

Synvista Therapeutics, Inc.  
Form 10-Q  
August 14, 2008

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM 10-Q**

**(Mark One)**

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **June 30, 2008**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number **001-16043**

**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 No.)

**221 West Grand Avenue, Suite 200, Montvale, New Jersey 07645**

(Address of principal executive offices)  
(Zip Code)

**(201) 934-5000**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year,  
if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ (Do not check if a smaller reporting company)  
Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes ☐ No ☒

On August 1, 2008, 2,586,326 shares of the registrant's Common Stock were outstanding.

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**SYNVISTA THERAPEUTICS, INC.**

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**PART I - FINANCIAL INFORMATION****ITEM 1. Condensed Consolidated Financial Statements (Unaudited).**

**SYNVISTA THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(Unaudited)**

	<b>June 30, 2008</b>	<b>December 31, 2007 (Note 1)</b>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 10,097,972	\$ 15,646,225
Other current assets	515,513	234,338
Total current assets	10,613,485	15,880,563
Property and equipment, net	18,773	17,096
Other assets	352,895	807,646
Total assets	\$ 10,985,153	\$ 16,705,305
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 626,215	\$ 1,503,355
Accrued expenses	717,809	458,731
Preferred stock dividends payable	1,875,000	875,000
Total current liabilities	3,219,024	2,837,086
<b>Stockholders' Equity:</b>		
Preferred stock, \$.01 par value; 15,000,000 shares authorized, 400,000 shares designated as Series A, none issued and outstanding, 12,500,000 shares designated as Series B convertible preferred stock, 10,000,000 shares issued and outstanding (aggregate liquidation preference of \$25,000,000) at June 30, 2008 and December 31, 2007	100,000	100,000
Common stock, \$.01 par value; 300,000,000 shares authorized, 2,586,326 shares issued and outstanding at June 30, 2008 and 2,586,377 issued and outstanding at December 31, 2007	25,863	25,864
Additional paid-in capital	280,665,438	276,834,875
Accumulated deficit	(273,025,172)	(263,092,520)
Total stockholders' equity	7,766,129	13,868,219
Total liabilities and stockholders' equity	\$ 10,985,153	\$ 16,705,305

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**SYNVISTA THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
License and other revenue	\$ 51,724	\$ 50,000	\$ 53,957	\$ 50,000
Operating expenses:				
Research and development	1,669,647	1,652,658	3,389,989	2,401,077
General and administrative	962,451	692,073	1,857,363	1,640,378
Selling and marketing	141,858	-	141,858	-
Total operating expenses	2,773,956	2,344,731	5,389,210	4,041,455
Loss from operations	(2,722,232)	(2,294,731)	(5,335,253)	(3,991,455)
Investment income	75,002	26,686	209,765	63,046
Interest expense	(1,864)	(3,229,734)	(3,008)	(5,235,316)
Other income/(expense)	(400,000)	-	(400,000)	-
Net loss	(3,049,094)	(5,497,779)	(5,528,496)	(9,163,725)
Preferred stock dividends - Series B	500,000	-	1,000,000	-
Deemed dividends to Series B preferred stockholders on beneficial conversion feature	1,702,078	-	3,404,156	-
Net loss applicable to common shares	\$ (5,251,172)	\$ (5,497,779)	\$ (9,932,652)	\$ (9,163,725)
Net loss per common share:				
Basic and diluted	\$ (2.03)	\$ (2.13)	\$ (3.84)	\$ (3.54)
Weighted average common shares outstanding:				
Basic and diluted	2,586,326	2,586,377	2,586,326	2,586,377

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**SYNVISTA THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN**  
**STOCKHOLDERS' EQUITY**  
**(Unaudited)**

	Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Equity
Balances, December 31, 2007	10,000,000	\$ 100,000	2,586,377	\$ 25,864	\$ 276,834,875	\$ (263,092,520)	\$ 13,868,219
Net loss	-	-	-	-	-	(5,528,496)	(5,528,496)
Fractional shares	-	-	(51)	(1)	1	-	-
Deemed dividends to Series B preferred stockholders on beneficial conversion feature	-	-	-	-	3,404,156	(3,404,156)	-
Series B preferred stock dividend payable	-	-	-	-	-	(1,000,000)	(1,000,000)
Stock-based compensation	-	-	-	-	416,964	-	416,964
Options issued for consulting services	-	-	-	-	4,106	-	4,106
Compensation costs related to restricted stock	-	-	-	-	5,336	-	5,336
Balances, June 30, 2008	10,000,000	\$ 100,000	2,586,326	\$ 25,863	\$ 280,665,438	\$ (273,025,172)	\$ 7,766,129

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**SYNVISTA THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
Cash Flows from Operating Activities:		
Net loss	\$ (5,528,496)	\$ (9,163,725)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	416,964	84,562
Options issued for consulting services	4,106	2,732
Compensation costs related to restricted stock	5,336	52,515
Amortization of debt discount	-	4,636,364
Amortization of deferred financing costs	-	463,322
Depreciation and amortization	6,523	4,290
Write-off of investment in Oxis stock	400,000	-
Changes in operating assets and liabilities:		
Other current assets	(281,175)	6,661
Other assets	54,751	39,491
Accounts payable and accrued expenses	(618,062)	148,886
Net cash used in operating activities	(5,540,053)	(3,724,902)
Cash Flows from Investing Activities:		
Capital expenditures	(8,200)	(12,066)
Net cash used in investing activities	(8,200)	(12,066)
Cash Flows from Financing Activities:		
Proceeds from debt financing	-	6,000,000
Deferred debt financing costs	-	(758,063)
Net cash provided by financing activities	-	5,241,937
Net increase/(decrease) in cash and cash equivalents	(5,548,253)	1,504,969
Cash and cash equivalents, beginning of period	15,646,225	1,478,780
Cash and cash equivalents, end of period	\$ 10,097,972	\$ 2,983,749
Supplemental disclosures of non-cash investing and financing activities:		
Deemed dividends to Series B preferred stockholders on beneficial conversion	\$ 3,404,156	\$ -
Series B stock dividends payable	\$ 1,000,000	\$ -
Accrual of deferred financing costs	\$ -	\$ 172,867
Warrants issued and embedded conversion feature associated with debt financing	\$ -	\$ 6,000,000
Accrued liability recognized pursuant to a share purchase agreement (Oxis), net of \$100,000 premium expensed during the period.	\$ -	\$ 400,000

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**SYNVISTA THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**Note 1 - Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission (the "Form 10-K"). The December 31, 2007 balance sheet is derived from the audited balance sheet included in the Form 10-K.

***Principles of Consolidation***

The accompanying condensed consolidated financial statements include the accounts of Synvista Therapeutics, Inc. and its wholly owned subsidiary, HaptoGuard, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

***Reclassifications***

Certain prior period balances have been reclassified to conform to the current presentation.

**Note 2 - Liquidity**

The Company has devoted substantially all of its resources to research, drug discovery and development programs. To date, it has not generated any revenues from the sale of products and does not expect to generate any such revenues for a number of years, if at all. As a result, the Company has incurred net losses since inception, has an accumulated deficit of \$273,025,172 as of June 30, 2008, and expects to incur net losses, potentially greater than losses in prior years, for a number of years, assuming the Company is able to continue as a going concern, of which there can be no assurance.

The Company has financed its operations through proceeds from the sale of common and preferred equity securities, debt securities, revenue from former collaborative relationships, reimbursement of certain of its research and development expenses by collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of the Company's New Jersey state net operating loss carryforwards and research and development tax credit carryforwards.

As of June 30, 2008, the Company had working capital of \$7,394,461, including \$10,097,972 of cash and cash equivalents. The Company's net cash used in operating activities for the six months ended June 30, 2008 was \$5,540,053 and for the year ended December 31, 2007 was \$7,947,000.



