Synvista Therapeutics, Inc.
Form S-3
September 07, 2007

As filed with the Securities and Exchange Commission on September 7, 2007

Registration No. 333-_____

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

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**13-3304550**
(State or other jurisdiction of incorporation or organization)	**(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. þ

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

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CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, $0.01 par value per share	628,268	$4.33	$2,720,400	$83.52
Rights to Purchase Series A Preferred Stock	(3)	(3)	(3)	None

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(1) Consists of 10,000,000 shares of common stock issuable upon conversion of the shares of Series B Preferred Stock sold as part of a private placement transaction as described herein, and 2,500,000 shares of common stock issuable upon conversion of the Series B Preferred Stock underlying warrants to purchase shares of Series B Preferred Stock issued in the same private placement. Pursuant to Rule 416 under the Securities Act of 1933, as amended, this Registration Statement also covers such number of additional shares of common stock as may be issuable in order to prevent dilution resulting from stock splits, dividends or other distributions, recapitalizations or similar events.

(2) Estimated solely for the purpose of determining the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based upon the average of the high and low prices for the common stock of Synvista Therapeutics, Inc. on September 6, 2007, as reported by the American Stock Exchange.

(3) No separate consideration will be received for the Rights, which are attached to the shares of common stock.

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.

SUBJECT TO COMPLETION, DATED SEPTEMBER 7, 2007

PROSPECTUS

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

We sold shares of our Series B Preferred Stock, $0.01 par value per share (the "Series B Preferred Stock") and warrants to purchase 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 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 6, 2007 the last reported sale price of our common stock was $4.31 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 "Risk Factors" 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

TABLE OF CONTENTS

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.

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, which warrants are exercisable for a period of five years commencing on July 25, 2007 at an exercise price of $2.50 per share.

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 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. 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:

- incur debt in excess of $2,000,000,
- 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,
- 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.

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).

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

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;
- 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

- 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. By statute and regulation, the FDA has 180 days to review an application for approval to market a 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 oDING-LEFT: 2px; PADDING-RIGHT: 2px" colspan="2">

Mr. Horrigan

(i)	Sole power to vote or to direct the vote:	10,988,922
(ii)	Shared power to vote or to direct the vote:	4,221,802
(iii)	Sole power to dispose or to direct the disposition of:	10,988,922
(iv)	Shared power to dispose or to direct the disposition of:	4,221,802

Item 5. Ownership of Five Percent or Less of a Class.

If this statement is being filed to report the fact that as of the date hereof the reporting person has ceased to be the beneficial owner of more than five percent of the class of securities, check the following. o

Item 6. Ownership of More than Five Percent on Behalf of Another Person.

Not applicable.

Item 7. Identification and Classification of the Subsidiary Which Acquired the Security Being Reported on by the Parent Holding Company or Control Person.

Not applicable.

Item 8. Identification and Classification of Members of the Group.

Not applicable.

Item 9. Notice of Dissolution of Group.

Not applicable.

Item 10. Certification.

Not applicable.

Signature

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: February 9, 2018

/s/ R. Philip Silver
R. Philip Silver

/s/ D. Greg Horrigan
D. Greg Horrigan

EXHIBIT 1

JOINT FILING AGREEMENT

In accordance with Rule 13d-1(k)(1) promulgated under the Securities Exchange Act of 1934, as amended, the undersigned hereby agree to the joint filing with each other on behalf of each of them of this Amendment No. 15 to Schedule 13G with respect to the Common Stock, $0.01 par value, of Silgan Holdings Inc. This Joint Filing Agreement shall be included as an exhibit to such Amendment No. 15 to Schedule 13G.

IN WITNESS WHEREOF, the undersigned have executed this Joint Filing Agreement as of the 9th day of February, 2018.

/s/ R. Philip Silver
R. Philip Silver

/s/ D. Greg Horrigan
D. Greg Horrigan