Synvista Therapeutics, Inc. Form S-3/A September 28, 2007

As filed with the Securities and Exchange Commission on September 28, 2007

Registration No. 333-145935

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

Amendment No. 1 to FORM S-3

#### REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**SYNVISTA THERAPEUTICS, INC.** (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 13-3304550 (I.R.S. Employer Identification Number)

221 West Grand Avenue Suite 200 Montvale, New Jersey 07645 (201) 934-5000 (Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

> Noah Berkowitz, M.D., Ph.D. President and Chief Executive Officer Synvista Therapeutics, Inc. 221 West Grand Avenue Suite 200 Montvale, New Jersey 07645 (201) 934-5000

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

with copies to: Megan N. Gates, Esq. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center

### Boston, Massachusetts 02111 (617) 542-6000

**Approximate date of commencement of proposed sale to the public:** From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. b

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. o\_\_\_\_\_

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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 of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders 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.

#### SUBJECT TO COMPLETION, DATED SEPTEMBER 28, 2007

#### PROSPECTUS

#### SYNVISTA THERAPEUTICS, INC. 628,268 SHARES OF COMMON STOCK

We sold 10 million shares of our Series B Preferred Stock, \$0.01 par value per share (the "Series B Preferred Stock") and warrants to purchase 2.5 million shares of our Series B Preferred Stock (the "Warrants") for an aggregate purchase price of approximately \$25 million in a private placement to accredited institutional investors which closed on July 25, 2007. This prospectus relates to the resale from time to time of a total of 598,391 shares of our common stock issuable upon conversion of the shares of Series B Preferred Stock, as well as 29,877 shares of our common stock issuable upon exercise of warrants to purchase our common stock issued to the placement agent in the private placement immediately following the closing of the sale of our Series B Preferred Stock, by the selling stockholders described in the section entitled "Selling Stockholders" on page 20 of this prospectus.

The selling stockholders will receive all of the proceeds from the disposition of the shares or interests therein and will pay any underwriting discounts and selling commissions relating thereto. We have agreed to pay the legal, accounting, printing and other expenses related to the registration of the shares.

Our common stock, par value \$0.01 per share, is listed on the American Stock Exchange under the symbol "SYI." On September 27, 2007 the last reported sale price of our common stock was \$3.03 per share. Our principal executive offices are located at 221 West Grand Avenue, Suite 200, Montvale, New Jersey 07645, and our telephone number is (201) 934-5000.

The selling stockholders or their pledges, assignees or successors-in-interest may offer and sell or otherwise dispose of the shares of common stock described in this prospectus from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. See "Plan of Distribution" beginning on page 23 for more information about how the selling stockholders may sell or dispose of their shares of common stock.

The selling stockholders may resell the common stock to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions.

You should consider carefully the risks that we have described in <u>"Risk Factors</u>" beginning on page 5 before deciding whether to invest in our common stock.

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

THE DATE OF THIS PROSPECTUS IS \_\_\_\_\_, 2007

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### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration or continuous offering process. Under this shelf process, certain selling stockholders may from time to time sell the shares of common stock described in this prospectus in one or more offerings.

You should read this prospectus and the information and documents incorporated by reference carefully. Such documents contain important information you should consider when making your investment decision. See "Incorporation of Certain Documents by Reference" on page 25. You should rely only on the information provided in this prospectus or documents incorporated by reference into this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with different information. The selling stockholders are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions in which offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

In this prospectus, we refer to Synvista Therapeutics, Inc. as the "Company" or "Synvista." Reference to "selling stockholders" refers to those stockholders listed herein under "Selling Stockholders," who may sell shares from time to time as described in this prospectus. All trade names used in this prospectus are either our registered trademarks or trademarks of their respective holders.

#### **OUR BUSINESS**

The following is only a summary and therefore does not contain all of the information you should consider before investing in our securities. We urge you to read this entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information incorporated by reference from our other filings with the Securities and Exchange Commission. Investing in our common stock involves risks. Therefore, please carefully consider the information provided under the heading "Risk Factors" beginning on page 5.

### Overview

We are a product-based biopharmaceutical company engaged in the development of drugs to treat and prevent cardiovascular disease and diabetes. We have identified several promising product candidates that we believe represent novel approaches to some of the largest pharmaceutical markets.

We have two lead product candidates in Phase 2 clinical trials:

•ALT-2074 is a glutathione peroxidase mimetic in clinical development for reducing the morbidity and mortality of patients with diabetes following a myocardial infarction. ALT-2074 has demonstrated potential efficacy in animal models of heart attack and in a 20-patient clinical trial in ulcerative colitis. Our goal is to develop ALT-2074 in acute coronary syndrome as a targeted drug for high risk diabetic patients. The compound has demonstrated the ability to reduce infarct size by approximately 85 percent in a mouse model of heart attack called ischemia reperfusion injury. It is currently being evaluated in a clinical trial for evidence of myocardial protection following angioplasty in high-risk diabetic patients. This Phase 2 clinical study was opened for enrollment in Israel, in May 2006. We expect to report results of this trial in the first half of 2008. In June 2007, we initiated a Phase 2 study using ALT-2074 in diabetic patients, testing positive for a marker of increased cardiovascular risk (haptoglobin genotype testing). Patients are being treated with ascending doses of ALT-2074 or placebo for 28 days as we track inflammatory biomarkers and functional improvement in their reverse cholesterol transport. Results from this study are anticipated in the first quarter of 2008.

•Alagebrium chloride or alagebrium (formerly ALT-711), is an advanced glycation end-product crosslink breaker being developed for diastolic heart failure ("DHF") and diabetic nephropathy. Alagebrium has demonstrated potential efficacy in two clinical trials in heart failure, as well as in animal models of heart failure, nephropathy, hypertension and erectile dysfunction ("ED"). These diseases represent rapidly growing markets of unmet medical needs, particularly common among diabetic patients. The compound has been tested in approximately 1,000 patients, which represents a sizeable human safety database, in a number of Phase 2 clinical studies in another cardiovascular indication.

We have been primarily focused on fund-raising activities and exploring strategic relationships to support our development programs. Since we have been able to complete our Series B Preferred Stock Financing, we hope to proceed with several studies involving ALT-2074 and alagebrium. With respect to ALT-2074, in addition to the myocardial protection study described above, and the Phase 2 biomarker study designed to correlate the dose and schedule of ALT-2074 with an effect on inflammatory biomarker levels and various components of cholesterol, we are considering other clinical development activities. With respect to alagebrium, we plan, among other things, to initiate a small Phase 2 study to examine the impact of alagebrium on heart function. As previously reported, we also expect that alagebrium will be studied in a clinical trial of patients with Type I diabetes and microalbuminuria (protein in the urine), funded by the Juvenile Diabetes Research Foundation.

We continue to evaluate potential pre-clinical and clinical studies in other therapeutic indications in which alagebrium and ALT-2074 may address significant unmet needs. For alagebrium, in addition to our anticipated clinical studies in heart failure, we have conducted preclinical studies focusing on atherosclerosis; Alzheimer's disease; photoaging of

the skin; eye diseases, including age-related macular degeneration ("AMD"), and glaucoma; and other diabetic complications, including renal diseases. For ALT-2074, we plan the exploration of indications for myocardial protection, atherosclerosis and other inflammatory diseases.

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On July 25, 2007, we closed a private placement of shares of our Series B Preferred Stock. At the closing of the financing, we issued 10,000,000 shares of our Series B Preferred Stock to the buyers. In connection with the closing of the financing, we also issued warrants to purchase 2,500,000 shares of Series B Preferred Stock to the buyers, and warrants to purchase 600,000 shares of common stock to the placement agent in the private placement, all of which warrants are exercisable for a period of five years commencing on July 25, 2007 at an exercise price of \$2.50 per share. This prospectus relates to 598,391 shares of our common stock that are issuable upon conversion of 598,391 of the shares of Series B Preferred Stock that we issued on July 25, 2007, along with 29,877 shares of our common stock that are issuable upon exercise of warrants issued to the placement agent in the private placement.

We relied upon the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated under that section. Each investor represented that it was an accredited investor, as such term is defined in Regulation D under the Securities Act, and that it was acquiring the common stock and warrants for its own account and not with a view to or for sale in connection with any distribution thereof, and appropriate legends are affixed to the common stock and warrants.