In August 2007, we entered into a share purchase agreement for the purchase of \$500,000 of newly issued shares of Oxis International Limited (“Oxis”) common stock at a premium over the then current market price. It is our understanding that Oxis held some value as of June 30, 2008, but it is our position that we will not recoup our investment in Oxis. On June 19, 2008, Oxis received a Notice of Disposition of Collateral from certain debenture holders. Our investment in Oxis of \$400,000 was written off as of June 30, 2008. This security was restricted for sale until the early part of February 2009.

The Company expects to continue to utilize cash and cash equivalents to fund its operating activities, including continued development of SYI-2074, alagebrium and its diagnostic test kits. The amount and timing of the Company’s future capital requirements will depend on numerous factors, including the progress of its research and development programs, the number and characteristics of product candidates that the Company pursues, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any. The Company expects to have sufficient cash and cash equivalents to satisfy its working capital requirements into the first quarter of 2009. At the request of the holders of its Series B preferred stock, the Company may be required to pay accrued dividends on its Series B preferred stock, totaling \$1,875,000 as of June 30, 2008, in cash rather than in shares of its Series B preferred stock. While this would reduce the Company’s liquidity, the Company believes that its ability to adjust spending levels in a number of its programs will permit its continued operations into the first quarter of 2009, regardless of the form of dividend payment elected by the holders of its Series B preferred stock.

The Company anticipates that it will require substantial new funding in 2009 to pursue development and commercialization of its product candidates and to continue its operations. The Company believes that satisfying these capital requirements over the long term will require successful commercialization of its product candidates and/or its diagnostic test kits. However, it is uncertain whether any of its products or diagnostic test kits will be approved or will be commercially successful.

Selling securities to satisfy its capital requirements may have the effect of materially diluting the current holders of the Company's outstanding stock. The Company may also seek additional funding through corporate collaborations and other financing vehicles. There can be no assurances that such funding will be available at all or on terms acceptable to the Company. If funds are obtained through arrangements with collaborative partners or others, the Company may be required to relinquish rights to its technologies or product candidates and alter its plans for the development of its technologies or product candidates. If the Company is unable to obtain the necessary funding, it will likely be forced to cease operations.

### Note 3 - Stock-Based Compensation

The Company has stockholder-approved stock incentive plans for employees, directors, officers and consultants.

The Company follows Statement of Financial Accounting Standards No. 123(R) ("SFAS 123(R)"), "Share-Based Payment," for employee options and uses the Black-Scholes option pricing model in valuing its options granted to employees and Directors.

The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of compensation charges relating to its option grants:

	Six months ended June 30	
	2008	2007
Expected volatility	107%	148%
Dividend yield	-	-
Expected term (in years)	8.31	6.12
Risk-free interest rate	3.88%	4.88%

Options granted to consultants and other non-employees are accounted for in accordance with Emerging Issue Task Force No. 96-18 "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Accordingly, such options are recorded at fair value at the date of grant and subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of the options, as adjusted, is charged to consulting expense over the related vesting period. For the six-months ended June 30, 2008, the Company recognized research and development consulting expenses of \$4,106.

For the three and six month periods ended June 30, 2008, the Company recognized share-based employee compensation cost of \$194,384 and \$222,580, respectively, in accordance with SFAS 123(R), "Share-Based Payment," which was recorded as general and administrative and research and development expense. This expense related to the granting of stock options to employees, directors and officers on or after January 1, 2006. None of this expense resulted from the grants of stock options prior to January 1, 2006. The Company recognized compensation expense related to these stock options, taking into consideration a forfeiture rate of approximately 1% based on historical experience, on a straight-line basis over the vesting period. The Company did not capitalize any share-based compensation cost.

As of June 30, 2008, the total compensation cost related to non-vested option awards not yet recognized is \$1,274,693. The weighted-average period over which this cost is expected to be recognized is approximately 2.29 years.

