Global Market Listing**

We have applied to have our common stock included for quotation on The Nasdaq Global Market under the symbol "MSRX."

#### **Transfer Agent And Registrar**

Upon the closing of this offering, the transfer agent and registrar for our common stock will be The Bank of New York.

**MATERIAL U.S. FEDERAL TAX CONSIDERATIONS  
FOR NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders with respect to their ownership and disposition of shares of our common stock. This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the United States federal, state, local and non-U.S. tax consequences of the acquisition, ownership and disposition of our common stock. For purposes of this discussion, a "non-U.S. holder" means a beneficial owner of our common stock who is not for U.S. federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation, partnership, or any other organization taxable for U.S. federal income tax purposes as a corporation or partnership created or organized in the United States or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is included in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) a valid election is in place to treat the trust as a U.S. person.

If a partnership holds our common stock, the tax treatment of its partners generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that are prospective investors in our common stock, and partners in such partnerships, should consult their tax advisors.

This discussion is based on current provisions of the United States Internal Revenue Code of 1986, as amended, existing and proposed United States Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all of which are in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation. Any change, which may or may not be retroactive, could alter the tax consequences to non-U.S. holders described in this prospectus.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes. This discussion does not address the consequences to non-U.S. holders subject to special rules, including, U.S. expatriates; "controlled foreign corporations" or "passive foreign investment companies;" or non-U.S. holders that own more than 5% of our common stock.

There can be no assurance that the Internal Revenue Service, or IRS, will not challenge one of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, an opinion of counsel with respect to the U.S. federal income or estate tax consequences to a non-U.S. holder of the acquisition, ownership, or disposition of our common stock. **We urge prospective investors to consult with their own tax advisors regarding the U.S. federal, estate, state and local, and non-U.S. income and other tax considerations of acquiring, holding and disposing of shares of our common stock.**

**Distributions with respect to Our Common Stock**

We have not declared or paid distributions on our common stock since our inception and do not intend to pay any distributions on our common stock in the foreseeable future. In the event we do pay

distributions on our common stock, however, these distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated first as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock and then any remaining excess will be treated as gain from the sale of common stock, subject to the tax treatment described below in "Gain on Sale or Other Disposition of Our Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty. In order to obtain a reduced rate of withholding, a non-U.S. holder will be required to provide an Internal Revenue Service Form W-8-BEN certifying its entitlement to a reduced rate of withholding under a treaty. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not qualify as a dividend because we do not anticipate having current or accumulated earnings and profits, we intend not to withhold any U.S. federal income tax on the distribution as permitted by United States Treasury Regulations.

Dividends paid to a non-U.S. holder that are treated as "effectively connected" with a trade or business conducted by such non-U.S. holder within the United States (and, if an applicable income tax treaty so provides, are also attributable to a permanent establishment of such non-U.S. holder), known as "United States trade or business income," are generally exempt from the 30% withholding tax if the non-U.S. holder provides a properly completed Internal Revenue Service Form W-8-ECI and satisfies certain other requirements. However, such United States trade or business income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons. Additionally, United States trade or business income received by a non-U.S. holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate specified by an applicable income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of United States withholding or other withholding exclusion under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund or credit with the IRS.

### **Gain on Sale or Other Disposition of Our Common Stock**

In general, a non-U.S. holder will not be subject to any U.S. federal income tax or withholding tax on any gain recognized upon such holder's sale or other disposition of shares of our common stock unless:

- the gain is United States trade or business income, in which case such holder will be subject to tax on the net gain derived from the sale or disposition at the graduated United States federal income tax rates applicable to United States persons; and, if the non-U.S. holder is a corporation, such holder may also be subject to the branch profits tax, both as described above in "Distributions with respect to Our Common Stock;"
- the non-U.S. holder is an individual who is present in the United States for 183 days or more during the taxable year of the disposition and meets certain other requirements in which case the holder will be subject to a flat 30% tax on the amount by which the gain derived from the sale, and certain other United States source capital gains recognized during such year exceed certain United States source capital losses recognized during such year; or
- certain rules relating to "United States real property holding corporation" status apply to such sale or other disposition. Under such rules, gain recognized on a sale or other disposition of our common stock may be subject to U.S. federal income tax (and, in certain circumstances, withholding tax) if (1) our common stock is not regularly traded on an established securities

market prior to the beginning of the calendar year in which the sale or disposition occurs and (2) we are, or have been, a United States real property holding corporation during the shorter of the five-year period ending on the date of such sale or other disposition or the period that the non-U.S. holder held our common stock. Generally, we would be considered a United States real property holding corporation if the fair market value of our "United States real property interests" were to equal or exceed 50% of the aggregate fair market value of our worldwide real property interests and our other assets used or held for use in our trade or business. Although there can be no assurance, we do not believe that we are, or have been, a United States real property holding corporation, or that we are likely to become one in the foreseeable future.

### **United States Federal Estate Tax**

Shares of our common stock that are owned or treated as owned by an individual non-U.S. holder at the time of such non-U.S. holder's death will be included in such individual's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise, and therefore may be subject to U.S. federal estate tax.

### **Backup Withholding, Information Reporting and Other Reporting Requirements**

We must report to the IRS and to each non-U.S. holder the gross amount of any dividends paid to such holder with respect to our common stock, and the tax withheld, if any, upon the payment of such dividends. In addition, information reporting and backup withholding (at a rate of 28% through 2010, and 31% thereafter) generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the United States office of a broker unless the holder certifies its status as a non-U.S. holder and satisfies certain other qualifications, or otherwise establishes an exemption. Generally, such information reporting and backup withholding will not apply to a payment of disposition proceeds if the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. However, for information reporting purposes, certain brokers with substantial United States ownership or operations are treated in a manner similar to United States brokers. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which a non-U.S. holder resides or is incorporated.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could adversely affect the price of our common stock.

Upon completion of this offering, we will have approximately \_\_\_\_\_ shares of our common stock outstanding (approximately \_\_\_\_\_ shares if the underwriters exercise their overallotment option in full). Of those shares, the \_\_\_\_\_ shares of common stock sold in this offering ( \_\_\_\_\_ shares if the underwriters exercise their overallotment option in full) will be freely transferable without restriction, unless purchased by our affiliates. The remaining approximately \_\_\_\_\_ shares of common stock to be outstanding immediately following the completion of this offering, which are "restricted securities" under Rule 144 of the Securities Act of 1933, as amended, or Rule 144, as well as any other shares held by our affiliates, may not be resold except pursuant to an effective registration statement or an applicable exemption from registration, including an exemption under Rule 144.

### Lock-Up Agreements

The holders of approximately \_\_\_\_\_ shares of outstanding common stock as of the closing of this offering, including all of our officers and directors, have entered into lock-up agreements under which they have generally agreed, subject to certain exceptions, not to offer or sell any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of at least 180 days from the date of this prospectus without the prior written consent of Cowen and Company, LLC. See "Underwriting—No sales of similar securities."

### Rule 144

In general, under Rule 144, an affiliate of ours who beneficially owns shares of our common stock that are not restricted securities, or a person who beneficially owns for more than one year shares of our common stock that are restricted securities, may generally sell, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; and
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four preceding calendar weeks.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice and the availability of current public information about us. Generally, a person who was not our affiliate at any time during the three months before the sale, and who has beneficially owned shares of our common stock that are restricted securities for at least two years, may sell those shares without regard to the volume limitations, manner of sale provisions, notice requirements or the requirements with respect to availability of current public information about us.

Rule 144 does not supersede the contractual obligations of our security holders set forth in the lock-up agreements described above.

### Rule 701

Generally, an employee, officer, director or consultant who purchased shares of our common stock before the effective date of the registration statement of which this prospectus is a part, or who holds options as of that date, under a written compensatory plan or contract, may rely on the resale provisions of Rule 701 under the Securities Act of 1933, as amended. Under Rule 701, these persons who are not our affiliates may generally sell their eligible securities, commencing 90 days after the

effective date of the registration statement of which this prospectus is a part, without having to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. These persons who are our affiliates may generally sell their eligible securities under Rule 701, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with Rule 144's one-year holding period restriction.

Neither Rule 144 nor Rule 701 supersedes the contractual obligations of our security holders set forth in the lock-up agreements described above.

### **Sale of Restricted Shares**

The \_\_\_\_\_ shares of our common stock that were outstanding will become eligible for sale, pursuant to Rule 144 or Rule 701, without registration approximately as follows:

- approximately \_\_\_\_\_ shares of common stock will be immediately eligible for sale in the public market without restriction;
- approximately \_\_\_\_\_ shares of common stock will be eligible for sale in the public market under Rule 144 or Rule 701, beginning 180 days after the effective date of the registration statement of which this prospectus is a part, subject to the volume, manner of sale and other limitations under those rules; and

The above does not take into consideration the effect of the lock-up agreements described above.

### **2007 Stock Incentive Plan**

We intend to file a registration statement on Form S-8 under the Securities Act to register the shares of common stock available for issuance under our 2007 Stock Incentive Plan. Subject to the lock-up agreements, shares issued under these plans after the effective date of such registration statement will be available for sale in the open market and, for our affiliates, subject to the conditions and restrictions of Rule 144. As of June 15, 2007, options to purchase a total of zero shares of common stock were outstanding under our 2007 Stock Incentive Plan and \_\_\_\_\_ shares of our common stock were available for future grant under the 2007 Stock Incentive Plan.





We estimate that the total expenses of the offering, excluding underwriting discount, will be approximately \$ \_\_\_\_\_ and are payable by us.