The Series B Preferred Stock is convertible into shares of common stock at the option of the holder at any time and is subject to automatic conversion into shares of common stock as further described in "Selling Stockholders-Conversion." The Series B Preferred Stock contains rights and preferences that are superior to those of our common stock, including cumulative dividends at an annual rate of 8% of the original issue price of the Series B Preferred Stock for a period of 5 years from the date of issuance, a liquidation preference, weighted-average anti-dilution protection, and other rights. Holders of Series B Preferred Stock are entitled to cast the number of votes equal to one-half of the number of shares of common stock into which their Series B Preferred Stock remain outstanding, we may not, without the consent of the holders of a majority of the shares held by holders of at least \$4,000,000 (measured as of the original issue date) worth of Series B Preferred Stock:

incur debt in excess of \$2,000,000,

 $\cdot$  authorize securities at a price per share less than the price per share at which the Series B Preferred Stock has been sold under the Purchase Agreement,

increase our authorized capital,

create any new classes or series of stock with rights senior to the common stock,

· issue any shares of our Series A Preferred Stock, other than in accordance with our shareholder rights plan,

·amend any provision of our Certificate of Incorporation or Bylaws that changes the rights of the Series B Preferred Stock,

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pay or declare any dividend on any of our capital stock,

purchase or redeem any securities,

·issue any securities to employees other than pursuant to our 2005 Stock Plan, or increase the number of shares of common stock reserved for issuance under the 2005 Stock Plan,

liquidate, dissolve or wind-up,

merge with another entity,

sell or dispose of any of our assets, including the sale or license of our intellectual property,

change the number of directors,

amend any portion of our Certificate of Incorporation or Bylaws,

materially change the nature of our business,

·intentionally take any action that may result in our stock no longer being approved for quotation on the AMEX or NASDAQ, or that would cause our common stock to no longer be registered pursuant to Section 12 of the Securities Exchange Act of 1934, or

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• amend any material agreement that has been filed with the Securities and Exchange Commission.

We were incorporated in Delaware in October 1986. Our headquarters are located at 221 West Grand Avenue, Suite 200, Montvale, New Jersey 07645. We maintain a web site at www.synvista.com and our telephone number is (201) 934-5000. Our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the "Investor Relations" section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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#### **RISK FACTORS**

The following factors should be considered carefully in evaluating whether to purchase shares of Synvista common stock. These factors should be considered in conjunction with any other information included or incorporated by reference herein, including in conjunction with forward-looking statements made herein. See "Where You Can Find More Information" on Page24.

#### **Risks Related To Our Business**

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#### We will continue to need additional capital, but access to such capital is uncertain.

As of August 31, 2007, we had cash and cash equivalents on hand of approximately \$18,001,000. Our future capital needs will depend on many factors, including our research and development activities and the success thereof, the scope of our clinical trial program, the timing of regulatory approval for our products under development and the successful commercialization of our products. Our needs may also depend on the magnitude and scope of our activities, the progress and the level of success in our clinical trials, the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in or terminations of existing collaboration and licensing arrangements, the establishment of new collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by us. In addition, the holders of our series B preferred stock have the option to receive dividends in the form of cash or additional shares of series B preferred stock. The amount of funds that we will have available in the future for the development of our product candidates may be reduced if the holders of our series B preferred stock choose to receive dividends in the form of cash. We currently do not have committed external sources of funding and may not be able to secure additional funding on any terms or on terms that are favorable to us. If we raise additional funds by issuing additional stock, further dilution to our existing stockholders will result, and new investors may negotiate for rights superior to existing stockholders. If adequate funds are not available, we may be required to:

delay, reduce the scope of or eliminate one or more of our development programs;

•obtain funds through arrangements with collaboration partners or others that may require us to relinquish rights to some or all of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves;

·license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available;

seek a buyer for all or a portion of our business; or

wind down our operations and liquidate our assets on terms that are unfavorable to us.

#### We have historically incurred operating losses and we expect these losses to continue.

We have historically incurred substantial operating losses due to our research and development and other operating activities and expect these losses to continue for the foreseeable future. As of June 30, 2007, we had an accumulated deficit of \$252,309,586. Our net losses during fiscal years 2006, 2005 and 2004 were \$17,679,737, \$12,614,459 and \$13,958,646, respectively. Our net losses applicable to common stockholders during fiscal years 2006, 2005 and 2004 were \$20,332,416, \$17,100,795 and \$18,093,791, respectively. We expect to expend significant amounts on research and development programs for alagebrium and ALT-2074. Research and development activities are time consuming and expensive, and will involve the need to engage in additional fund-raising activities, identify appropriate strategic

and collaborative partners, reach agreement on basic terms, and negotiate and sign definitive agreements. We expect to continue to incur significant operating losses for the foreseeable future.

#### Clinical studies required for our product candidates are time-consuming, and their outcome is uncertain.

Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through preclinical and clinical studies that the product is safe and effective for use in each target indication. Success in preclinical studies of a product candidate may not be predictive of similar results in humans during clinical trials. None of our products has been approved for commercialization in the United States or elsewhere. In December 2004, we announced that findings of a routine two-year rodent toxicity study indicated that male Sprague Dawley rats exposed to high doses of alagebrium over their natural lifetime developed dose-related increases in liver cell alterations and tumors, and that the liver tumor rate was slightly over the expected background rate in this gender and species of rat. In February 2005, based on the initial results from one of the follow-on preclinical toxicity experiments, we voluntarily and temporarily suspended enrollment of new subjects into each of the ongoing clinical studies pending receipt of additional preclinical data. We withdrew our investigational new drug application, or IND, for the EMERALD study (Efficacy and Safety of Alagebrium in Erectile Dysfunction in Male Diabetics) in February 2006 in order to focus our resources on the development of alagebrium in cardiovascular indications. We subsequently submitted an IND to the Cardio-Renal Division of the U.S. Food and Drug Administration, or FDA, for a trial using alagebrium to treat heart failure. The FDA has indicated that we may proceed with trials in this indication. The BENEFICIAL trial, a double-blind, placebo-controlled, randomized trial evaluating the efficacy and safety of alagebrium in patients with chronic heart failure, was planned and submitted under a Clinical Trial Application in the Netherlands, where the health authorities have permitted us to proceed with initiation of the study. Freedom to initiate clinical studies does not mean that regulatory agencies will not require additional explanation of the two-year rodent toxicity study.

If we do not prove in clinical trials that our product candidates are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our product candidates may not exhibit the expected medical benefits in humans, may cause harmful side effects, may not be effective in treating the targeted indication or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved.

The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

•slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;

adverse results in preclinical safety or toxicity studies;

lower than expected recruitment or retention rates of subjects in a clinical trial;

·inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;

delays in approvals from a study site's review board, or other required approvals;

· longer treatment time required to demonstrate effectiveness or determine the appropriate product dose;

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lack of sufficient supplies of the product candidate;

adverse medical events or side effects in treated subjects;

lack of effectiveness of the product candidate being tested; and

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#### regulatory changes.

Even if we obtain positive results from preclinical or clinical studies for a particular product, we may not achieve the same success in future studies of that product. Data obtained from preclinical and clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted new drug application. We may encounter similar delays in foreign countries. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical or preclinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products.

The FDA regulates the development, testing, manufacture, distribution, labeling and promotion of pharmaceutical products in the United States pursuant to the Federal Food, Drug, and Cosmetic Act and related regulations. We must receive pre-market approval by the FDA prior to any commercial sale of any drug candidates. Before receiving such approval, we must provide preclinical data and proof in human clinical trials of the safety and efficacy of our drug candidates, which trials can take several years. In addition, we must show that we can produce any drug candidates consistently at quality levels sufficient for administration in humans. Pre-market approval is a lengthy and expensive process. We may not be able to obtain FDA approval for any commercial sale of any drug candidate; however, the FDA frequently exceeds the 180-day time period, at times taking up to 18 months. In addition, based on its review, the FDA or other regulatory bodies may determine that additional clinical trials or preclinical data are required. Except for any potential licensing or marketing arrangements with other pharmaceutical or biotechnology companies, we will not generate any revenues in connection with any of our drug candidates unless and until we obtain FDA approval to sell such products in commercial quantities for human application.

Even if a clinical trial is commenced, the FDA may delay, limit, suspend or terminate clinical trials at any time, or may delay, condition or reject approval of any of our product candidates, for many reasons. For example:

- · ongoing preclinical or clinical study results may indicate that the product candidate is not safe or effective;
- •the FDA may interpret our preclinical or clinical study results to indicate that the product candidate is not safe or effective, even if we interpret the results differently; or
- the FDA may deem the processes and facilities that our collaborative partners, our third-party manufacturers or we propose to use in connection with the manufacture of the product candidate to be unacceptable.

# Our success will largely depend on the development of ALT-2074, and we cannot be sure that the efforts to commercialize ALT-2074 will succeed.

ALT-2074 is still in early clinical trials and any success to date should not be seen as indicative of the probability of any future success. The failure to complete clinical development and commercialize ALT-2074 for any reason or due to a combination of reasons will have a material adverse impact on our business.

We are dependent on the successful outcome of clinical trials and will not be able to successfully develop and commercialize products if clinical trials are not successful.

We received approval from Israel's Ministry of Health to conduct Phase 2 trials in diabetic patients recovering from a recent myocardial infarction or acute coronary syndrome. The purpose of the study is to evaluate the biological effects on cardiac tissue in patients treated with ALT-2074. The study was opened for enrollment in May 2006 and we now have six sites open for enrollment. Recruitment has been slow and while we predict that the study will be completed in the first half of 2008, we can neither guarantee its completion nor the likelihood of gaining positive results. The same is true for the biomarker study using ALT-2074 begun in June 2007.