A summary of the status of the Company's stock options outstanding as of June 30, 2008 and changes during the six months then ended is presented below:

	Shares	Weighted average exercise price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	876,706	\$ 16.00		
Granted	16,000	1.88		
Exercised	-	-		
Cancelled	(23,801)	100.64		
Outstanding at June 30, 2008	868,905	\$ 13.42	8.29	\$ 450.00
Options exercisable at June 30, 2008	239,622	\$ 40.74	5.83	\$ -

#### *Restricted Stock*

The Company periodically grants awards of restricted stock to its Board of Directors as compensation for service on the Board of Directors. The awards vest during various periods ranging from one to three years. There were no shares of restricted stock granted during the period ended June 30, 2008. There were 19,200 shares of restricted stock granted during the year ended December 31, 2006, of which 6,400 were forfeited in prior periods. Of the 8,520 shares of restricted stock that vested, the vesting of 4,280 shares had been accelerated by the Board of Directors. The Company recognized compensation cost of \$2,668 and \$5,336 for the three and six months ended June 30, 2008, respectively, which was recorded as general and administrative expense.

A summary of the status of the Company's non-vested shares as of June 30, 2008 and changes during the six months ended June 30, 2008, is presented below:

	Shares	Weighted average grant date fair value
Nonvested Shares		
Nonvested at December 31, 2007	4,280	\$ 7.50
Granted	-	-
Vested	-	-
Forfeited	-	-
Nonvested at June 30, 2008	4,280	\$ 7.50

As of June 30, 2008, there was \$11,286 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted. That cost is expected to be recognized over a weighted-average period of 1 year.

#### **Note 4 - Net Loss Per Share Applicable to Common Stockholders**

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares outstanding during the period. Diluted net loss per share is the same as basic net loss per share applicable to common stockholders, since the assumed exercise of stock options and warrants and the conversion of preferred stock would be antidilutive. The amount of potentially dilutive shares excluded from the calculation as of June 30, 2008 and 2007, was 14,412,421 and 1,194,932 shares, respectively.

#### **Note 5 - Collaborative Research and Development Agreement**

On January 20, 2008, the Company entered into a License Agreement (the "Agreement") with Novel Therapeutic Technology Inc. ("NTT"). The Agreement states that NTT will develop a formulation of the Company's product candidate SYI-2074. The Agreement also states that NTT will grant the Company an exclusive worldwide license to the product formulation developed as well as to the intellectual property rights resulting under the Agreement. An insignificant upfront payment was made in January 2008. The Company will also make specified payments to NTT upon the occurrence of certain milestone events in the clinical development of the product formulated under the Agreement. In addition, the Company would also have to pay NTT royalties on any sales of the developed product and a separate fee if any of the rights granted under the Agreement are sublicensed by the Company.

The license granted under the Agreement will be terminated upon the earlier to occur of (i) the date the Company notifies NTT that it does not intend to proceed further with development of formulation of SYI-2074 subject to the Agreement, (ii) the date the Company notifies NTT that it does not intend to continue to commercialize the products developed pursuant to the Agreement, and (iii) the later of (a) the expiration of the last valid patent covering the formulation of the Company's intellectual property pursuant to the Agreement, which, absent the Agreement, would infringe an existing patent, or (b) 15 years from the date of the first commercial sale of a product pursuant to the Agreement.

#### **Note 6 - Series B Preferred Stock and Warrant Purchase Agreement**

On July 20, 2007, at the Company's annual meeting of stockholders, the stockholders of the Company approved the issuance of securities pursuant to the Series B Preferred Stock and Warrant Purchase Agreement dated as of January

11, 2007, as amended. At the closing of the financing on July 25, 2007, the Company issued 10,000,000 shares of its Series B Preferred Stock and warrants to purchase 2,500,000 shares of Series B Preferred Stock to the investors. The Series B Preferred Stock accrues dividends at a rate of 8% per year on the original issue price of \$2.50 per share for a period of five years from the date on which the shares of Series B Preferred Stock were issued. As of July 31, 2008, the holders of the Series B Preferred Stock have not designated their dividends as payable either in cash or preferred stock.