	Total		
	Per Share	Without Overallotment	With Overallotment
Public offering price			
Underwriting discount			
Proceeds, before expenses, to us			

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of \$ \_\_\_\_\_ per share. The underwriters may allow, and the dealers may reallow, a discount not in excess of \$ \_\_\_\_\_ per share to other dealers. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

*Discretionary Accounts.* The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

*Market Information.* Prior to this offering, there has been no public market for shares of our common stock. The initial public offering price will be determined by negotiations between us and the representative of the underwriters. In addition to prevailing market conditions, the factors to be considered in these negotiations will include:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial information;
- an assessment of our management; its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

We have applied for the quotation of our common stock on the Nasdaq Global Market under the symbol "MSRX."

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate short covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the

overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. 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 with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions 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 our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Lock-Up Agreements.* Pursuant to certain "lock-up" agreements, we and our executive officers, directors and certain of our other stockholders, have agreed, subject to certain exceptions, not to offer, sell, contract to sell, announce any intention to sell, pledge or otherwise dispose of, enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, for a period of 180 days after the date of the pricing of the offering. The 180-day restricted period will be automatically extended if (i) during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results or become aware that material news or a material event will occur during the 16-day period beginning on the last day of the 180-day restricted period, in either of which case the restrictions described above 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.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (a) issue common stock or options pursuant to employee benefit plans, or (b) issue common stock upon exercise of outstanding options or warrants. The exceptions permit parties to the "lock up" agreements, among other things and subject to restrictions, to: (a) participate in tenders involving the acquisition of a majority of our stock, (b) participate in transfers or exchanges involving common stock or securities convertible into common stock or (c) make certain gifts. In addition, the

lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

*Directed Share Program.* At our request, the underwriters have reserved up to \_\_\_\_\_ shares of our common stock for sale, at the initial public offering price, through a directed share program to members of our management, and our employees and directors. There can be no assurance that any of the reserved shares will be so purchased. The number of shares available for sale to the general public in the offering will be reduced to the extent the reserved shares are purchased in the directed share program. Any reserved shares of common stock not purchased through the directed share program will be offered to the general public on the same basis as the other common stock offered hereby.

*Electronic Offer, Sale and Distribution of Shares.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Other Relationships.* Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

#### *Selling Restrictions.*

*United Kingdom.* Each of the underwriters has represented and agreed that:

- it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended), or FSMA, except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority, or FSA;
- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and
- it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

*Switzerland.* The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

*European Economic Area.* In relation to each Member State of the European Economic Area (Iceland, Norway and Lichtenstein in addition to the member states of the European Union) that has implemented the Prospectus Directive, each, a Relevant Member State, each underwriter has

represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, it has not made and will not make an offer of the securities to the public in that Relevant Member State prior to the publication of a prospectus in relation to the securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of the securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any securities under, the offer contemplated in this prospectus will be deemed to have represented, warranted and agreed to and with us and each underwriter that:

- it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and
- in the case of any securities acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (1) the securities acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives of the underwriters has been given to the offer or resale; or (2) where securities have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of the provisions in the two immediately preceding paragraphs, the expression an "offer of the securities to the public" in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

## LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Fulbright & Jaworski L.L.P., Dallas, Texas. Willkie Farr & Gallagher LLP, New York, New York, is counsel for the underwriters in connection with this offering.

## EXPERTS

The financial statements of Monosol Rx LLC for the year ended December 31, 2004, and as of and for the years ended December 31, 2005 and 2006, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere in this prospectus, and upon and the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and the exhibits which are part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's Public Reference Room, which is located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549.

You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet website, which is located at [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

This prospectus includes statistical data obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Members  
Monosol Rx LLC:

We have audited the accompanying balance sheets of Monosol Rx LLC as of December 31, 2006 and 2005, and the related statements of operations, changes in members' equity, and cash flows for each of the years in the three-year period ended December 31, 2006. 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). 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 Monosol Rx LLC as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs—an Amendment of ARB No. 43, Chapter 4*.

/s/ KPMG LLP

Chicago, Illinois

May 14, 2007

Monosol Rx LLC

Balance sheets

	December 31,	
	2006	2005
	(in thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,256	\$ 1,332
Trade receivables	567	196
Other receivables	11	4
Due from the Predecessor	200	—
Inventories	455	665
Prepaid expenses and other current assets	170	99
	<u>16,659</u>	<u>2,296</u>
Total current assets	16,659	2,296
Property and equipment, net	8,556	7,614
Other assets	300	496
Intangible asset, net	1,664	1,900
	<u>27,179</u>	<u>12,306</u>
	\$ 27,179	\$ 12,306
<b>LIABILITIES AND MEMBERS' EQUITY</b>		
Current liabilities:		
Current maturities of long-term debt	\$ —	\$ 278
Accounts payable	1,096	1,239
Due to the Predecessor	—	10
Accrued expenses	733	189
	<u>1,829</u>	<u>1,716</u>
Total current liabilities	1,829	1,716
Other liabilities — asset retirement obligations	87	—
Long-term debt, less current maturities	—	5,925
Members' equity:		
Preferred A interests, no par value, 100,000,000 units authorized; 16,886,750 issued and outstanding in 2006 and none in 2005	16,887	—
	<u>16,887</u>	<u>—</u>
Preferred A-1 interests, no par value, 100,000,000 units authorized; 21,526,850 issued and outstanding in 2006 and none in 2005	21,883	—
Common interests, no par value, 500,000,000 units authorized; 63,000,000 issued and outstanding in 2006 and 12,500,000 in 2005	11,088	11,304
Additional paid in capital	—	5,204
	<u>27,968</u>	<u>16,508</u>
Accumulated deficit	(24,595)	(11,843)
	<u>3,373</u>	<u>4,665</u>
Total members' equity	\$ 25,263	\$ 4,665
	<u>\$ 27,179</u>	<u>\$ 12,306</u>
	\$ 27,179	\$ 12,306

See accompanying notes to financial statements.



**Monosol Rx LLC**  
**Statements of operations**

	Year ended December 31,		
	2006	2005	2004
	(in thousands)		
<b>Revenues:</b>			
Manufacture and supply revenue	\$ 1,765	\$ 1,458	\$ 1,947
Co-development and research fees	950	665	100
	2,715	2,123	2,047
<b>Cost of goods sold:</b>			
Manufacture and supply	1,623	1,282	1,388
	1,092	841	659
<b>Operating expenses:</b>			
General and administrative	11,296	7,372	3,168
Research and development	1,993	1,258	1,010
	13,289	8,630	4,178
Operating loss	(12,197)	(7,789)	(3,519)
Other income, principally related-party	64	41	—
Interest income	226	46	—
Interest expense	(845)	(581)	(41)
	\$ (12,752)	\$ (8,283)	\$ (3,560)
Net loss	\$ (12,752)	\$ (8,283)	\$ (3,560)

See accompanying notes to financial statements.

**Monosol Rx LLC**  
**Statements of changes in members' equity**  
**(in thousands, except for unit data)**

	Members Contribution Interest										
	Preferred A Interests		Preferred A-1 Interests		Common Interests		Additional Paid In Capital	Accumulated Deficit	Predecessor Division Equity	Total Members Equity	
	Units	Amount	Units	Amount	Units	Amount					
Balance, December 31, 2003	—	\$ —	—	\$ —	—	—	\$ —	—	—	1,862 \$	1,862
Formation of MonoSol Rx, LLC and contribution of net assets					12,500,000	11,304		—	(1,862)		9,442
Net loss								(3,560)			(3,560)
Balance, December 31, 2004	—	—	—	—	12,500,000	11,304	—	(3,560)			7,744
Issuance of unit purchase warrants							3,024	—			3,024
Capital contribution related to debt modification							2,180	—			2,180
Net loss								(8,283)			(8,283)
Balance, December 31, 2005	—	—	—	—	12,500,000	11,304	5,204	(11,843)			4,665
Issuance of unit purchase warrants							4,668	—			4,668
Authorization and issuance of additional units					50,500,000						
Issuance of Series A—preferred interest	16,886,750	16,887						—			16,887
Conversion of Tranche A&B Note Series A-1—preferred interest			21,526,850	21,883				(9,872)	—		12,011
Return of capital contribution to Predecessor							(216)	—			(216)
Net loss								(12,752)			(12,752)
Balance, December 31, 2006	16,886,750	\$ 16,887	21,526,850	\$ 21,883	63,000,000	\$ 11,088	\$ —	(24,595)			\$ 25,263

See accompanying notes to financial statements.

**Monosol Rx LLC**  
**Statements of cash flows**

	Year ended December 31,		
	2006	2005	2004
	(in thousands)		
<b>Cash flows from operating activities:</b>			
Net loss	\$ (12,752)	\$ (8,283)	\$ (3,560)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	1,730	479	295
Asset retirement obligation accretion	2	—	—
Amortization of debt discount	248	83	—
Amortization of intangible	236	236	222
Non-cash interest expense	575	452	—
Write-down of unapplied vendor credit	296	—	—
Loss from disposal of assets	226	—	—
Loss from impairment of assets	132	—	—
Bad debt expense	16	—	—
Compensation expense related to the issuance of debt and warrants	—	25	—
Write-off of accounts receivable	—	296	—
<b>Changes in operating assets and liabilities:</b>			
Trade receivables	(387)	647	(1,073)
Other receivables	(7)	—	—
Inventories	210	29	(695)
Prepaid expenses	(71)	(51)	(47)
Accounts payable	(143)	(306)	1,200
Due to the Predecessor	(10)	(129)	232
Accrued expenses	544	127	(17)
Other assets	(100)	—	—
	(9,255)	(6,395)	(3,443)
<b>Cash flows from investing activities:</b>			
Capital expenditures	(3,378)	(2,761)	(1,194)
Proceeds from sale of assets	18	—	—
	(3,360)	(2,761)	(1,194)