# If we are unable to form the successful collaborative relationships that our business strategy requires, our programs will suffer and we may not be able to develop products.

Our strategy for developing and deriving revenues from our products depends, in large part, upon entering into arrangements with research collaborators, corporate partners and others. The potential market, preclinical and clinical study results and safety profile of our product candidates may not be attractive to potential corporate partners. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

# If we are able to form collaborative relationships, but are unable to maintain them, our product development may be delayed and disputes over rights to technology may result.

We may form collaborative relationships that, in some cases, will make us dependent upon outside partners to conduct preclinical testing and clinical studies and to provide adequate funding for our development programs.

In general, collaborations involving our product candidates pose the following risks to us:

- ·collaborators may fail to adequately perform the scientific and preclinical studies called for under our agreements with them;
- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- •collaborators may not pursue further development and commercialization of our product candidates or may elect not to continue or renew research and development programs based on preclinical or clinical study results, changes in their strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;
- •collaborators may delay clinical trials, provide insufficient funding for a clinical program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- •collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive; collaborators with marketing and distribution rights to one or more products may not commit enough resources to their marketing and distribution;
- •collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- ·disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development of the applicable product candidates.

In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development program could be delayed, diminished or terminated.

# If we are unable to attract and retain the key personnel on whom our success depends, our product development, marketing and commercialization plans could suffer.

We depend heavily on the principal members of our management and scientific staff to realize our strategic goals and operating objectives. Over the past year, due to the reduction in our clinical trial activities, the number of our employees has decreased from 16 as of December 31, 2005 to 7 as of August 1, 2007. We depend on Dr. Noah Berkowitz as the Company's Chief Executive Officer and Dr. Malcolm MacNab as the Company's Vice President of Clinical Development. The loss of services in the near term of any of our principal members of management and scientific staff could impede the achievement of our development priorities. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future will also be critical to our success, and there is significant competition among companies in our industry for such personnel. We may be required to provide additional retention and severance benefits to our employees in the future if we prepare to effect a strategic transaction, such as a sale or merger with another company. However, we cannot assure you that we will be able to attract and retain personnel on acceptable terms given the competition between pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced managers and scientists, and given the recent clinical and regulatory setbacks that we have experienced. In addition, we rely on consultants to assist us in formulating our research and development strategy. All of our consultants are employed by other entities and may have commitments to or consulting or advisory contracts with those other entities that may limit their availability to us.

# If we do not successfully develop any products, or are unable to derive revenues from product sales, we will never be profitable.

Virtually all of our revenues to date have been generated from collaborative research agreements and investment income. We have not received any revenues from product sales. We may not realize product revenues on a timely basis, if at all, and there can be no assurance that we will ever be profitable.

At June 30, 2007, we had an accumulated deficit of \$252,309,586. We anticipate that we will incur substantial, potentially greater, losses in the future as we continue our research, development and clinical studies. We have not yet requested or received regulatory approval for any product candidate from the FDA or any other regulatory body. All of our product candidates are still in research, preclinical or clinical development. We may not succeed in the development and marketing of any therapeutic or diagnostic product. We do not have any product candidates other than alagebrium and ALT-2074 in clinical development, and there can be no assurance that we will be able to bring any other compound into clinical development. Adverse results of any preclinical or clinical study could cause us to materially modify our clinical development programs, resulting in delays and increased expenditures, or cease development for all or part of our ongoing studies of alagebrium.

To achieve profitable operations, we must, alone or with others, successfully identify, develop, introduce and market proprietary products. Such products will require significant additional investment, development and preclinical and clinical testing prior to potential regulatory approval and commercialization. The development of new pharmaceutical products is highly uncertain and expensive and subject to a number of significant risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Potential products may be found ineffective or cause harmful side effects during preclinical testing or clinical studies, fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. We may not be able to undertake additional clinical studies. In addition, our product development efforts may not be successfully completed, we may not have the funds to complete any ongoing clinical trials, we may not obtain regulatory approvals, and our products, if introduced, may not be successfully marketed or achieve customer acceptance. We do not expect any of our products, including alagebrium, to be commercially available for a number of years, if at all.

# Failure to remediate the material weaknesses in our internal controls and to achieve and maintain effective internal control in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

During the review of our financial statements for the three and six-month periods ended June 30, 2007, our independent registered public accounting firm identified material weaknesses regarding our internal control over financial reporting relating to the recording of an obligation related to the restructuring of a licensing agreement related in part to the financing and an obligation to purchase an investment during the second quarter ended June 30, 2007. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, a material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Since this material weakness was identified by our independent registered public accounting firm in connection with its review of the financial statements for the filing of our Form 10-Q for the period ended June 30, 2007, the transactions subject to these issues are correctly accounted for and disclosed by us in the financial statements included in our Form 10-O for the period ended June 30, 2007 and no restatement of any previously filed financial statements is required. However, on a going forward basis, management will continue to evaluate our disclosure controls and procedures concerning the recording of obligations in order to prevent the recurrence of the circumstance that resulted in the material weakness identified in connection with the review of the financial statements for the filing of our Form 10-Q for the period ended June 30, 2007. However, we cannot currently assure you that the remedial measures that are currently being implemented will be sufficient to result in a conclusion that our internal controls no longer contain any material weaknesses, and that our internal controls are effective. In addition, we cannot assure you that, even if we are able to achieve effective internal control over financial reporting, our internal controls will remain effective for any period of time. The failure to maintain effective internal control over financial reporting could have a material adverse effect on our business and stock price.

#### Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the approval could be granted with the condition that we conduct additional costly post-approval studies or that we limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of the FDA and other applicable United States and foreign regulatory authorities or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

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restrictions on the products, manufacturers or manufacturing processes;

warning letters;

civil or criminal penalties;

fines;

injunctions;

product seizures or detentions;

import bans;

voluntary or mandatory product recalls and 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 drugs or supplements to approved applications.

In similar fashion to the FDA, foreign regulatory authorities require demonstration of product quality, safety and efficacy prior to granting authorization for product registration which allows for distribution of the product for commercial sale. International organizations, such as the World Health Organization, and foreign government agencies, including those for the Americas, Middle East, Europe, Asia and the Pacific, have laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new drug products. Although most of these laws, regulations and guidelines are very similar, each of the individual nations reviews all of the information available on the new drug product and makes an independent determination for product registration. A finding of product quality, safety or efficiency in one jurisdiction does not guarantee approval in any other jurisdiction, even if the other jurisdiction has similar laws, regulations and guidelines.

### If we cannot successfully form and maintain suitable arrangements with third parties for the manufacturing of the products we may develop, our ability to develop or deliver products may be impaired.

We have no experience in manufacturing products and do not have manufacturing facilities. Consequently, we will depend on contract manufactures for the production of any products for development and commercial purposes. The manufacture of our products for clinical trials and commercial purposes is subject to current good manufacturing practices, or cGMP, regulations promulgated by the FDA. In the event that we are unable to obtain or retain third-party manufacturing capabilities for our products, we will not be able to commercialize our products as planned. Our reliance on third-party manufacturers will expose us to risks that could delay or prevent the initiation or completion of our clinical trials, the submission of applications for regulatory approvals, the approval of our products by the FDA or the commercialization of our products or result in higher costs or lost product revenues. In particular, contract manufacturers:

•could encounter difficulties in achieving volume production, quality control and quality assurance and suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of drugs to meet our clinical schedules or to commercialize our product candidates;

 $\cdot$  could terminate or choose not to renew the manufacturing agreement, based on their own business priorities, at a time that is costly or inconvenient for us;

•could fail to establish and follow FDA-mandated cGMP, as required for FDA approval of our product candidates, or fail to document their adherence to cGMP, either of which could lead to significant delays in the availability of material for clinical study and delay or prevent filing or approval of marketing applications for our product candidates; and

could breach, or fail to perform as agreed, under the manufacturing agreement.

Changing any manufacturer that we engage for a particular product or product candidate may be difficult, as the number of potential manufacturers is limited, and we will have to compete with third parties for access to those manufacturing facilities. cGMP processes and procedures typically must be reviewed and approved by the FDA, and changing manufacturers may require re-validation of any new facility for cGMP compliance, which would likely be costly and time-consuming. We may not be able to engage replacement manufacturers on acceptable terms quickly or at all. In addition, contract manufacturers located in foreign countries may be subject to import limitations or bans. As a result, if any of our contract manufacturers are unable, for whatever reason, to supply the contracted amounts of our products that we successfully bring to market, a shortage would result which would have a negative impact on our revenues.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency and corresponding state and foreign agencies to ensure strict compliance with cGMP, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party

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contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions. Our dependence upon others for the manufacture of any products that we develop may adversely affect our profit margin, if any, on the sale of any future products and our ability to develop and deliver such products on a timely and competitive basis.