**Note 7 - Subsequent Events**

On July 22, 2008, at the Company's annual meeting of stockholders, the stockholders of the Company approved an amendment to the Company's 2005 Stock Plan (the "Plan") that increased the number of shares of common stock reserved for issuance under the Plan from 1,060,000 shares to 2,000,000 shares.

The stockholders of the Company also approved an amendment to the Company's Restated Certificate of Incorporation to decrease the number of shares of common stock authorized for issuance from 300,000,000 to 150,000,000. The Company amended its Restated Certificate of Incorporation to reflect this change on July 24, 2008.

## ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### Overview

We are a product-based biotechnology company developing diagnostic and therapeutic products to deliver personalized medicine. Our primary therapeutic interest is the cardiovascular complications of diabetes. Our diagnostic products under development are being designed to identify patients at risk for cardiovascular complications of diabetes such as stroke, heart attack and death, and may be used to guide medical therapy.

We are developing a diagnostic kit to identify the subset of patients with diabetes who are at increased risk for cardiovascular disease. The technology underlying this kit relates to a serum protein called haptoglobin, or Hp. A common variant of this protein, known as Hp2-2, which is found in 40% of the population, is associated with increased cardiovascular risk in diabetic patients. We own intellectual property relating to typing using haptoglobin, which is a protein found in the blood. This diagnostic test can be used to determine a patient's risk for adverse cardiovascular events. It may also be used to identify a subset of diabetic patients in whom daily use of vitamin E could potentially reduce the rate of heart attack by 50% annually. We are evaluating commercial arrangements that would allow our technology or intellectual property to be used by commercial enterprises for the aforementioned purposes. Further, we are developing a kit that may be submitted to the U.S. Food and Drug Administration for pre marketing approval under the 510k pathway for use in determining cardiovascular disease risk in diabetic patients. Any successful commercialization of such a kit could generate revenues for us in future years and could help focus the development of one of our therapeutic product programs, known as glutathione peroxidase mimetics, described below.

We also own intellectual property relating to CML testing. CML, or carboxy-methyl-lysine, is a marker of cardiovascular aging that can predict adverse health outcomes in the general population and a subpopulation with heart failure in particular. A "Research Use Only" kit for quantifying CML levels, using our proprietary reagents, has been sold in the research community in recent years. Given the correlation of CML levels and cardiovascular outcomes that has been appearing in the scientific literature, the Company believes that a CML test may strategically complement the haptoglobin test in the clinical diagnostic setting.

Research and discovery relating to haptoglobin testing has revealed that some patients, identified using the haptoglobin test, exhibit dysfunction in their HDL, or high density lipoprotein. This HDL dysfunction may explain the increased atherosclerosis and adverse cardiovascular outcomes observed in this patient population. We have developed a family of new chemical entities that work by virtue of their ability to reduce oxidized lipids. Some of these compounds have been shown to reverse the HDL dysfunction seen in some diabetic patients. We are evaluating these personalized medicines in animal models designed to better characterize HDL function.

As previously reported, one of our GPx mimetics, SYI-2074, under development for the treatment of diabetic patients with Haptoglobin subtype 2-2, did not demonstrate a dose-related improvement in all oxidized lipids and all markers of oxidative stress after treatment with SYI-2074 for one month in Trial 201. In addition, in Trial 203, SYI-2074 did not provide evidence of protection against cardiac injury in diabetic patients who were undergoing angioplasty. The Company has therefore decided not to advance the development of SYI-2074 as a treatment for acute coronary syndrome, while it continues to review and analyze the results of these studies.

One of our product candidates, SYI-2074, which is an older in-licensed family of compounds that can reduce oxidized lipids, has been formulated into an ointment that may permit topical application and the treatment of mild-moderate plaque psoriasis.

We are developing a compound relevant to the CML marker described above. Alagebrium chloride, or alagebrium (formerly ALT-711), is an Advanced Glycation End-product Crosslink Breaker being developed for diastolic heart failure 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. 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.