**Monosol Rx LLC**  
**Statements of cash flows (Continued)**

	Year ended December 31,		
	2006	2005	2004
	(in thousands)		
<b>Cash flows from financing activities:</b>			
Contributed capital	\$ 16,887	\$ —	\$ 5,181
Principal payments on long-term debt	(348)	(278)	(278)
Proceeds from debt and warrants issuances	10,000	10,500	—
	26,539	10,222	4,903
Net cash provided by financing activities	26,539	10,222	4,903
Net increase in cash and cash equivalents	13,924	1,066	266
<b>Cash and cash equivalents:</b>			
Beginning of year	1,332	266	—
	15,256	1,332	266
Ending of year	\$ 15,256	\$ 1,332	\$ 266
<b>Supplemental disclosure of cash flow information:</b>			
Cash payments for interest	\$ 22	\$ 38	\$ 41
<b>Supplemental schedule of noncash investing activities:</b>			
<b>Formation of Monosol Rx LLC:</b>			
<b>Assets acquired and liabilities assumed from Predecessor and Kosmos:</b>			
Other assets—future vendor credits to be applied to capital expenditures	\$ —	\$ —	\$ 1,196
Property and equipment	—	—	2,045
Intangible assets	—	—	2,358
Accounts payable	—	—	(345)
Long-term debt	—	—	(904)
	\$ —	\$ —	\$ 4,350
Other asset—vendor credits applied to capital expenditures	\$ —	\$ —	\$ 700
Contributed capital related to debt conversion	12,011	—	—
Contributed capital related to debt modification	—	2,180	—
Return of capital contribution to Predecessor	216	—	—
Asset retirement obligation included in property and equipment	85	—	—
Accounts receivable from the Predecessor related to asset transfer	200	—	—
Capital contribution—fixed assets from Predecessor	—	—	1,688
Capital contribution—intercompany payable owed to Predecessor	—	—	79
Offset of due to Monosol, LLC with amounts due from Predecessor	—	—	94

See accompanying notes to financial statements.

Notes to financial statements

(in thousands, except per share amounts)

**(1) Nature of Business and Significant Accounting Policies**

*Nature of Business*

Monosol Rx LLC (Monosol Rx or the Company) was founded on January 21, 2004 and is a drug delivery company specializing in proprietary dissolving thin film drug delivery products. The Company's thin film drug delivery dosage form is similar in size, shape and thickness to a postage stamp and dissolves readily on the tongue for easy use by patients. The Company's thin film drug delivery technology is now used in the over-the-counter, or OTC, marketplace and is currently emerging in the prescription drug market. The Company's films are environmentally friendly given their biodegradable properties and ability to yield inert materials once dissolved in water. For the years ended December 31, 2006, 2005 and 2004, most of the Company's customers were principally located in the Northeastern and Southeastern parts of the United States.

Prior to the formation of Monosol Rx LLC, the activities of the Company were carried out as part of the research and development efforts of Monosol, LLC, a manufacturer of commercial soluble films (the Predecessor). For the time period of January 1, 2004 to January 21, 2004, the results of operations and the assets and liabilities have been assigned to the Company based upon those items specifically related to the Predecessor's business.

During 2004, in connection with the formation of Monosol Rx LLC, the Company received from the Predecessor a capital contribution in the form of assets of \$1,793. Additionally, on formation, the Company also received capital of \$375 in cash from Monosol RX Genpar, L.P., a private investor, and \$2,557 of contributed capital in the form of assets from Kosmos Pharma Limited (Kosmos) in exchange for equity ownership (see note 2).

During 2004, the Company received additional capital contributions from the Predecessor of \$6,579 in the form of cash of \$4,812 and assets of \$1,767.

During 2005, the Company received additional capital contributions from its members as a result of unit purchase warrants issued in connection with two debt issuances. Contributed capital of \$3,024 represented the estimated fair values assigned to the unit purchase warrants issued in connection with the debt issuances. An additional \$2,180 in contributed capital was recorded as a result of a modification of the terms of certain previously outstanding debt. The modifications were made in connection with the second debt issuance made in 2005. See note 9 for further explanation.

During 2006, the Company received additional capital contributions from its members as a result of unit purchase warrants issued in connection with debt issuances. Contributed capital of \$4,668 represented the estimated fair value assigned to the unit purchase warrants issued in connection with the debt issuances.

In October 2006, the Company issued Preferred Members' Interests, Series A and Series A-1 representing a 37.878% interest in the Company. The Series A interestholders contributed \$16,887 in cash in exchange for their interest. All of the then existing secured debt holders converted their notes, plus related accrued interest, in to Series A-1 interests, resulting in an additional capital contribution of \$12,011.

The Company maintains a production plant in Portage, Indiana, a research facility in Kingsport, Tennessee, a business development office in Washington, DC and its headquarters in Warren, New Jersey.

## Significant Accounting Policies

### (a) Accounting Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### (b) Cash Equivalents

The Company considers investments with an original maturity of three months or less to be cash equivalents. The Company's cash equivalents were comprised principally of overnight or short-term investment grade debt instruments.

### (c) Trade Receivables

The Company's standard credit terms are 30 days for customers in the United States and 45 days for international customers. Trade receivables are carried at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a periodic basis. Management determines the allowance for doubtful accounts by identifying troubled accounts and in the absence of historical experience, applying an estimate that management believes is a reasonable indicator of future potential losses. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received. The following table presents the changes in the allowance for bad debts account for the years ended December 31, 2006, 2005 and 2004.

	Balance Beginning of Year	Charged to Costs and Expenses	Acquisitions	Deductions	Balance at End of Year
Allowance for bad debts					
2004	—	—	—	—	—
2005	—	381	—	381	—
2006	—	16	—	—	16

### (d) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis.

Inventories are evaluated periodically and the cost of any nonusable inventory is written-off to expense. In addition, the Company reserves for any inventory where carrying value may be in excess of its estimated realizable value, or where the items could potentially be nonusable. Charges for such write-offs and reserves are recorded as a component of cost of goods sold.

### (e) Property and Equipment

Property and equipment are stated at cost. Depreciation for equipment, furniture, and fixtures is calculated using the straight-line method over the estimated useful lives of the assets. Machinery and equipment are depreciated over 2 to 15 years and furniture and fixtures are depreciated over 5 to 10 years. Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives. Total depreciation for the years ended December 31, 2006, 2005, and 2004 was \$1,730, \$479 and \$295, respectively.

**(f) Other Assets**

Other assets consist principally of unapplied vendor credits available for application against the purchase price of additional machinery configured similarly to that currently used by the Company, and restricted cash.

**(g) Intangible Asset**

The technology intangible relates to composition and process technology used in edible soluble film manufacturing. It was acquired as part of the Kosmos Pharma Limited asset purchase in 2004 (see note 2). The Company amortizes the technology intangible using the straight-line method over 10 years, which is the expected useful life of the associated products.

**(h) Research and Development Costs**

Research and development costs are expensed as incurred. Research and development costs reflect costs incurred for the Company's internal proprietary research and development projects as well as costs incurred under arrangements with third parties for which the Company generates co-development and research fees. All research and development costs are presented within operating expenses. Research and development expenses amounted to \$1,993, \$1,258, and \$1,010 for the years ended December 31, 2006, 2005, and 2004, respectively.

**(i) Income Taxes**

Monosol Rx LLC is a limited liability company and its owners are referred to as members. Limited liability companies operate under sections of federal and state income tax law which provide that, in lieu of company-level income taxes, the members separately account for their pro rata shares, as allocated in accordance with the members' operating agreement, of the Company's items of income, deductions, losses, and credits. No income taxes have been recognized in the accompanying financial statements except for certain state taxes, which are immaterial and included in general and administrative expense.

**(j) Impairment of Long-Lived Assets**

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets, such as property and equipment, and purchased intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

In 2006, as a result of management's evaluation of the recoverability of the carrying value of its property and equipment, the Company recorded an impairment charge of \$132.

**(k) Revenue Recognition**

The Company recognizes revenue when products are shipped and the customer takes ownership and assumes risk of loss, collection of the related receivable is probable, persuasive evidence of an arrangement exists, and the sales price is fixed or determinable. The Company occasionally uses a third party to complete the packaging process. In these instances, revenue is recognized when the completed product is shipped from the third party. In the case of co-development and research fees, revenue is recognized when appropriate contractual milestones are realized, contractual amounts for those services are billed, and collection of related receivables is probable.

At the present time, the Company's agreements for co-development fees and manufacturing and supply revenue are separate and distinct from each other. The arrangements will generally be for the delivery of one product element per agreement. A customer will generally enter into a co-development agreement with the Company and then upon successful completion may enter into a supply agreement for the product that was developed. Whether revenue is earned from development fees or milestone payments, deliverables under these contracts are discrete and sequential.

The Company's revenue recognition policy is governed by Staff Accounting Bulletin (SAB) No. 101 *Revenue Recognition in Financial Statements*, as amended by SAB No. 104. The Company recognizes revenue based on the following:

- *Evidence of an arrangement:* The Company considers a non-cancellable purchase order or contract to be representative of persuasive evidence of an arrangement.
- *Delivery has occurred:* The Company considers delivery of manufacture and supply products to have occurred when the products are shipped from our facility and the risk of loss has passed to the customer. When we utilize third parties to complete the manufacturing process, revenue is recognized when the product is shipped from the third party. The Company's co-development arrangements call for either a specific result to have occurred or a milestone to have been reached. Upon the completion of the event or attainment of the milestone, the Company will recognize revenue.
- *Fees are fixed or determinable:* The Company's pricing is stipulated in our contractual arrangements or in customers' non-cancellable purchase order.
- *Collection is deemed probable:* The Company conducts a review of the customer and the relevant arrangement agreement at the inception to determine the probability of collection. If the Company determines that collection is not probable, revenue is deferred until the receipt of cash.