# If we are not able to protect the intellectual property rights that are critical to our success, the development and any possible sales of our product candidates could suffer and competitors could force our products completely out of the market.

Our success will depend on our ability to obtain patent protection for our products, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others, both in the United States and abroad.

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Competitors may develop competitive products outside the protection that may be afforded by the claims of our patents. We are aware that other parties have been issued patents and have filed patent applications in the United States and foreign countries with respect to other agents that have an effect on A.G.E.s, or the formation of A.G.E. crosslinks. In addition, although we have several patent applications pending to protect proprietary technology and potential products, these patents may not be issued, and the claims of any patents that do issue, may not provide significant protection of our technology or products. In addition, we may not enjoy any patent protection beyond the expiration dates of our currently issued patents.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to maintain, develop and expand our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and certain, but not all, corporate partners and consultants. Relevant inventions may be developed by a person not bound by an invention assignment agreement. Binding agreements may be breached, and we may not have adequate remedies for such breach. In addition, our trade secrets may become known to or be independently discovered by competitors.

# If we are unable to operate our business without infringing upon intellectual property rights of others, we may not be able to operate our business profitably.

Our success depends on our ability to operate without infringing upon the proprietary rights of others. We are aware that patents have been applied for and/or issued to third parties claiming technologies for A.G.E.s or glutathione peroxidase mimetics that may be similar to those needed by us. To the extent that planned or potential products are covered by patents or other intellectual property rights held by third parties, we would need a license under such patents or other intellectual property rights to continue development and marketing of our products. Any required licenses may not be available on acceptable terms, if at all. If we do not obtain such licenses on reasonable terms, we may not be able to proceed with the development, manufacture or sale of our products.

Litigation may be necessary to defend against claims of infringement or to determine the scope and validity of the proprietary rights of others. Litigation or interference proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unsuccessful in defending against claims of infringement, we may be unable to operate profitably.

# ALT-2074 and other compounds are licensed by third parties and if we are unable to continue licensing this technology, our future prospects may be materially adversely affected.

We are a party to various license agreements with third parties that give us exclusive and partial exclusive rights to use specified technologies applicable to research, development and commercialization of our products, including alagebrium and ALT-2074. We anticipate that we will continue to license technology from third parties in the future. To maintain the license for certain technology related to ALT-2074 that we received from OXIS, we are obligated to meet certain development and clinical trial milestones and to make certain payments. There can be no assurance that we will be able to meet any milestone or make any payment required under the license with OXIS. In addition, if we

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fail to meet any milestone or make any payment, there can be no assurance that we may be able to negotiate an arrangement with OXIS, as we have successfully done in the past, whereby we will continue to have access to the ALT-2074 technology.

The technology that our subsidiary HaptoGuard has licensed from third parties would be difficult or impossible to replace and the loss of this technology would materially adversely affect our business, financial condition and any future prospects.

# If we are not able to compete successfully with other companies in the development and marketing of cures and therapies for cardiovascular diseases, diabetes, and the other conditions for which we seek to develop products, we may not be able to continue our operations.

We are engaged in pharmaceutical fields characterized by extensive research efforts and rapid technological progress. Many established pharmaceutical and biotechnology companies with financial, technical and human resources greater than ours are attempting to develop, or have developed, products that would be competitive with our products. Many of these companies have extensive experience in preclinical and human clinical studies. Other companies may succeed in developing products that are safer, more efficacious or less costly than any we may develop and may also be more successful than us in production and marketing. Rapid technological development by others may result in our products becoming obsolete before we recover a significant portion of the research, development or commercialization expenses incurred with respect to those products.

Certain technologies under development by other pharmaceutical companies could result in better treatments for cardiovascular disease, and diabetes and its related complications. Several large companies have initiated or expanded research, development and licensing efforts to build pharmaceutical franchises focusing on these medical conditions, and some companies already have products approved and available for commercial sale to treat these indications. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products. In addition, other companies have initiated research in the inhibition or crosslink breaking of A.G.E.s.

Our ability to compete successfully against currently existing and future alternatives to our product candidates and systems, and competitors who compete directly with us in the small molecule drug industry will depend, in part, on our ability to:

attract and retain skilled scientific and research personnel;

develop technologically superior products;

develop competitively priced products;

obtain patent or other required regulatory approvals for our products;

be early entrants to the market; and

manufacture, market and sell our products, independently or through collaborations.

### We depend on third parties for research and development activities necessary to commercialize certain of our patents.

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We utilize the services of several scientific and technical consultants to oversee various aspects of our protocol design, clinical trial oversight and other research and development functions. We contract out most of our research and development operations using third-party contract manufacturers for drug inventory and shipping services and third-party contract research organizations in connection with preclinical and/or clinical studies in accordance with our designed protocols, as well as conducting research at medical and academic centers.

Because we rely on third parties for much of our research and development work, we have less direct control over our research and development. We face risks that these third parties may not be appropriately responsive to our time frames and development needs and could devote resources to other customers. In addition, certain of these third parties may have to comply with FDA regulations or other regulatory requirements in the conduct of this research and development work, which they may fail to do.

# If governments and third-party payers continue their efforts to contain or decrease the costs of healthcare, we may not be able to commercialize our products successfully.

In the United States, we expect that there will continue to be federal and state initiatives to control and/or reduce pharmaceutical expenditures. In certain foreign markets, pricing and/or profitability of prescription pharmaceuticals are subject to government control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical pricing. Cost control initiatives could decrease the price that we receive for any products for which we may receive regulatory approval to develop and sell in the future and could have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that cost control initiatives have a material adverse effect on our corporate partners, our ability to commercialize our products may be adversely affected.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from government health administration authorities, private health insurers and other third-party payers. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and third-party payers, including Medicare, frequently challenge the prices charged for medical products and services. In addition, third-party insurance coverage may not be available to subjects for any products developed by us. Government and other third-party payers are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. If government and other third-party payers for our products do not provide adequate coverage and reimbursement levels, the market acceptance of these products would be adversely affected.

# If the users of the products that we are developing claim that our products have harmed them, we may be subject to costly and damaging product liability litigation, which could have a material adverse effect on our business, financial condition and results of operations.

We may face exposure to product liability and other claims due to allegations that our products cause harm. These risks are inherent in the clinical trials for pharmaceutical products and in the testing, and future manufacturing and marketing of, our products. Although we currently maintain product liability insurance, such insurance is becoming increasingly expensive, and we may not be able to obtain adequate insurance coverage in the future at a reasonable cost, if at all. If we are unable to obtain product liability insurance in the future at an acceptable cost or to otherwise protect against potential product liability claims, we could be inhibited in the commercialization of our products, which could have a material adverse effect on our business. The coverage will be maintained and limits reviewed from time to time as the combined company progresses to later stages of its clinical trials, and as the length of the trials and the number of patients enrolled in the trials changes.

We intend to obtain a combined coverage policy that includes tail coverage in order to cover any claims that are made for any events that have occurred prior to the merger. We currently have a policy covering \$10 million of product liability for our clinical trials, for which our annual premium is approximately \$118,000. However, insurance coverage and our resources may not be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

### **Risks Related to Owning Synvista's Common Stock**

#### The holders of the Series B Preferred Stock are entitled to rights and preferences that are significantly greater than the rights and preferences of the holders of our common stock, including preferential payments upon a liquidation, as well as a dividend and registration rights associated with their shares.

Holders of the Company's Series B Preferred Stock are entitled to a number of rights and preferences which holders of shares of our outstanding common stock do not and will not have. Among these rights and preferences is a preference on liquidation of the Company, which means that holders of the Series B Preferred Stock will be entitled to receive the proceeds out of any sale or liquidation of the Company before any such proceeds are paid to holders of our common stock. In general, if the proceeds received upon any sale or liquidation do not exceed the total liquidation proceeds payable to the holders of the Series B Preferred Stock, holders of common stock would received no value for their shares upon such a sale or liquidation. In addition, shares of the Series B Preferred Stock accrue dividends at a rate of 8% per year for a period of five years from the date on which the shares of Series B Preferred Stock were issued.

Holders of the Series B Preferred Stock also have significant rights with respect to certain actions that we may wish to take from time to time. At any time when any shares of Series B Preferred Stock remain outstanding, we may not, without the consent of the holders of a majority of the shares held by holders of at least \$4,000,000 (measured as of

the original issue date) worth of Series B Preferred Stock:

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incur debt in excess of \$2,000,000;

 $\cdot$  authorize securities at a price per share less than the price per share that the Series B Preferred Stock has been sold under the Series B Purchase Agreement;

increase our authorized capital;

create any new classes or series of stock with rights senior to the common stock;

issue any shares of Series A Preferred Stock, other than in accordance with our shareholder rights plan;

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• amend any provision of our Certificate of Incorporation or Bylaws that changes the rights of the Series B Preferred Stock;

pay or declare any dividend on any of our capital stock;

purchase or redeem any securities;

·issue any securities to employees other than pursuant to our 2005 Stock Plan, or increase the number of shares of common stock reserved for issuance under the 2005 Stock Plan;

liquidate, dissolve or wind-up;

merge with another entity;

sell or dispose of any of our assets, including the sale or license of our intellectual property;

change the number of directors;

amend any portion of our Certificate of Incorporation or Bylaws;

materially change the nature of our business;

•intentionally take any action that may result in our stock no longer being approved for quotation on the AMEX or NASDAQ, or that would cause our common stock to no longer be registered pursuant to Section 12 of the Securities Exchange Act of 1934; or

• amend any material agreement that has been filed with the Securities and Exchange Commission.