During the second quarter of 2008, we announced that we had dosed the first patient in a 160-patient Phase 2 study of alagebrium in patients with diastolic heart failure. **BREAK (Beginning a Randomized Evaluation of the A.G.E. (Advanced Glycation End Product) Breaker Alagebrium in Diastolic Heart Failure)** is a randomized, double-blind, placebo controlled study to assess the effect of six months of oral treatment with 400mg (200mg twice daily) alagebrium versus placebo in patients diagnosed with diastolic heart failure as verified by echocardiography. The trial is ultimately expected to enroll 80 patients per cohort and be conducted in as many as 25 centers in the United States. Investigators intend that at least half of the study subjects will have diabetes mellitus. The primary efficacy measure of the study is improvement of exercise tolerance as assessed by the six-minute walk test, an accepted regulatory endpoint. In addition, there will be a number of secondary and tertiary measurements including the effect of alagebrium on CML levels. The Company has also surpassed 50% enrollment in the **BENEFICIAL** study. This trial, being conducted at the University of Gronigen, The Netherlands, is designed to test the efficacy of alagebrium in heart failure patients with low ejection fractions, by measuring their improvement in maxVO<sub>2</sub> (maximum oxygen consumption), a measure of exercise tolerance.



### ***Future Development Plans***

We are also managing a discovery and development program aiming to produce small molecule drugs that mimic the enzyme glutathione peroxidase, or GPx. We believe that GPx is one of the only enzymes in the human body that reduces oxidized lipids. By recreating the activity of this enzyme in a small molecule we may be able to treat diseases in which oxidized lipids are thought to play a significant role.

In January 2008, we announced the signing of an agreement with privately-held Novel Therapeutic Technologies Inc. to provide us with formulation work for a topical cream formulation of one of our GPx mimetics, SYI-2074, for the treatment of psoriasis. This work will be performed at a major clinical institution in Israel. SYI-2074 may have potential in the treatment of plaque psoriasis because SYI-2074 can block TNF- $\alpha$  activated expression of cell adhesion molecules, I-CAM and V-CAM, which may be essential for cellular migration. TNF- $\alpha$  is an established target for drug development in psoriasis and other autoimmune diseases. We have identified sites in Israel to perform a planned Phase 2 clinical trial beginning in the third quarter of 2008, pending approval from the Ministry of Health in Israel.

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. This study has already dosed its first patient, but as observers of the trial without responsibility for its performance, we cannot project the date or likelihood of this trial's completion.

We continue to evaluate potential pre-clinical and clinical studies in other therapeutic indications in which alagebrium and SYI-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, and glaucoma; and other diabetic complications, including renal diseases.

Since our inception in October 1986, we have devoted substantially all of our resources to research, drug discovery and development programs. To date, we have not generated any revenues from the sale of products and do not expect to generate any such revenues for a number of years, if at all. We have incurred an accumulated deficit of \$273,025,172 as of June 30, 2008, and expect to incur net losses, potentially greater than losses in prior years, for a number of years.

We have financed our operations through proceeds from public offerings of common stock, private placements of common and preferred equity and debt securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by our collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of our New Jersey State net operating loss carryforwards and research and development tax credit carryforwards.

Our business is subject to significant risks including, but not limited to, (1) our ability to obtain and maintain sufficient financial resources to conduct and continue enrollment in our clinical studies of SYI-2074 and alagebrium, (2) the risks associated with our development of a diagnostic kit, (3) the risks inherent in our research and development efforts, including clinical trials and the length, expense and uncertainty of the process of seeking regulatory approvals for our product candidates, (4) uncertainties associated with obtaining and enforcing our patents and with the patent rights of others, (5) uncertainties regarding government healthcare reforms and product pricing and reimbursement levels, (6) technological change and competition, (7) manufacturing uncertainties, and (8) dependence on collaborative partners and other third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. These reasons include the possibilities that the products will prove ineffective or unsafe during preclinical or clinical studies, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties, or that we will be unable to develop

and commercialize our proposed diagnostic kit. These risks and others are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 that we filed with the Securities and Exchange Commission on March 31, 2008 under the heading “Item 1A - Risk Factors.”