**(l) Asset Retirement Obligations**

SFAS No. 143, *Accounting for Asset Retirement Obligations*, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company's asset retirement obligation consists of estimated future spending to remove certain leasehold improvements and return the leased facility to its original condition. Spending estimates are discounted at the credit-adjusted risk-free rate. The Company records an Asset Retirement Obligations (ARO) asset (a component of property and equipment) associated with the discounted liability. The ARO asset is amortized on



the straight-line method over the lesser of its expected life or the lease term, and the ARO liability is accreted to the projected spending date.

**(m) Reclassifications**

Costs written off for inventory excess and obsolescence in 2005 have been reclassified from general and administrative expenses to cost of goods sold to conform to the 2006 presentation.

**(n) Change in Method of Accounting for Patent Costs**

In 2006, the Company elected to change its method of accounting for patent costs. In prior years, the Company capitalized all external costs incurred in seeking patent protections, consisting primarily of legal fees for patent applications, and commenced amortization upon approval of the patent. Internal costs related to patent applications were expensed as incurred. Beginning in 2006, the Company adopted a policy of expensing both internal and external patent application costs as incurred. Legal costs incurred to successfully defend an existing patent are capitalized and amortized over the remaining life of the patent. Legal costs related to an unsuccessful outcome are expensed when the outcome is known. The comparative financial statements of prior years have been adjusted to reflect the change in accounting policy retroactively.

**(o) Recently Adopted Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123R) which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services, with a primary focus on transactions in which an entity obtains employee services in equity-based payment transactions. This Statement is a revision to Statement 123 and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. This Statement requires measurement of the cost of employee services received in exchange for equity-based awards using the grant-date fair value of the awards. Incremental compensation costs arising from subsequent modifications of awards after the grant date must also be recognized. The Company adopted this Statement on January 1, 2006 under the modified prospective method of application. The Company considers its performance unit plan (see footnote 14) to be within the scope of SFAS 123R. Under the modified prospective method, the Company will recognize compensation costs in accordance with SFAS 123R for new grants of performance units, grants modified after the effective date, and the remaining portion of the fair value of the unvested grants at the adoption date. Vested grants under the performance unit plan are not redeemable until the Company either experiences a change in control or completes an Initial Public Offering (IPO). These are considered to be performance conditions which render the grants contingent until they are satisfied. As neither of these performance conditions were met at December 31, 2006, the adoption of SFAS 123R had no impact on the Company's operating loss or net loss. If either of the performance conditions were met at December 31, 2006, the Company's operating loss and net loss would have included an additional \$9,016 in compensation expense.

Effective January 1, 2006, the Company adopted FASB Statement No. 151, *Inventory Costs—an Amendment of ARB No. 43, Chapter 4* (Statement 151). Statement 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) requiring that those items be recognized as current period charges. In addition, Statement 151 requires that allocation of fixed production overheads be based on the normal capacity of the

production facilities. Prior to the adoption of Statement 151, the Company's inventory cost included fixed overhead costs determined as a percentage of direct costs.

**(p) Recently Issued Accounting Standards**

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement 109 (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a threshold of more-likely-than-not for recognition of the benefits of uncertain tax positions taken or expected to be taken in a tax return. FIN 48 also provides related guidance on measurement, derecognition, classification, interest and penalties, and disclosure. The provisions of FIN 48 will be effective for the Company on January 1, 2007, with any cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is in the process of assessing the impact of adopting FIN 48 on its results of operations and financial position, but does not believe that it will be significant.

**(2) Purchase of Assets from Kosmos Pharma Limited**

On January 22, 2004, the Company purchased substantially all of the assets of Kosmos Pharma Limited (Kosmos), a drug research company, in exchange for the assumption of certain liabilities and the issuance of limited liability interests in the Company. At the date of purchase, Kosmos had no commercially viable products, but had developed certain development applications. The Company believed that the combination of the Predecessor's production capabilities and Kosmos' technology would accelerate the growth of the Predecessor.

The following table presents a summary of the assets purchased and the liabilities assumed based on their approximate fair value:

Receivables	\$ 1,196
Property and equipment	252
Technology intangible asset	2,358
	<hr/>
Total assets acquired	3,806
	<hr/>
Accounts payable	345
Long-term debt	904
	<hr/>
Total liabilities assumed	1,249
	<hr/>
Net assets acquired	\$ 2,557
	<hr/>

Fair value for property and equipment and the technology intangible were determined using estimated replacement cost.

**(3) Cash and Liquidity**

At December 31, 2006, the Company had \$15,256 of cash. Management believes, even absent any actions to access the capital markets, that the Company has sufficient cash resources to meet its needs at least through December 31, 2007.

**(4) Major Customers**

Most of the Company's customers are located in the United States and Europe. Customers are considered major customers when sales exceed 10% of the Company's total net sales for the year or outstanding receivable balances exceed 10% of total receivables. The Company had four major customers with sales totaling \$2,509 for the year ended December 31, 2006 and outstanding receivable balances totaling \$563 at December 31, 2006. In 2006, the Company's four major customers had sales of \$1,233, \$896, \$280 and \$100, respectively. The Company had no major customers in 2005. The Company had one major customer in 2004 with sales of \$1,774 and had an outstanding receivable balance from this customer of \$1,015 at December 31, 2004.

**(5) Trade Receivables**

Trade receivables consist of the following at December 31, 2006 and 2005:

	<u>2006</u>	<u>2005</u>
Trade receivable	\$ 583	\$ 196
Less allowance for bad debts	16	—
	<u>\$ 567</u>	<u>\$ 196</u>

**(6) Inventory**

Inventory consists of the following at December 31, 2006 and 2005:

	<u>2006</u>	<u>2005</u>
Raw material	\$ 242	\$ 234
Packaging material	213	221
Finished goods	—	210
	<u>\$ 455</u>	<u>\$ 665</u>

**(7) Property and Equipment**

Property and equipment consists of the following at December 31, 2006 and 2005:

	<u>2006</u>	<u>2005</u>
Machinery and equipment	\$ 6,698	\$ 4,028
Furniture and fixtures	544	247
Leasehold improvements	3,469	2,016
Construction in process	242	2,098
	<u>10,953</u>	<u>8,389</u>
Less accumulated depreciation and amortization	2,397	775
	<u>\$ 8,556</u>	<u>\$ 7,614</u>

## (8) Other Assets

As of December 31, 2006, the Company had \$100 in restricted cash on deposit in support of a stand-by letter of credit issued in favor of the Indiana Board of Pharmacy. This is a statutory requirement based on the regulations of the Indiana Board of Pharmacy. Additionally, the Company is entitled to credits from a supplier of machinery. At December 31, 2006 and 2005, the Company was entitled to \$200 and \$496 of vendor credits, respectively, to be applied towards the purchase of production machinery configured similarly to the machinery it currently uses. During June 2006, the Company reconfigured a portion of its production, machinery, and equipment. As a result, \$296 of vendor credits were no longer usable and were charged off. The Company also has a purchase obligation related to the machinery. See note 11.

## (9) Intangible Asset

The following table presents a summary of the intangible asset at December 31, 2006 and 2005.

	2006	2005
Purchased intangible	\$ 2,358	\$ 2,358
Less accumulated amortization	694	458
	<u>\$ 1,664</u>	<u>\$ 1,900</u>

Amortization expense for the years ended December 31, 2006, 2005, and 2004 was \$236, \$236, and \$222, respectively. Estimated annual amortization expense for each of the next five years is \$236.

## (10) Long-Term Debt

The Company had no long-term debt outstanding at December 31, 2006. Long-term debt at December 31, 2005 consisted of the following:

Unsecured term note due to member	\$ 348
Note Payable Tranche A	5,365
Note Payable Tranche B	5,587
Less discounts on notes	(5,097)
Less current maturities	(278)
	<u>\$ 5,925</u>

During 2006, the Company repaid the unsecured note due to member and the Tranche A & B Notes were converted to Series A-1 Preferred Interests (see below).

The unsecured note was assumed as a result of the Kosmos transaction (see note 2) and was payable to a related party.

### **Tranche A & B Notes**

In 2005, the Company issued \$5,000 of notes payable (Tranche A Notes) along with stock purchase warrants. The Tranche A Notes bore 15% payment in kind (PIK) interest with a maturity date of 2010. Management held \$275 of the Notes, with the remainder held by affiliates of the members of the

Company. The estimated fair value of the warrants at the date of issue was \$431 and the Company recognized \$25 of compensation expense related to the warrants held by management. In August 2005, the Company modified the Tranche A Notes by reducing the interest rate to 4.33% and extending the maturity date to 2015. The modification of the Tranche A note terms was considered a significant debt modification and resulted in the recognition of a capital contribution in the amount of \$2,180.

In August 2005, the Company completed a financing transaction in which it issued \$5,500 of notes payable (2005 Tranche B Notes) and stock purchase warrants to an affiliate of the Company. The notes were issued with a maturity date of 2015 and 4% payment-in-kind (PIK) interest. The warrants were recorded at fair value and gave rise to the recognition of a discount on the 2005 Tranche B Notes of \$2,567.

During 2006, the Company issued \$10,000 of notes payable (2006 Tranche B Notes) along with warrants to several investors, including affiliates of the Company. The notes were issued with a 10-year term and 4% PIK interest. The warrants were recorded at fair value and gave rise to the recognition of a discount on the 2006 Tranche B Notes of \$4,668.

The warrants are immediately exercisable at price of \$0.01 per unit and expire at various times in 2015 and 2016. At December 31, 2006, the warrants represent a 35.5% ownership interest in the Company.

In October and November 2006, the Tranche A and B Notes, with an original principal amount of \$20,500 and accrued interest of \$1,027, were converted to Series A-1 Preferred Interests.

## **(11) Commitments and Contingent Liabilities**

### ***(a) Leases:***

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options; some contain purchase options and some require the Company to pay for taxes, maintenance and operating expenses.