As a result, we will not be able to take any of these actions without first seeking and obtaining the approval of the holders of the Series B Preferred Stock. We may not be able to obtain such approval in a timely manner or at all, even if we think that taking the action for which we seek approval is in our best interests.

We have also entered into a Registration Rights Agreement with the holders of the Series B Preferred Stock, under which we have agreed to register the resale by those holders of the shares of common stock issuable upon conversion of the shares of Series B Preferred Stock, as well as upon conversion of the shares of Series B Preferred Stock underlying the Warrants sold in the financing. A failure to file a registration statement or to have a registration statement declared effective in a timely manner, among other things, would result in payment by us to each investor of liquidated damages in cash, subject to limitations set forth in the Registration Rights Agreement. These liquidated damages would generally be equal to 1% of the aggregate purchase price paid by the holder of the Series B Preferred Stock, payable on the date the failure occurs and on each monthly anniversary of such date until the event is cured, subject to an overall limit of 8% for each calendar year. If we are required to pay liquidated damages under this agreement, the payments could have a material adverse effect on our results of operations.

The holders of the Series B Preferred Stock represent a significant voting interest in the Company.

The Series B Preferred Stock is convertible into common stock at any time at the option of the holder at an initial conversion rate of 1:1, subject to adjustment. Assuming the full conversion of all of the shares of Series B Preferred Stock into our common stock, and the exercise all of warrants to acquire shares of Series B Preferred Stock which are then converted into shares of our common stock, the holders of the Series B Preferred Stock would represent approximately 83% of our issued and outstanding capital stock as of June 30, 2007. Accordingly, in the event that all of the shares of Series B Preferred Stock were to be converted into our common stock, a change in control of the Company would occur. Prior to such conversion, each holder of Series B Preferred Stock is entitled to cast the number of votes equal to one-half of the number of whole shares of common stock into which the shares of Series B Preferred Stock, the holders of series B Preferred Stock held approximately 41% of the voting power of the Company.

# We have been notified by the American Stock Exchange, Inc. ("AMEX") that we are not in compliance with continued listing standards, which may result in a delisting of our common stock if we cannot regain compliance.

On January 30, 2007, we reported that we had received a notice from AMEX indicating that AMEX has accepted our plan to regain compliance with AMEX continued listing standards, and that our listing will be continued pursuant to an extension until April 9, 2008. We submitted a plan of compliance to AMEX on November 6, 2006, outlining our operational plan and strategic objectives, and amended our plan of compliance on January 3, 2007 and January 5, 2007 (the "Plan of Compliance"). The Plan of Compliance was prepared in response to a notice we received from AMEX on October 9, 2006, indicating that we were below certain AMEX continuing listing standards due to (i) sustaining losses from continuing operations and/or net losses in two out of our three most recent fiscal years with stockholders' equity below \$2,000,000; (ii) sustaining losses from continuing losses fro

### Our stock price is volatile and you may not be able to resell your shares at a profit.

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We first publicly issued common stock on November 8, 1991 at \$15.00 per share in our initial public offering and it has been subject to fluctuations since that time. For example, during 2007, the closing sale price of our common stock has ranged from a high of \$7.50 per share to a low of \$2.50 per share. The market price of our common stock could continue to fluctuate substantially due to a variety of factors, including:

quarterly fluctuations in results of operations;

material weaknesses in our internal control over financial reporting;

the announcement of new products or services by us or competitors;

sales of common stock by existing stockholders or the perception that these sales may occur;

adverse judgments or settlements obligating the combined company to pay damages;

negative publicity;

loss of key personnel;

developments concerning proprietary rights, including patents and litigation matters; and

clinical trial or regulatory developments in both the United States and foreign countries.

In addition, overall stock market volatility has often significantly affected the market prices of securities for reasons unrelated to a company's operating performance. In the past, securities class action litigation has been commenced against companies that have experienced periods of volatility in the price of their stock. Securities litigation initiated against the combined company could cause it to incur substantial costs and could lead to the diversion of management's attention and resources, which could have a material adverse effect on revenue and earnings.

### We have a large number of authorized but unissued shares of common stock, which our Board of Directors may issue without further stockholder approval, thereby causing dilution of your holdings of our common stock.

As of August 1, 2007, there were 283,642,857 shares of authorized but unissued shares of our common stock. Our management will continue to have broad discretion to issue shares of our common stock in a range of transactions, including capital-raising transactions, mergers, acquisitions, for anti-takeover purposes, and in other transactions, without obtaining stockholder approval, unless stockholder approval is required for a particular transaction under the rules of AMEX, Delaware law, or other applicable laws. If our management determines to issue shares of our common stock from the large pool of such authorized but unissued shares for any purpose in the future without obtaining stockholder approval, your ownership position would be diluted without your further ability to vote on that transaction.

# The sale of a substantial number of shares of our common stock could cause the market price of our common stock to decline and may impair the company's ability to raise capital through additional offerings.

We currently have outstanding warrants and options to purchase an aggregate of 3,757,966 shares of our common stock. Sales of these shares and the sale of the shares issued in the recent private financing, in the public market, or the perception that future sales of such shares could occur, could have the effect of lowering the market price of our common stock below current levels and make it more difficult for us and our stockholders to sell our equity securities in the future.

Our executive officers, directors and holders of more than 5% of our common stock collectively beneficially own approximately 29% of the outstanding common stock, which includes fully vested options to purchase common stock. In addition, approximately 171,424 shares of common stock issuable upon exercise of vested stock options could become available for immediate resale if such options were exercised.

Sale or the availability for sale, of shares of common stock by stockholders could cause the market price of our common stock to decline and could impair our ability to raise capital through an offering of additional equity securities.

# Anti-takeover provisions may frustrate attempts to replace our current management and discourage investors from buying our common stock.

We have entered into a Stockholders' Rights Agreement pursuant to which each holder of a share of our common stock is granted a Right to purchase our Series A Preferred Stock ("Preferred Stock") under certain circumstances if a person or group acquires, or commences a tender offer for, 20% of our outstanding common stock. In addition, the Board of Directors has the authority, without further action by the common stockholders, to fix the rights and preferences of, and issue shares of, Preferred Stock. These and other provisions of our charter and Delaware corporate law may discourage certain types of transactions involving an actual or potential change in control.

#### FORWARD-LOOKING STATEMENTS AND CAUTIONARY STATEMENTS

Statements in this prospectus and the documents incorporated by reference herein that are not statements or descriptions of historical facts are "forward-looking" statements under Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995, and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by us or our representatives are based on a number of assumptions. The words "believe", "expect", "anticipate", "intend", "estimate", "plan", "predict", "could", "will", " "potential", "continue" or other expressions, which are predictions of or indicate future events and trends and which do not relate to historical matters, identify forward-looking statements. The forward-looking statements represent our judgments and expectations as of the date of this prospectus. We assume no obligation to update any such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, as they involve risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, including those set forth in this section and elsewhere in this prospectus. These factors include, but are not limited to, the risks set forth in this prospectus.

The forward-looking statements set forth in this document represent our judgment and expectations as of the date of this prospectus. We assume no obligation to update any such forward-looking statements.

Discussions containing these forward-looking statements are also contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference from our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q for the quarters ended since our most recent Annual Report, our Current Reports on Form 8-K, as well as any amendments we make to those filings with the SEC.

#### **USE OF PROCEEDS**

The proceeds from the sale or other disposition of the common stock covered by this prospectus are solely for the accounts of the selling stockholders named in this prospectus. We will not receive any proceeds from the sale or other disposition of these shares of common stock.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our independent registered public accounting firm.

#### SELLING STOCKHOLDERS

On July 25, 2007, we issued approximately \$25 million worth of our Series B Preferred Stock and warrants to purchase our Series B Preferred Stock in a private placement exempt from the registration requirements of the Securities Act (the "Financing"), which shares are comprised of the following securities: (i) 10,000,000 shares of common stock issuable upon conversion of the Series B Preferred Stock, and (ii) 2,500,000 shares of common stock issuable upon conversion of the Series B Preferred Stock underlying the Warrants, at an exercise price of \$2.50 per share.

This prospectus relates to the resale from time to time of up to a total of 598,391 shares of our common stock issuable upon conversion of the shares of the Series B Preferred Stock issued in the Financing, as well as 29,877 shares of our common stock issuable upon exercise of warrants to purchase our common stock issued to the placement agent immediately following the closing of the Financing.