#### *Production and Research Facilities:*

The Company leases its current production facility in Portage, Indiana, which houses research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. Prior to September 2006, the property was leased through the Predecessor and rent was charged to the Company by the Predecessor. In September 2006, the Predecessor, with the landlord's agreement and acceptance, assigned to the Company all rights and obligations under the existing lease. As part of the assignment, the Predecessor agreed to guarantee the lease payment through March 2008. See note 18.

In October 2006, the Company entered into a lease for a 73,000 square foot cGMP facility (Ameriplex) in Portage, Indiana. The Ameriplex facility will become the primary research, development, and manufacturing facility for the Company. The current term of the lease expires in March 2012, with options to extend through March 2021. The lease contains a right of first refusal to purchase the facility.

The Company leases a technology development laboratory in Kingsport, Tennessee. The lease expires in December 2009.

*Office Facilities:*

In July 2006, the Company entered into a lease for its headquarters in Warren, New Jersey. The lease expires in August 2011.

The Company is a guarantor of a lease for office space in Washington, D.C. The underlying lease was entered into by a consultant to the Company and extends through May 2007.

Rent expense totaled \$360, \$233, and \$124 for the years ended December 31, 2006, 2005, and 2004, respectively.

The following is a schedule of future minimum lease payments under operating leases as of December 31, 2006:

	<u>Amount</u>
Year:	
2007	\$ 588
2008	536
2009	539
2010	532
2011	556
Thereafter	128
	<u>\$ 2,879</u>

***(b) Equipment Purchase Obligations***

The Company has entered into an agreement to purchase a new film coating line during 2007 for a total purchase price of \$3,690. The equipment will be used to fulfill production requirements under a commercial supply agreement. The customer that is a party to the supply agreement is obligated to make capacity payments over two years that equal the cost of the equipment and other capital expenditures related to its installation.

**(12) Employee Benefit Plans**

The Company sponsors a defined contribution 401(k) plan covering all full-time employees. Participants may contribute up to 50% of their salary not to exceed applicable statutory limitations. The Company makes matching contributions to the plan equal to 100% of the first 6% contributed by employees. The Company may also make a discretionary profit sharing contribution to the plan. In 2006, the Company's matching contributions to the plan were \$169. The discretionary profit-sharing contribution totaled \$0 in 2006. In 2005, the Company's matching contributions to the plan were \$64. The Company also made a discretionary profit-sharing contribution of 9% of annual compensation for employees who had completed more than one year of service. The discretionary profit-sharing contribution totaled \$101 in 2005. In 2004, the Company's matching contributions to the plan were \$22. The Company also made a discretionary profit-sharing contribution of 9% of annual compensation for employees who had completed more than one year of service in 2004. The discretionary profit-sharing contribution totaled \$31.

### **(13) Research and Development Arrangements**

The Company periodically enters into arrangements to test the applicability of various products on thin film. These arrangements are usually for a finite period of time and are directed at a certain defined result. The fees charged are usually on a cost-plus basis. These arrangements may or may not lead to future research and development arrangements or product production. In 2006, 2005, and 2004, revenue derived from these types of arrangements was \$950, \$665, and \$100, respectively. In 2006, 2005, and 2004, research and development expenses related to co-development and research fees were \$799, \$359 and \$69, respectively.

### **(14) Performance Units Plan**

The Company has established two Performance Unit Plans (the Plans) for the purpose of enhancing the long-term growth in earnings of the Company by providing incentives to key employees and other service providers of the Company. The Plans authorize grants of up to 22,796 performance units and can be modified at the Company's discretion to make additional performance units available. Performance units may be granted with a base value equal to their estimated fair value on the date of grant. The base value and fair value are determined by the Company's board of directors after consideration of factors such as cumulative contributions, the presence of third party contributors and their participation in debt and equity offerings of the Company, net cash flows and general economic conditions. The performance units granted to employees are equity classified instruments. The performance units granted to consultants are liability classified instruments. All performance units granted vest over either a two or a three-year period with accelerated vesting upon a change in control or an Initial Public Offering (IPO) of the Company. Vested grants under the Plans are not redeemable until the Company either experiences a change in control or completes an IPO. These are considered to be performance conditions which render the awards contingent until they are satisfied. Vested units can be redeemed for cash or in the form of the same equity instruments received by the Company or members of the Company at the time of a change in control or an IPO, at the Company's discretion. The payment to a participant is based on the spread between the fair value at the time of a change in control and the base value of the performance units at the date of grant. Performance units do not expire; the units continue until employee termination or a triggering event.

There were 21,215, 3,750, and 2,775 performance units granted to plan participants that would be redeemable in the event of a change in control or IPO of the Company as of December 31, 2006, 2005, and 2004, respectively. As neither of these performance conditions have been met, no compensation expense has been recorded. If either of the performance conditions were met at December 31, 2006, the Company would have recognized an additional \$9,016 in compensation expense. Compensation expense is determined as the fair value of the equity awards at grant date or amendment date and the fair value of the liability awards at the date the awards are triggered by a change in control or IPO.

Certain participants of the plan, principally senior management, have been granted protection against future dilution of their interests (dilution protection). As of December 31, 2006, 2005 and 2004, 19,776, 654, and zero of the outstanding units, respectively, are covered by dilution protection through June 2007 or the completion of an IPO of the Company, whichever comes first. In addition, during 2006, 2005 and 2004, 13,599, 379, and zero units, respectively, were issued due to dilutive events or changes in the capital structure of the Company, and 3,380, 654 and 900 units, during 2006, 2005 and 2004 respectively, were issued in connection with new hires.

Performance Unit Plan activity for the year ended December 31, 2006 and changes during the year ending December 31, 2006 was as follows:

	Units	Weighted Average Exercise Price(1)	Aggregate Intrinsic Value(2)
Outstanding at December 31, 2005	3,750	\$ 15,178	
Granted	17,637	\$ 83,250	
Exercised	—		
Forfeited/cancelled/expired	(172)	15,565	
<b>Outstanding at December 31, 2006</b>	<b>21,215</b>	<b>\$ 56,902</b>	<b>\$ 9,016</b>
Vested and expected to vest at December 31, 2006	6,131	\$ 19,738	\$ 4,852
<b>Exercisable at December 31, 2006</b>	<b>—</b>		

- (1) Represents the weighted average base value of the outstanding performance units. There is no per unit price for the performance units under the performance unit plan.
- (2) Represents the total pretax intrinsic value (the difference between the Company's estimated fair-value and the weighted average base value of the performance units multiplied by the percentage of ownership which the performance units represent).

Performance Unit Plan activity for the years ended December 31, 2005 and 2004 were as follows:

	2005	2005	2004	2004
	Units	Weighted Average Exercise Price(1)	Units	Weighted Average Exercise Price(1)
Outstanding at beginning of year	2,775	\$ 12,586	—	
Granted	994	\$ 18,845	2,775	\$ 12,586
Exercised	—		—	
Forfeited/cancelled/expired	(19)	\$ 17,857	—	
<b>Outstanding at end of year</b>	<b>3,750</b>	<b>\$ 15,178</b>	<b>2,775</b>	<b>\$ 12,586</b>
Exercisable at end of year	—		—	

- (1) Represents the weighted average base value of the outstanding performance units. There is no per unit price for the performance units under the performance unit plan.



Activity in nonvested performance units for the years ended December 31, 2004, 2005 and 2006 was as follows:

	Units		Weighted Average Grant Date Fair Value
Nonvested at December 31, 2003	—		—
Granted	2,775	\$	12,586
Vested	(1,250)		12,500
Forfeited	—		—
Nonvested at December 31, 2004	1,525	\$	12,725
Granted	994	\$	18,845
Vested	(69)	\$	13,750
Forfeited	(19)	\$	17,587
Nonvested at December 31, 2005	2,431	\$	16,207
Granted	17,637	\$	83,250
Vested	(4,812)	\$	24,190
Forfeited	(172)	\$	15,565
Nonvested at December 31, 2006	15,084	\$	72,008

#### (15) Related-Party Transactions

Holders of the Tranche A and B Notes are affiliates of the Company. See note 9.

At December 31, 2006 and 2005, \$0 and \$10, respectively, were due to the Predecessor as accounts payable.

At December 31, 2006, \$200 was due from the Predecessor as other receivables. In December 2006, the Company sold an asset with a book value of \$416 to the Predecessor for \$200. The asset was originally part of Monosol Rx LLC's capital contribution in 2004 and was found to be unsuitable for use in pharmaceutical film casting. Prior to the transaction, in order to determine an appropriate sale price for the asset, the Company obtained independent estimates from dealers in the secondary market, the sales price was in excess of the estimates obtained. See note 18.

Interest expense on the term note with the interestholder was \$22, \$38, and \$41 for the years ended December 31, 2006, 2005, and 2004, respectively.

The statements of operations include certain costs allocated by the Predecessor. Charges for rent, insurance, employee fringe benefits, and other overhead costs are based on the ratio of payroll expense for the Company's or the Predecessor's employees to aggregate payroll expense for the Predecessor employees. In the opinion of management, the costs charged have been allocated on a basis that is believed to be reasonable within the structure of the Predecessor. However, the costs charged are not necessarily indicative of the level of expenses that might have been incurred if the Company and the Predecessor had operated as a standalone entity. The total amount of costs allocated to the Company was \$250, \$696, and \$727 for 2006, 2005, and 2004, respectively.

In conjunction with the Company's purchase of all of the assets of Kosmos, Dr. Richard Fuisz and his son, Joseph Fuisz, Esq., significant shareholders in Kosmos, entered into consulting agreements with

the Company. These consulting agreements were each for a three-year term and provided for a monthly and annual fee of \$13 and \$160, respectively, plus the reimbursement of certain expenses.

In September 2006, the consulting agreement between the Company and Dr. Fuisz was extended through September 2009 with substantially the same terms. The contract between the Company and Joseph Fuisz, Esq. was terminated and Mr. Fuisz became an employee of the Company.

#### **(16) Asset Retirement Obligations**

SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement cost. The Company's asset retirement obligation consists of estimated future spending related to removing certain leasehold improvements at its Portage, Indiana laboratory and returning the facility to its original condition.

Below is a schedule of the Company's liability for asset retirement obligations for the year ended December 31, 2006:

	<u>Amount</u>
Balance at December 31, 2005	\$ —
Liability incurred, September 2006	85
Accretion	2
	<hr/>
Balance at December 31, 2006	\$ 87

For the year ended December 31, 2006, the Company recorded expense of \$14 included in depreciation expense related to the ARO asset.

#### **(17) Preferred Interests**

In November 2006, the Company closed a Private Placement Offering for \$38,414 Series A and Series A-1 Preferred Interests representing a 37.9% ownership in the Company. The interests were purchased by several investors, including affiliates of the Company. The balance of the Company's equity is represented by common interests.

The Company received \$16,887 in cash proceeds from the Series A offering. The proceeds are to be used to fund research and development activities, capital expenditures for facilities, expansion of manufacturing capabilities and working capital needs. The Series A-1 preferred interests were issued in settlement of all amounts due on the Tranche A and B Notes issued in 2005 and 2006, consisting of \$20,500 in principal along with accrued interest.

The Series A interests rank senior to the Series A-1 interests and common interests with respect to payment of dividends and amounts due upon liquidation, dissolution, or winding up of the Company. The Series A-1 interests are senior to the common interests with respect to dividends and liquidation.

The Series A and A-1 interests hold the same voting rights as the common interests.

The Company is required to receive the written consent of more than 50% of the Preferred Interests prior to:

- Liquidating, dissolving or winding up the Company;
- Amending or repealing the LLC Agreement; and

- Creating or authorizing a security senior to the preferred interest or increasing the authorized number of preferred interests.

#### **(18) Subsequent Events**

In January 2007, the landlord of the Portage, Indiana production facility released the Predecessor from its guarantee in consideration of the Company providing a security deposit in the amount of three months rent.

In January 2007, the Company issued an additional 210 performance units to various employees. The performance units are subject to the terms of the Performance Unit Plan, as described in note 13.

In February 2007, the Company received the \$200 classified as other receivables from the Predecessor.

In April 2007, the holders of the warrants issued in 2005 and 2006 in connection with the Tranche A & B Notes, (see Note 10) exercised their rights to purchase common membership interests in Monosol Rx LLC. An additional 55,785 membership interests were issued for \$155.

In May 2007, the Company amended and restated its Executive Employment Agreement with Joseph Fuisz and amended its Consulting Agreement with Dr. Richard Fuisz. Dr. Fuisz's Consulting Agreement was amended to require the Company to pay him a fee of \$100 upon the effectiveness of a registration statement for an initial public offering of MonoSol Rx, Inc., if the effectiveness occurs by December 31, 2007. See note 19. Joseph Fuisz's amended and restated Executive Employment Agreement terminates on December 31, 2007, and provides for a consulting agreement between Joseph Fuisz and the Company commencing January 1, 2008, and ending December 31, 2008.

The agreement that amended Dr. Fuisz's Consulting Agreement with the Company also provided for the Company's transfer of certain intellectual property to a new limited liability company of which Dr. Fuisz will own a 55% interest and the current equity interest holders of Monosol Rx LLC will own a 45% interest. The intellectual property transferred is not related to thin film products. Thus management does not believe that it has value to the Company in its current form.

The Company has also agreed to indemnify Dr. Fuisz to the same extent we have agreed to indemnify our officers and directors.

#### **(19) Planned Transactions (unaudited)**

The Company is planning to merge with and into a newly formed entity, MonoSol Rx, Inc. The merger is in connection with MonoSol Rx, Inc. filing a Registration Statement relating to the proposed public offering of its common stock. Immediately after merger, but prior to the offering the Company's common interests, preferred interests and outstanding performance units will be converted to the Common Stock of MonoSol Rx, Inc.

Monosol Rx LLC

Balance sheets

(in thousands, except for unit data)

ASSETS	March 31, 2007	December 31, 2006
	(unaudited)	
<b>Current assets:</b>		
Cash and cash equivalents	\$ 11,306	\$ 15,256
Trade receivables	204	567
Other receivables	3	11
Due from the Predecessor	—	200
Inventories	865	455
Prepaid expenses and other current assets	136	170
	<u>12,514</u>	<u>16,659</u>
Total current assets	12,514	16,659
Property and equipment, net	9,579	8,556
Other assets	103	300
Intangible assets, net	1,605	1,664
	<u>\$ 23,801</u>	<u>\$ 27,179</u>
	<u>\$ 23,801</u>	<u>\$ 27,179</u>
<b>LIABILITIES AND MEMBERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	1,815	1,096
Asset retirement obligations	90	—
Accrued expenses	619	733
	<u>2,524</u>	<u>1,829</u>
Total current liabilities	2,524	1,829
Other liabilities—asset retirement obligations	—	87
<b>Members' equity:</b>		
Preferred A interests, no par value, 100,000,000 units authorized; 16,886,750 issued and outstanding, respectively	16,887	16,887
Preferred A-1 interests, no par value, 100,000,000 units authorized; 21,526,850 issued and outstanding, respectively	21,883	21,883
Common interests, no par value, 500,000,000 units authorized; 63,000,000 issued and outstanding, respectively	11,088	11,088
Accumulated deficit	(28,581)	(24,595)
	<u>21,277</u>	<u>25,263</u>
Total Members' equity	21,277	25,263
	<u>\$ 23,801</u>	<u>\$ 27,179</u>
	<u>\$ 23,801</u>	<u>\$ 27,179</u>

See accompanying notes to unaudited financial statements.

Monosol Rx LLC

Statements of operations

(in thousands)

Three Months ended March 31, 2007 and March 31, 2006

	Three Months Ended March 31,	
	2007	2006
	(unaudited)	(unaudited)
Revenues:		
Manufacture and supply revenue	\$ 429	963
Co-development and research fees	80	190
Total revenues	509	1,153
Cost of goods sold:		
Manufacture and supply	251	644
Gross profit	258	509
Operating expenses:		
General and administrative	3,729	1,923
Research and development	685	379
Operating expenses	4,414	2,302
Operating loss	(4,156)	(1,793)
Other income, principally related-party	—	13
Interest income	170	3
Interest expense	—	(188)
Net loss	\$ (3,986)	(1,965)

See accompanying notes to unaudited financial statements.

Monosol Rx LLC

Statements of changes in members' equity

(in thousands, except for unit data)

Three Months Ended March 31, 2007

Members Contribution Interest

	Preferred A Interests		Preferred A-1 Interests		Common Interests		Accumulated Deficit	Total Members Equity
	Units	Amount	Units	Amount	Units	Amount		
Balance, December 31, 2006	16,886,750	\$ 16,887	21,526,850	\$ 21,883	63,000,000	\$ 11,088	\$ (24,595)	\$ 25,263
Net loss (unaudited)							(3,986)	(3,986)
Balance, March 31, 2007 (unaudited)	16,886,750	\$ 16,887	21,526,850	\$ 21,883	63,000,000	\$ 11,088	\$ (28,581)	\$ 21,277

See accompanying notes to unaudited financial statements.

Monosol Rx LLC

Statements of cash flows

(in thousands)

Three Months ended March 31, 2007 & March 31, 2006

	Three Months Ended March 31,	
	2007	2006
	(unaudited)	(unaudited)
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,986)	\$ (1,965)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	608	301
Asset retirement obligation accretion	3	—
Amortization of debt discount	—	51
Amortization of intangible	59	59
Non-cash interest expense	—	129
Loss from disposal of assets	—	95
Bad debt expense	10	—
<b>Changes in operating assets and liabilities:</b>		
Trade receivables	353	(280)
Other receivables	8	—
Inventories	(410)	(58)
Prepaid expenses	34	29
Accounts payable	719	(193)
Due to the Predecessor	—	(4)
Accrued expenses	(114)	(71)
Other assets	(3)	—
	<u>(2,719)</u>	<u>(1,907)</u>
<b>Net cash used in operating activities</b>		
<b>Cash flows from investing activities:</b>		
Capital expenditures	(1,431)	(456)
	<u>(1,431)</u>	<u>(456)</u>
<b>Net cash used in investing activities</b>		
<b>Cash flows from financing activities:</b>		
Proceeds from asset transfer to the Predecessor	200	—
Principal payments on long-term debt	—	(69)
Proceeds from debt and warrant issuances	—	6,000
	<u>200</u>	<u>5,931</u>
<b>Net cash provided by financing activities</b>		
	<u>(3,950)</u>	<u>3,568</u>
<b>Net (decrease) increase in cash and cash equivalents</b>		
<b>Cash and cash equivalents:</b>		
Beginning of period	15,256	1,332
	<u>11,306</u>	<u>4,900</u>
End of period	\$	\$
<b>Supplemental disclosure of cash flow information:</b>		
Cash payments for interest	\$ —	\$ 7
	<u>200</u>	<u>—</u>
Other asset—vendor credits applied to capital expenditures	\$	\$

See accompanying notes to unaudited financial statements.

Notes to financial statements

(unaudited)

(in thousands)

(1) Nature of Business and Basis of presentation

*Nature of Business*

Monosol Rx LLC (Monosol Rx or the Company) was founded on January 21, 2004 and is a drug delivery company specializing in proprietary dissolving thin film drug delivery products. The Company's thin film drug delivery dosage form is similar in size, shape and thickness to a postage stamp and dissolves readily on the tongue for easy use by patients. The Company's thin film drug delivery technology is now used in the over-the-counter, or OTC, marketplace and is currently emerging in the prescription drug market. The Company's films are environmentally friendly given their biodegradable properties and ability to yield inert materials once dissolved in water. For the three months ending March 31, 2007 and 2006, most of the Company's customers were principally located in the Northeastern and Southeastern parts of the United States.