The following is a summary of the rights and preferences of the Series B Preferred Stock and warrants that were issued in the Financing:

*Dividends*. Holders of Series B Preferred Stock will be entitled to receive cumulative dividends at an annual rate of 8% of the Series B Preferred Stock original issue price for a period of 5 years from the date of issuance. Such dividends, shall, at the option of the holders of a majority of the Series B Preferred Stock outstanding, be paid in cash or in shares of Series B Preferred Stock. We will not declare any dividends on our junior preferred or common stock until after we have paid all accrued but unpaid dividends on our Series B Preferred Stock.

*Voting*. Holders of Series B Preferred Stock are entitled to cast the number of votes equal to one-half of the number of shares of common stock into which their Series B Preferred Stock would be convertible on the applicable record date. The Series B Preferred Stock votes on a 1-for-1 basis following its conversion into common stock.

*Liquidation Preference*. Upon liquidation, including deemed liquidations pursuant to a merger, consolidation or a sale of all or substantially all of our assets, holders of Series B Preferred Stock are entitled to a payment per share equal to the price at which shares of Series B Preferred Stock were sold in the Financing, plus accrued but unpaid dividends, prior to payment of any amounts on our junior preferred or common stock. The holders of the Series B Preferred Stock are entitled to receive the proceeds out of any sale or liquidation of our company before any such proceeds are paid to holders of our common stock. In general, if the proceeds received upon any sale or liquidation do not exceed the total liquidation proceeds payable to the holders of the Series B Preferred Stock, which, prior to any adjustment in accordance with the terms of the Series B Preferred Stock is equal to the aggregate cash proceeds received by us in the Financing, holders of common stock would receive no value for their shares upon such a sale or liquidation.

*Protective Provisions.* At any time when any shares of Series B Preferred Stock remain outstanding, we may not, without the consent of the holders of a majority of the shares held by holders of at least \$4,000,000 (measured as of the original issue date) worth of Series B Preferred Stock: (i) incur debt in excess of \$2,000,000, (ii) authorize securities at a price per share less than the price per share that the Series B Preferred Stock was sold, (iii) increase our authorized capital, (iv) create any new classes or series of stock with rights senior to the common stock, (v) issue any shares of our Series A preferred stock, other than in accordance with our shareholder rights plan, (vi) amend any provision of our amended and restated certificate of incorporation or bylaws that changes the rights of the Series B Preferred Stock, (vii) pay or declare any dividend on any capital stock, (viii) purchase or redeem any securities, (ix) issue any securities to employees other than pursuant to our 2005 Stock Plan, or increase the number of shares of common stock reserved for issuance under the 2005 Stock Plan, (x) liquidate, dissolve or wind-up, (xi) merge with another entity or (xii) sell or dispose of any of our assets, including the sale or license of our intellectual property, (xiii) change the number of directors, (xiv) amend any portion of our amended and restated certificate of or bylaws, (xv) materially change the nature of our business, (xvi) intentionally take any action that may result in our

common stock no longer being approved for quotation on the AMEX or NASDAQ, or that would cause our common stock to no longer be registered pursuant to Section 12 of the Securities Exchange Act of 1934, or (xvii) amend any material agreement that has been filed with the Securities and Exchange Commission.

*Conversion.* Holders of Series B Preferred Stock have an option to convert their Series B Preferred Stock at any time, plus, prior to the fifth anniversary of the original issuance of Series B Preferred Stock, all accrued and unpaid dividends, into common stock at the initial conversion price equal to the price at which shares of Series B Preferred Stock were sold in the Financing, as adjusted in accordance with the provisions of our amended and restated certificate of incorporation. An equivalent of \$7,500,000 (measured as of the original issue date) of Series B Preferred Stock will automatically be converted into common stock when (i) the thirty-day prior trailing average closing price of our common stock, as reported by the American Stock Exchange, for the entire six months preceding such time is equal to at least the price at which shares of Series B Preferred Stock were sold in the Financing and (ii) the registration statement for resale of securities issued in the Financing has been declared effective by the SEC and is continuously effective for a one and one-half year period. Thereafter, the remainder of the outstanding Series B Preferred Stock will automatically be converted into common stock when (i) the 30-day prior trailing average closing price of our common stock, as reported by the American Stock Exchange for the entire six months preceding such time is equal to at least two times the price at which shares of Series B Preferred Stock were sold in the Financing and (ii) the registration statement for resale of securities into common stock when (i) the 30-day prior trailing average closing price of our common stock, as reported by the American Stock Exchange for the entire six months preceding such time is equal to at least two times the price at which shares of Series B Preferred Stock were sold in the Financing and (ii) the registration statement for resale of securities issued in the Financing has been declared effective by the SEC and is continuously effective for a one and one-half year period

*Anti-Dilution Protection.* The rights and preferences of the Series B Preferred Stock include weighted-average anti-dilution protection. Each share of Series B Preferred Stock is initially convertible into shares of our common stock by multiplying the number of shares of Series B Preferred Stock to be converted, by a ratio, the numerator of which is the purchase price, or the price per share at which the Series B Preferred Stock was initially sold, and the denominator of which is the conversion price. Initially, the purchase price and the conversion price are the same, which makes the initial conversion rate of the Series B Preferred Stock (other than certain excluded issuances such as options pursuant to our approved stock option plans), the conversion price would decrease based upon a formula in the our amended and restated certificate of incorporation, and the ratio against which the number of shares of Series B Preferred Stock will convert.

The warrants that were issued in the Financing are immediately exercisable for shares of our Series B Preferred Stock, for a period of five years, at an exercise price of \$2.50 per share. In addition, the warrants may be exercised by means of a cashless exercise. The exercise price of the warrants is adjustable, from time to time, in the event of stock splits, rights offerings, fundamental transactions or dilutive issuances.

We also issued warrants to purchase 600,000 shares of our common stock to the placement agent in the private placement, which warrants are immediately exercisable at an exercise price of \$2.50 per share.

Pursuant to the terms of the Financing, we filed a Registration Statement on Form S-3, of which this prospectus constitutes a part, in order to permit the selling stockholders to resell to the public 598,391 shares of our common stock issuable upon conversion of the Series B Preferred Stock, and 29,877 shares of our common stock issuable upon exercise of warrants to purchase our common stock issued to a placement agent immediately following the Financing. Pursuant to the terms of the Financing, we are required to file additional registration statements covering all of the shares of common stock issuable upon conversion of the Series B Preferred Stock underlying the warrant issued to the placement agent. The selling stockholders have each represented to us that they have obtained the shares for their own account for investment only and not with a view to, or resale in connection with, a distribution of the shares, except through sales registered under the Securities Act or exemptions thereto.

We are registering the above-referenced shares to permit each of the selling stockholders and their pledgees, donees, transferees or other successors-in-interest that receive their shares after the date of this prospectus to resell or otherwise dispose of the shares in the manner contemplated under the "Plan of Distribution." The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them. We currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares. The shares offered by this prospectus may be offered from time to time by the selling stockholders.

The following table, to our knowledge, sets forth information regarding the beneficial ownership of our common stock by the selling stockholders as of August 22, 2007 and the number of shares being offered hereby by each selling stockholder. For purposes of the following description, the term "selling stockholder" includes pledgees, donees, permitted transferees or other permitted successors-in-interest selling shares received after the date of this prospectus from the selling stockholders. The information is based in part on information provided by or on behalf of the selling stockholders. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, and includes voting or investment power with respect to shares, as well as any shares as to which the selling stockholder has the right to acquire beneficial ownership within sixty (60) days after August 22, 2007 through the exercise or conversion of any stock options, warrants, convertible debt or otherwise. All shares that are issuable to a selling stockholder upon exercise of the warrants are included in the number of shares being offered in the table below. Unless otherwise indicated below, each selling stockholder has sole voting and investment power with respect to its shares of common stock. The inclusion of any shares in this table does not constitute an admission of beneficial ownership by the selling stockholder. We will not receive any of the proceeds from the sale of our common stock by the selling stockholders.