Prior to the formation of Monosol Rx LLC, the activities of the Company were carried out as part of the research and development efforts of Monosol, LLC, a manufacturer of commercial soluble films (the Predecessor).

**Basis of presentation**

In the opinion of management, the accompanying Financials Statements of Monosol Rx contain all adjustments, including normal recurring adjustments, necessary to fairly present the Company's financial position as of March 31, 2007, its results of operations for the three months ended March 31, 2007 and 2006 and its cash flows for the three months ended March 31, 2007 and 2006. The balance sheet as of December 31, 2006 is derived from the December 31, 2006 audited financial statements included elsewhere herein.

The results of operations for the three months ended March 31, 2007 are not necessarily indicative of the results to be expected for the full year. The information included in the accompanying interim statements should be read in conjunction with the audited financial statements.

The preparation of financial statements in accordance with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the Company's financial statements and accompanying notes. Actual results could differ materially from those estimates.

*Significant Accounting Policies*

(a) *Recently Adopted Accounting Standards*

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123R) which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services, with a primary focus on transactions in which an entity obtains employee services in equity-based payment transactions. This Statement is a revision to Statement 123 and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. This Statement requires measurement of the cost of



employee services received in exchange for equity-based awards using the grant-date fair value of the awards. Incremental compensation costs arising from subsequent modifications of awards after the grant date must also be recognized. The Company adopted this Statement on January 1, 2006 under the modified prospective method of application. The Company considers its performance unit plan (see footnote 5) to be within the scope of SFAS 123R. Under the modified prospective method, the Company will recognize compensation costs in accordance with SFAS 123R for new grants of performance units grants modified after the effective date, and the remaining portion of the fair value of the unvested grants at the adoption date. Vested grants under the performance unit plan are not redeemable until the Company either experiences a change in control or completes an Initial Public Offering (IPO). These are considered to be performance conditions which render the grants contingent until they are satisfied. As neither of these performance conditions were met at December 31, 2006, the adoption of SFAS 123R had no impact on the Company's operating loss or net loss. If either of the performance conditions were met at December 31, 2006, the Company's operating loss and net loss would have included an additional \$9,016 in compensation expense.

Effective January 1, 2007 the Company adopted, FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes (FIN 48)*, an interpretation of FASB Statement 109, *Accounting for Income Taxes*. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a threshold of more-likely-than-not for recognition of the benefits of uncertain tax positions taken or expected to be taken in a tax return. FIN 48 also provides related guidance on measurement, derecognition, classification, interest and penalties, and disclosure. The adoption of FIN 48 had no impact on the Company's results of operations and financial position.

**(2) Balance Sheet Details**

**(a) Trade Receivables**

Trade receivables consist of the following at March 31, 2007 and December 31, 2006:

	March 31, 2007	December 31, 2006
Trade receivable	\$ 230	\$ 583
Less allowance for bad debts	26	16
<b>Total trade receivables</b>	<b>\$ 204</b>	<b>\$ 567</b>

**(b) Inventory**

Inventory consists of the following at March 31, 2007 and December 31, 2006:

	March 31, 2007	December 31, 2006
Raw material	\$ 371	\$ 242
Packaging material	338	213
Finished goods	156	—
Total inventories	\$ 865	\$ 455

**(c) Property and Equipment**

Property and equipment consists of the following at March 31, 2007 and December 31, 2006:

	March 31, 2007	December 31, 2006
Machinery and equipment	\$ 6,835	\$ 6,698
Furniture and fixtures	555	544
Leasehold improvements	3,469	3,469
Construction in process	1,725	242
	12,584	10,953
Less accumulated depreciation and amortization	3,005	2,397
Total property and equipment	\$ 9,579	\$ 8,556

**(3) Commitments and Contingent Liabilities**

***Equipment Purchase Obligations***

The Company has entered into an agreement to purchase a new film coating line during 2007 for a total purchase price of \$3,690. The equipment will be used to fulfill production requirements under a commercial supply agreement. As of March 31, 2007, the Company has made \$1,297 in progress payments to the equipment vendor which are included in property and equipment as construction in process. The customer that is a party to the supply agreement will make capacity payments to the Company over two years that equal the cost of the equipment and other capital expenditures related to its installation.

**(4) Operating Leases**

The Company is party to a commercial supply agreement (see Note 3), the terms of which call for certain identified production equipment and facilities to be dedicated to the customer that is party to the agreement and also permits the customer to terminate the agreement without penalty. Upon installation and acceptance, the capacity payments under the agreement will be recognized as rental revenue on a straight line basis over the remaining term of the agreement. As of March 31, 2007, no payments have been received by the Company under the agreement. See note 6.

## (5) Performance Units Plan

The Company has established two Performance Unit Plans (the Plans) for the purpose of enhancing the long-term growth in earnings of the Company by providing incentives to key employees and other service providers of the Company. The Plans authorize grants of up to 22,796 performance units and can be modified at the Company's discretion to make additional performance units available. Performance units may be granted with a base value equal to their estimated fair value on the date of grant. The base value and fair value are determined by the Company's board of directors after consideration of factors such as cumulative contributions, the presence of third party contributions and their participation in debt and equity offerings of the Company, net cash flows and general economic conditions. The performance units granted to employees are equity classified instruments. The performance units granted to employees are equity classified instruments. The performance units granted to consultants are liability classified instruments. All performance units granted vest over either a two or a three-year period with accelerated vesting upon a change in control or an Initial Public Offering (IPO) of the Company. Vested grants under the Plans are not redeemable until the Company either experiences a change in control or completes an IPO. These are considered to be performance conditions which render the awards contingent until they are satisfied. Vested units can be redeemed for cash or in the form of the same equity instruments received by the Company or members of the Company at the time of a change in control or an IPO, at the Company's discretion. The payment to a participant is based on the spread between the fair value at the time of a change in control and the base value of the performance units at the date of grant. Performance units do not expire; the units continue until employee termination or a triggering event.

There were 21,418 and 21,215 performance units granted to plan participants that would be redeemable in the event of a change in control or IPO of the Company as of March 31, 2007 and December 31, 2006, respectively. As neither of the performance conditions have been met, no compensation expense has been recorded. If either of the performance conditions were met at March 31, 2007, the Company would have included an additional \$9,016 in compensation expense. Compensation expense is determined as the fair value of the equity awards at grant date or amendment date and the fair value of the liability awards at the date the awards are triggered by a change in control or IPO.

Certain participants of the plan, principally senior management, have been granted protection against future dilution of their interests (dilution protection). As of March 31, 2007, 19,776 of the outstanding units are covered by dilution protection through June 2007 or the completion of an IPO of the Company, whichever comes first.

Performance Unit Plan activity for the three months ended March 31, 2007 was as follows:

	Units	Weighted Average Exercise Price(1)	Aggregate Intrinsic Value(2)
Outstanding at December 31, 2006	21,215	\$ 56,902	
Granted	210	\$ 100,000	
Exercised	—	—	
Forfeited/cancelled/expired	(7)	\$ 100,000	
<b>Outstanding at March 31, 2007</b>	<b>21,418</b>	<b>\$ 57,311</b>	<b>\$ 9,016</b>
Vested at March 31, 2007	7,061	\$ 21,908	\$ 5,437
Exercisable at March 31, 2007	—		

- (1) Represents the weighted average base value of the outstanding performance units. There is no per unit price for the performance units under the performance unit plan.
- (2) Represents the total pretax intrinsic value (the difference between the Company's estimated fair-value and the weighted average base value of the performance units multiplied by the percentage of ownership which the performance units represent).

Activity in nonvested performance units for the three months ended March 31, 2007 was as follows:

	Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2006	15,084	\$ 72,008
Granted	210	\$ 100,000
Vested	(930)	\$ 36,219
Forfeited	(7)	\$ 100,000
<b>Nonvested at March 31, 2007</b>	<b>14,357</b>	<b>\$ 74,722</b>

## (6) Subsequent Events

In April 2007, the holders of the warrants issued in 2005 and 2006 in connection with the Tranche A & B Notes, exercised their rights to purchase common membership interests in Monosol Rx LLC. An additional 55,785 membership interests were issued for \$155.

In May 2007, the Company amended and restated its Executive Employment Agreement with Joseph Fuisz and amended its Consulting Agreement with Dr. Richard Fuisz. Dr. Fuisz's Consulting Agreement was amended to require the Company to pay him a fee of \$100 upon the effectiveness of a registration statement for an initial public offering of MonoSol Rx, Inc., if the effectiveness occurs by December 31, 2007. Joseph Fuisz's amended and restated Executive Employment Agreement terminates on December 31, 2007, and provides for a consulting

agreement between Joseph Fuisz and the Company commencing January 1, 2008, and ending December 31, 2008.

The agreement that amended Dr. Fuisz's Consulting Agreement with the Company also provided for the Company's transfer of certain intellectual property to a new limited liability company of which Dr. Fuisz will own a 55% interest and the current equity interest holders of Monosol Rx LLC will own a 45% interest. The intellectual property transferred is not related to thin film products. Thus management does not believe that it has value to the Company in its current form.

The Company has also agreed to indemnify Dr. Fuisz to the same extent we have agreed to indemnify our officers and directors.

In June 2007, the Company received \$1,393 under the commercial supply agreement. See notes 3 and 4.

**(7) Planned Transactions**

The Company is planning to merge with and into a newly formed entity, MonoSol Rx, Inc. The merger is in connection with MonoSol Rx, Inc. filing a Registration Statement relating to the proposed public offering of its common stock. Immediately after merger, but prior to the offering, the Company's common interests, preferred interests and outstanding performance units will be converted to the Common Stock of MonoSol Rx, Inc.

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Shares



Common Stock

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PROSPECTUS

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**Cowen and Company**

**CIBC World Markets**

**Susquehanna Financial Group, LLLP**

, 2007

Until \_\_\_\_\_, 2007, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other expenses of issuance and distribution.**

Set forth below are the expenses (other than underwriting discounts and commissions) expected to be incurred in connection with the issuance and distribution of the securities registered hereby. With the exception of the Securities and Exchange Commission registration fee and the Nasdaq Global Market filing fee, the amounts set forth below are estimates.

SEC Registration Fee	\$ 2,647.87
NASD Filing Fee	\$ 9,125
Nasdaq Global Market Listing Fee	
Printing and Engraving Expenses	
Fees and Expenses of Legal Counsel	
Accounting Fees and Expenses	
Transfer Agent and Registrar Fees	
Miscellaneous	
	_____
<b>Total</b>	<b>\$</b> _____

**Item 14. Indemnification of directors and officers.**

Our certificate of incorporation provides that none of our directors will be personally liable to us or our stockholders for monetary damages for breaches of fiduciary duty, except for (i) breach of our director's duty of loyalty to us or our stockholders, (ii) acts or omissions that are not in good faith, or which involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends, stock purchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law, or DGCL, or (iv) any transaction from which the director derives an improper personal benefit.

Our bylaws provide that, to the fullest extent permitted by applicable law, we will indemnify, hold harmless, and advance expenses to any person that is made or threatened to be made a party to an action or proceeding by reason of the fact that he or she is or was one of our directors or officers. However, we are not required to indemnify such person for a proceeding initiated by or on behalf of such person, unless our board of directors authorizes indemnification for that particular proceeding.

Section 145 of the DGCL 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 attorneys' fees) actually and reasonably incurred by the person in connection with defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation 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, Section 145 of the DGCL requires that, 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 defense of any 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.

Section 145 of the DGCL also provides that 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 DGCL.

We expect to obtain insurance policies under which our directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities which may be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers.

Prior to the completion of this offering, we will enter into indemnification agreements with each of our officers and directors under which we agreed to indemnify each of them against: (a) expenses, judgments, and settlements paid in connection with third-party claims and (b) expenses and settlements paid in connection with claims on our behalf, in each case provided that the director acted in good faith. In addition, we will agree to indemnify each director to the extent permitted by the DGCL, our certificate of incorporation and our bylaws against all expenses, judgments, and amounts paid in settlement unless the director's conduct constituted a breach of his or her duty of loyalty to the stockholders. Subject to the director's obligation to pay us in the event that he or she is not entitled to indemnification, we will pay the expenses of the director prior to a final determination as to whether the director is entitled to indemnification.

Reference is also made to the Underwriting Agreement filed as Exhibit 1.1 to the Registration Statement for information concerning the underwriters' obligation to indemnify us and our officers and directors in certain circumstances.

#### **Item 15. Recent sales of unregistered securities.**

Set forth below is information regarding securities sold by us since March 1, 2004 which were not registered under the Securities Act of 1933, as amended, or Securities Act.

From February 2005 to April 2005, we conducted an offering in which we issued and sold promissory notes and related warrants to seven investors for an aggregate offering price of approximately \$5,000,000 in exchange for cash.

From August 2005 to November 2006 we conducted an offering in which we issued and sold promissory notes and related warrants to two investors for an aggregate offering price of approximately \$15,500,000 in exchange for cash.

In September 2006, we issued and sold two series of preferred membership interests in Monosol Rx LLC to nine investors for an aggregate offering price of approximately \$38,913,600 in exchange for cash. A portion of the proceeds of this offering was used to retire our outstanding indebtedness, including accrued interest, under the promissory notes described above.

No underwriters were involved in the foregoing sales of securities. The securities were issued to U.S. investors in reliance upon the exemption from 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 relating to sales by an issuer not involving any public offering to the extent an exemption from such registration was required. The purchaser of our notes, warrants, and preferred membership interests described above represented to us in connection with their purchase that they were accredited investors and were acquiring the securities 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.

**Item 16. Exhibits.**

- (a) The following documents are filed as exhibits to this registration statement:

<u>Exhibit</u>	
1.1*	Form of Underwriting Agreement
2.1*	Form of Agreement and Plan of Merger between Monosol Rx LLC and MonoSol Rx, Inc.
3.1**	Certificate of Incorporation of MonoSol Rx, Inc.
3.2**	Bylaws of MonoSol Rx, Inc.
4.1*	Specimen Stock Certificate
5.1*	Opinion of Fulbright & Jaworski L.L.P. as to the legality of the securities being registered
10.1**	Executive Employment Agreement dated November 17, 2005 by and between Monosol Rx LLC and A. Mark Schobel
10.2**	Executive Employment Agreement dated June 16, 2006 by and between Monosol Rx LLC and Keith J. Kendall
10.3**	Amended and Restated Executive Employment Agreement dated May 12, 2007 by and between Monosol Rx LLC and Joseph Fuisz
10.4**	Executive Employment Agreement dated August 1, 2006 by and between Monosol Rx LLC and Pradeep Sanghvi
10.5**	Executive Employment Agreement dated January 1, 2007 by and between Monosol Rx LLC and Carl G. Fischer
10.6**	Supply Agreement dated March 15, 2007 by and between Monosol Rx LLC and Adams Respiratory Operations, Inc.
10.7**	Development Agreement dated March 15, 2007 by and between Monosol Rx LLC and Adams Respiratory Products, Inc.
10.8**	License Agreement dated March 15, 2007 by and between Monosol Rx LLC and Adams Respiratory Operations, Inc.
10.9**	Exclusive Strategic Supply Agreement dated February 8, 2007 by and between Monosol Rx LLC and Philip Morris USA Inc.
10.10**	Agreement dated October 12, 2006 by and between Monosol Rx LLC and Medtech Products, Inc.
10.11**	Supply Agreement dated March 20, 2007 by and between Monosol Rx LLC and L. Perrigo Company
10.12**	Benzydamine Development Agreement dated April 1, 2006 by and between Monosol Rx LLC and Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.

- 10.13\*\* Commercial Supply Agreement dated June 4, 2004 by and between Monosol Rx LLC and Dr. Harold Katz LLC
- 10.14\*\* Development and Supply Agreement dated June 29, 2006 by and between Monosol Rx LLC and Vita Health Products Inc.
- 10.15\* Form of Director and Officer Indemnification Agreement
- 10.16\* Form of MonoSol Rx, Inc. 2007 Stock Incentive Plan
- 10.17\* Form of Stock Option Agreement under the MonoSol Rx, Inc. 2007 Stock Incentive Plan
- 10.18\* Form of Restricted Stock Agreement under the MonoSol Rx, Inc. 2007 Stock Incentive Plan
- 10.19\* Form of Stock Appreciation Rights Agreement under the MonoSol Rx, Inc. 2007 Stock Incentive Plan
- 10.20\*\* Summary of Director Compensation
- 10.21\*\* Monosol Rx, LLC Amended and Restated Performance Units Plan Amended and Restated Effective September 18, 2006
- 10.22\*\* Monosol Rx, LLC Amended and Restated Performance Units Plan B Amended and Restated Effective September 18, 2006
- 10.23\*\* Letter Agreement dated May 13, 2007 from Monosol Rx LLC to Joseph M. Fuisz related to the Performance Unit Plan established January 22, 2004, as amended
- 16.1 Letter regarding change in certifying accountant
- 21.1\* List of Subsidiaries of MonoSol Rx, Inc.
- 23.1 Consent of KPMG LLP
- 23.2\* Consent of Fulbright & Jaworski L.L.P. (contained in Exhibit 5.1)
- 24.1\*\* Powers of attorney (included on the signature page hereof)

\* To be filed by amendment.

\*\* Previously filed.

**Item 17. Undertakings.**

(1) 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.

(2) 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 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 Act and will be governed by the final adjudication of such issue.

(3) The undersigned registrant hereby undertakes that:

- (i) 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 a 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 this registration statement as of the time it was declared effective.
- (ii) For the purpose 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.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York on June 26, 2007.

MONOSOL RX, INC.

By: /s/ KEITH J. KENDALL

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Keith J. Kendall  
Executive Vice President and Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
*	Chief Executive Officer, President and Director (Principal Executive Officer)	June 26, 2007
A. Mark Schobel		
/s/ KEITH J. KENDALL	Executive Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	June 26, 2007
Keith J. Kendall		
*	Chairman of the Board and Director	June 26, 2007
Douglas Bratton		
*		
Dr. Gregory Brown	Director	June 26, 2007
*		
John Cochran	Director	June 26, 2007
*		
Robert Flanagan	Director	June 26, 2007
*		
Frank Tanki	Director	June 26, 2007
/s/ *KEITH J. KENDALL		
*Attorney-in-fact		

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## EXHIBIT INDEX

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\* To be filed by amendment.

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**McGladrey & Pullen**  
Certified Public Accountants

May 14, 2007

Securities and Exchange Commission  
100 F Street, N.E.  
Washington, DC 20549

Commissioners:

We have read the statements made by Monosol Rx, Inc., concerning our Firm included in the second paragraph under the caption "Changes In and Disagreements with Accountants on Accounting and Financial Disclosure," in the Company's Registration Statement on Form S-1, which was filed with the Commission.

We agree with the statements made by Monosol Rx, Inc. Please note, however, that for purposes of clarity, McGladrey & Pullen, LLP did not issue an audit opinion on the Company's financial statements for the year ended December 31, 2005.

/s/ McGladrey & Pullen, LLP



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Members  
Monosol Rx LLC:

We consent to the use of our report dated May 14, 2007, with respect to the balance sheets of Monosol Rx LLC as of December 31, 2006 and 2005, and the related statements of operations, changes in members' equity and cash flows for each of the years in the three-year period ended December 31, 2006, included herein and to the reference to our firm under the heading "Experts" in the prospectus.

/S/ KPMG LLP

Chicago, Illinois  
June 25, 2007

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