	SHARES			SHARES		
	BENEFICALLY			BENEFICALLY		
	OWNED BEFORE		SHARES	OWNED AFTER		
	OFFERING(1)		BEING	OFFERING(2)		
SELLING STOCKHOLDER	NUMBER	PERCENT	OFFERED	NUMBER	PERCENT	
Baker/Tisch Investments,						
L.P. (3)	70,971	2.67%	3,397	67,574	2.55%	
	2,740,840	51.45%	131,208	2,609,632	50.22%	

Baker Biotech Fund I,					
L.P.(4)					
Baker Brothers Life					
Sciences, L.P. (5)	7,438,590	74.20%	356,095	7,082,495	73.25%
14159, L.P. (6)	240,276	8.5%	11,502	228,774	8.13%
Baker Brothers Investments					
II, L.P.(7)	9,323	*%	446	8,877	*%
Atticus Global Advisors, Ltd.					
L.P. (8)	1,750,000	40.36%	83,775	1,666,225	39.18%
Green Way Managed Acct.					
Series, Ltd.(9)	250,000	8.81%	11,968	238,032	8.43%
Rodman & Renshaw, LLC					
(10)	624,106	*%	29,877	594,229	*%
*Less than 1%					

- (1)Percentages prior to the offering are based on 2,586,377 shares of common stock that were issued and outstanding as of August 22, 2007. We deem shares of common stock that may be acquired by an individual or group within 60 days of August 22, 2007 pursuant to the exercise of options or warrants or the conversion of convertible securities to be outstanding for the purpose of computing the percentage ownership of such individual or group, but such shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other individual or entity shown in the table.
- (2) We do not know when or in what amounts the selling stockholders may offer for sale the shares of common stock pursuant to this offering. The selling stockholders may choose not to sell any of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares of common stock pursuant to this offering, and because there are currently no agreements, arrangements or undertakings with respect to the sale of any of the shares of common stock, we cannot estimate the number of shares of common stock that the selling stockholders will hold after completion of the offering. For purposes of this table, we have assumed that the selling stockholders will have sold all of the shares covered by this prospectus upon the completion of the offering.
- (3) The number of shares beneficially owned before the offering includes 56,777 shares of common stock issuable upon conversion of Series B Preferred Stock and 14,194 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 3,397 shares of common stock issuable upon conversion of Series B Preferred Stock. Felix Baker and Julian Baker, as managing members, have the power to vote or dispose of the securities owned by Baker Biotech Fund I, L.P.
- (4) The number of shares beneficially owned before the offering includes 2,192,672 shares of common stock issuable upon conversion of Series B Preferred Stock and 548,168 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 131,208 shares of common stock issuable upon conversion of Series B Preferred Stock. Felix Baker and Julian Baker, as managing members, have the power to vote or dispose of the securities owned by Baker/Tisch Investments, L.P.
- (5) The number of shares beneficially owned before the offering includes 5,950,872 shares of common stock issuable upon conversion of Series B Preferred Stock and 1,487,718 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 356,095 shares of common stock issuable upon conversion of Series B Preferred Stock. Felix Baker and Julian Baker, as managing members, have the power to vote or dispose of the securities owned by Baker Brothers Life Sciences, L.P.
- (6) The number of shares beneficially owned before the offering includes 192,221 shares of common stock issuable upon conversion of Series B Preferred Stock and 48,055 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 11,502 shares of common stock issuable upon conversion of Series B Preferred Stock. Felix Baker and Julian Baker, as managing members, have the power to vote or dispose of the securities owned by 14159, L.P.
- (7) The number of shares beneficially owned before the offering includes 7,458 shares of common stock issuable upon conversion of Series B Preferred Stock and 1,865 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of

the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 446 shares of common stock issuable upon conversion of Series B Preferred Stock. Felix Baker and Julian Baker, as managing members, have the power to vote or dispose of the securities owned by Baker Brothers Investments II, L.P.

- (8) The number of shares beneficially owned before the offering includes 1,400,000 shares of common stock issuable upon conversion of Series B Preferred Stock and 350,000 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 83,775 shares of common stock issuable upon conversion of Series B Preferred Stock. Timothy R. Barakett may be deemed to have control over the voting or disposition of the securities owned by Atticus Global Advisors, Ltd. L.P.
- (9) The number of shares beneficially owned before the offering includes 200,000 shares of common stock issuable upon conversion of Series B Preferred Stock and 50,000 shares of common stock issuable upon conversion of Series B Preferred Stock issuable upon exercise of the warrants that are exercisable beginning as of the date of issuance of the Warrants for a period of five years at an exercise price of \$2.50 per share. The number of shares being offered consists of 11,968 shares of common stock issuable upon conversion of Series B Preferred Stock. Timothy R. Barakett may be deemed to have control over the voting or disposition of the securities owned by Green Way Managed Account Series, Ltd.
- (10) The number of shares beneficially owned before the offering includes 624,106 shares of common stock issuable upon exercise of warrants. The number of shares being offered consists of 29,877 shares of common stock issuable upon exercise of warrants to purchase our common stock that are exercisable beginning as of the date of issuance of the warrants for a period of five years at an exercise price of \$2.50 per share.

#### PLAN OF DISTRIBUTION

Each Selling Stockholder (the "Selling Stockholders") of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the American Stock Exchange or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

·block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

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an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

• settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

·broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;

•through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the common stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Common Stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented

or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Common Stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each Selling Stockholder has advised us that they have not entered into any written or oral agreements, understandings, or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

#### LEGAL MATTERS

The validity of the common stock offered in this prospectus will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts.

#### EXPERTS

The consolidated financial statements of Synvista as of December 31, 2006 and 2005, and for each of the years in three year period ended December 31, 2006, have been incorporated by reference herein in reliance upon the report, which includes an explanatory paragraph relating to our ability to continue as a going concern, of J.H. Cohn LLP, independent registered public accounting firm, and upon the authority of that firm as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We are a public company and file annual, quarterly and special reports, proxy statements and other information with the U.S. Securities and Exchange Commission. You may read and copy any document we file at the SEC's Public Reference Room at Station Place, 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents 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 Public Reference Room. Our SEC filings are also available to the public at the SEC's web site at http://www.sec.gov, or at our web site at www.synvista.com. In addition, our common stock is

listed for trading on the American Stock Exchange under the symbol "SYI."

This prospectus is only part of a Registration Statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the Registration Statement. We have also filed exhibits and schedules with the Registration Statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may:

·inspect a copy of the Registration Statement, including the exhibits and schedules, without charge at the Public Reference Room,

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obtain a copy from the SEC upon payment of the fees prescribed by the SEC, or

obtain a copy from the SEC's web site.

# INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with them, which means that we can disclose important information in this prospectus by referring to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934. The documents we are incorporating by reference as of their respective dates of filing are:

•Our Annual Report on Form 10-K for the year ended December 31, 2006, filed on March 30, 2007 (File No. 001-16043);

•Our Annual Report on Form 10-K/A for the year ended December 31, 2006, filed on April 30, 2007 (File No. 001-16043);

•Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 14, 2007 (File No. 001-16043);

• Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 14, 2007 (File No. 001-16043);

- Our Current Report on Form 8-K, filed on January 16, 2007 (File No. 001-16043);
- Our Current Report on Form 8-K, filed on January 22, 2007 (File No. 001-16043);
- Our Current Report on Form 8-K, filed on January 30, 2007 (File No. 001-16043);
- Our Current Report on Form 8-K, filed on February 2, 2007 (File No. 001-16043);
- Our Current Report on Form 8-K, filed on February 8, 2007 (File No. 001-16043);
- · Our Current Report on Form 8-K, filed on April 5, 2007 (File No. 001-16043);
- · Our Current Report on Form 8-K, filed on April 6, 2007 (File No. 001-16043);
  - Our Current Report on Form 8-K, filed on April 11, 2007 (File No. 001-16043);

Our Current Report on Form 8-K, filed on May 18, 2007 (File No. 001-16043);
Our Current Report on Form 8-K, filed on June 7, 2007 (File No. 001-16043);
Our Current Report on Form 8-K, filed on June 28, 2007 (File No. 001-16043);
Our Current Report on Form 8-K, filed on July 25, 2007 (File No. 001-16043);
Our Current Report on Form 8-K, filed on July 31, 2007 (File No. 001-16043);
Our Current Report on Form 8-K, filed on September 13, 2007 (File No. 001-16043);

•The portions of the Registrant's Definitive Proxy Statement on Schedule 14A that are deemed "filed" with the Commission under the Exchange Act, filed on June 22, 2007;

•The description of our common stock, \$0.01 par value per share, which is contained in our Registration Statement on Form 8-A, filed on November 1, 1991, including any amendments or reports filed for the purpose of updating such description; and

•The description of the Rights under the Registrant's Stockholders' Rights Agreement (which are currently transferred with the Registrant's common stock) contained in the Registrant's Registration Statement on Form 8-A (File No. 000-19529), filed under the Exchange Act, filed on August 4, 1995, including any amendment or report filed for the purposes of updating such description.

You may request, orally or in writing, a copy of these filings, which will be provided to you at no cost, by contacting Investor Relations c/o Nancy Regan, at our principal executive offices, which are located at 221 West Grand Avenue, Suite 200, Montvale, New Jersey 07645, (201) 934-5000.

To the extent that any statements contained in a document incorporated by reference are modified or superseded by any statements contained in this prospectus, such statements shall not be deemed incorporated in this prospectus except as so modified or superseded.

All documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of this offering are incorporated by reference and become a part of this prospectus from the date such documents are filed. We also specifically incorporate by reference any documents filed by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement and prior to the effectiveness of the registration statement. Any statement contained in this prospectus or in a document incorporated by reference is modified or superseded for purposes of this prospectus to the extent that a statement contained in any subsequent filed document modifies or supersedes such statement.

Synvista Therapeutics, Inc. 628,268 shares of common stock

Prospectus

\_\_\_\_\_, 2007

### PART II

#### **INFORMATION NOT REQUIRED IN PROSPECTUS**

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the Company's estimates (other than the SEC registration fee) of the expenses in connection with the issuance and distribution of the shares of common stock being registered. None of the following expenses are being paid by the selling stockholders.

SEC registration fee	\$	83.52	
Accounting fees and expenses	\$	5,000	
Legal fees and expenses	\$	25,000	
TOTAL	\$	30,083.52	

#### Item 15. Indemnification of Directors and Officers

Subsection (a) of Section 145 of the General Corporation Law of the State of Delaware ("DGCL") empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding 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, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a resumption believed to be in or not opposed to the best interests of the corporation approach to the person and, with respect to any criminal action or proceeding, had reasonable cause to believe the person's conduct was unlawful.

Subsection (b) of Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee, or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the 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 except that no indemnification shall be made in respect of 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 the court in which such action or suit was brought shall determine upon application 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.

Section 145 further provides that to the extent a director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (a) and (b) or in defense of any claim, issue or matter therein, the person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith; that the indemnification provided by Section 145 shall

not be deemed exclusive of any other rights to which the indemnified party may be entitled; and that the scope of indemnification extends to directors, officers, employees, or agents of a constituent corporation absorbed in a consolidation or merger and persons serving in that capacity at the request of the constituent corporation for another. Section 145 also empowers the corporation to purchase and maintain insurance on behalf of a director or officer of the corporation against any liability asserted against such person or incurred by such person in any such capacity or arising out of such person's status as such whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

Article IX of the registrant's amended and restated by-laws specifies that the registrant shall indemnify its directors and officers to the full extent permitted by the DGCL. This provision of the amended and restated by-laws is deemed to be a contract between the registrant and each director and officer who serves in such capacity at any time while such provision and the relevant provisions of the DGCL are in effect, and any repeal or modification thereof shall not offset any rights or obligations then existing with respect to any state of facts then or theretofore existing or in any action, suit or proceeding theretofore or thereafter brought or threatened in whole or in part upon any such state of facts.

Section 102(b)(7) of the DGCL enables a corporation in its certificate of incorporation to limit the personal liability of members of its board of directors for violation of a director's fiduciary duty of care. This Section does not, however, limit the liability of a director for breaching his duty of loyalty, failing to act in good faith, engaging in intentional misconduct or knowingly violating a law, or from any transaction in which the director derived an improper personal benefit. This Section also will have no effect on claims arising under the federal securities laws. The registrant's restated certificate of incorporation limits the liability of its directors as authorized by Section 102(b)(7).

The registrant currently carries liability insurance for the benefit of its directors and officers which provides coverage for losses of directors and officers for liabilities arising out of claims against such persons acting as directors or officers of the registrant (or any subsidiary thereof) due to any breach of duty, neglect, error, misstatement, misleading statement, omission or act done by such directors and officers, except as prohibited by law. The liability limit, however, shall be reduced by amounts incurred for legal defense, which amounts are to be applied against the retention amount. The insurance policy also provides for the advancement of reasonable fees, costs and expenses, including attorneys' fees under certain circumstances, incurred by directors and officers in investigating, adjusting, defending and appealing any claim, subject to repayment by such director or officer if it is ultimately determined that such insureds are not entitled under the terms of the policy to payment of such loss.

The insurance policy will not provide coverage to the directors and officers to the extent that the registrant has indemnified the directors or officers. The policy provides for the reimbursement of the registrant to the extent the registrant has indemnified the directors and officers pursuant to law, contract or the restated certificate of incorporation or amended and restated by-laws of the registrant. Moreover, the policy does not provide coverage for any claim: (i) based upon, or arising from, personal injury, slander, defamation or a similar matter, (ii) based upon, or arising from, personal profit or advantage to which he or she was not legally entitled, (iii) based upon, or arising from, any deliberately dishonest, malicious or fraudulent act or omission or any willful violation of law by any insured if a judgment or other final adjudication adverse to the insured established such an act, omission or willful violation, (iv) brought or maintained by or on behalf of the insured organization or any insured person, in any capacity, subject to certain exceptions, including those related to stockholders' derivative actions, set forth in the policy, (v) based upon, or arising from, environmental claims and violations, (vi) based upon, or arising from a loss insured by any other valid or collectible insurance, except as such loss may exceed the policy amount or other limitations of such other insurance.

At present, there is no pending litigation or proceeding involving a director or officer of the registrant as to which indemnification is being sought nor is the registrant aware of any threatened litigation that may result in claims for indemnification by any director or officer.

# Item 16. Exhibits

The exhibits required to be filed are listed on the "Exhibit Index" attached hereto, which is incorporated herein by reference.

# Item 17. Undertakings

(a)

The undersigned registrant hereby undertakes:

- (1)To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
  - (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
- (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement: and
- (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the

registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus or any prospectus supplement filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus or prospectus supplement 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.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus or prospectus supplement 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, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Montvale, State of New Jersey, on September 28, 2007.

#### SYNVISTA THERAPEUTICS, INC.

By: /s/ Noah Berkowitz

Noah Berkowitz, M.D., Ph.D. President and Chief Executive 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	
/s/ Noah Berkowitz	President, Chief Executive Officer and Director	September 28, 2007	
Noah Berkowitz, M.D., Ph.D.			
*	(principal financial and accounting officer)	September 28, 2007	
Jeffrey P. Stein, CPA			
*	Director	September 28, 2007	
Wayne P. Yetter			
*	Director	September 28, 2007	
Mary C. Tanner		_007	
/s/ John F. Bedard	Director	September 28, 2007	
John F. Bedard			
*By Noah Berkowitz Attorney-in-fact			
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# EXHIBIT INDEX

# EXHIBIT

# NUMBER DESCRIPTION OF DOCUMENT

- 4.1 Form of Series 1 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
- 4.2 Form of Series 2 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
- Form of Common Stock Purchase Warrant, dated July 2, 2004. (Incorporated by reference to Exhibit 4.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004, SEC File Number 000-16043.)
- 4.4 Form of Common Stock Purchase Warrant, dated January 5, 2005. (Incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004, SEC File Number 000-16043.)
- 4.5 Amended and Restated Stockholder Rights Agreement between Synvista Therapeutics, Inc. and American Stock Transfer & Trust Company, as Rights Agent, dated as of July 27, 2005. (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A/A filed on July 27, 2005, SEC File Number 001-16043.)
- 4.6 Registration Rights Agreement by and between Synvista Therapeutics, Inc. and the Purchasers named therein dated as of April 19, 2006. (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on May 31, 2006, SEC File No. 333-134584.)
- 4.7 Form of Warrant issued to investors pursuant to the Securities Purchase Agreement dated as of April 19, 2006, by and between the Company and the Purchasers named therein. (Incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-3 filed on May 31, 2006, SEC File No. 333-134584.)
- 4.8 Registration Rights Agreement by and between Synvista Therapeutics, Inc. and the Purchasers named therein, dated as of September 13, 2006. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 19, 2006, SEC File No. 001-16043.)
- 4.9 Form of Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of September 13, 2006, by and between the Company and the Purchasers named therein. (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on September 19, 2006, SEC File No. 001-16043.)
- 4.10 Series B Preferred Stock and Warrant Purchase Agreement, as amended, among Synvista Therapeutics, Inc. and the Purchasers named therein, dated as of April 5, 2007 (Incorporated by reference to Annex A to the Company's Definitive Proxy Statement filed on June 22, 2007), SEC File No. 001-16043.)
- 4.11 Form of Preferred Stock Purchase Warrant issued to investors pursuant to the Series B Preferred Stock and Warrant Purchase Agreement. (Incorporated by reference to Exhibit 10.4 of Registrant's Current Report on Form 8-K filed on April 11, 2007, SEC File No. 001-16043.)

- 4.12 Registration Rights Agreement by and between Synvista Therapeutics, Inc and the Purchasers named therein dated as of July 25, 2007. (Incorporated by reference to Exhibit 10.3 of Registrant's Current Report on Form 8-K, filed on April 11, 2007, SEC File No. 001-16043.)
- 5.1 Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Incorporated by reference to Exhibit 5.1 of Registrant's Form S-3, filed on September 7, 2007, SEC File No. 333-145935.)
- 23.1\* Consent of J.H. Cohn LLP.
- 23.2 Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Included in opinion of counsel filed as Exhibit 5.1). (Incorporated by reference to Exhibit 5.1 of Registrant's Form S-3, filed on September 7, 2007, SEC File No. 333-145935.)
- 24.1 Power of Attorney. (Incorporated by reference to signature page by Registrant's Form S-3, filed on September 7, 2007, SEC File No. 333-145935.)

\* Filed herewith