## Results of Operations

### Three Months ended June 30, 2008 and 2007

#### *License and Other Revenue*

Total license and other revenue for the three months ended June 30, 2008 and 2007, was \$52,000 and \$50,000, respectively, inclusive of \$50,000 received from a licensing agreement with Avon Products, Inc., which we entered into in June 2005.

#### *Other Income/Expense*

Investment income for the three months ended June 30, 2008 and 2007, was \$75,000 and \$27,000, respectively. Income was derived from interest earned on cash and cash equivalents and short-term investments. The increase in investment income was due to higher cash balances as a result of our preferred stock financing in July 2007.

Our interest expense was \$2,000 for the three months ended June 30, 2008, compared to \$3,230,000 for the period ended June 30, 2007. The decrease was the result of interest expense relating to our private debt financing completed in January 2007.

We recognized \$400,000 of other expense in June 2008, as a result of the write-off of our investment in Oxis International common stock.

#### *Operating Expenses*

Total operating expenses were \$2,774,000 for the three months ended June 30, 2008, compared to \$2,345,000 for the three months ended June 30, 2007, and consisted primarily of research and development expenses and general and administrative expenses in 2008 and 2007. Research and development expenses normally include third-party expenses associated with pre-clinical, clinical, and diagnostic studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses, and facility expenses.

#### *Research and Development*

Research and development expenses were \$1,670,000 for the three months ended June 30, 2008, as compared to \$1,653,000 for the same period in 2007, an increase of \$17,000, or 1%. This increase was attributed to higher research study costs and personnel-related costs, partially offset by \$800,000 of lower license fees.

For the three months ended June 30, 2008, personnel-related research and development costs totaled \$227,000, compared to \$54,000 for the same period in 2007, an increase of \$173,000, or 320%. This increase was primarily driven by the hiring of additional personnel within the Clinical, Pre-Clinical, and Diagnostic departments.

Outside of license fees, research study costs were higher for the three months ended June 30, 2008 as compared to 2007. For the three months ended June 30, 2008, the total amount spent on research study costs was \$1,415,000, inclusive of \$778,000 of clinical trial costs, \$298,000 of third party consulting costs, \$117,000 of manufacturing and storage expenses, \$80,000 of patent expenses, \$53,000 of product liability insurance, \$44,000 of regulatory costs, and \$35,000 of sponsored research and research funding expenses. For the same period in 2007, we incurred \$1,587,000 of research study costs, inclusive of \$800,000 of license fees, \$534,000 of clinical trial expenses, \$121,000 of third party consulting expenses, \$85,000 of patent expenses, and \$36,000 of product liability insurance.



### *General and Administrative*

General and administrative expenses were \$962,000 for the three months ended June 30, 2008, as compared to \$692,000 for the same period in 2007, for an increase of \$270,000, or 39%. The increase in 2008 was primarily related to higher personnel-related expenses by \$234,000 and an increase in investor relations costs of \$81,000, partially offset by lower administrative and consulting expenses.

### *Selling and Marketing*

In the second quarter of 2008, we began commercial planning efforts surrounding our haptoglobin diagnostic kits. Selling and marketing expenses for the three months ended June 30, 2008, were \$142,000, inclusive of \$89,000 of personnel-related expenses, and \$28,000 of medical education expenses. There were no such expenses during the comparable period in 2007.

### *Net Loss*

We had net losses of \$3,049,000, and \$5,498,000 in the three months ended June 30, 2008 and 2007, respectively. We had net losses applicable to common stockholders for the three months ended June 30, 2008 and 2007, of \$5,251,000 and \$5,498,000, respectively, inclusive of preferred stock dividends of \$2,202,000 and \$0 for the three months ended June 30, 2008 and 2007, respectively.

### **Six Months ended June 30, 2008 and 2007**

#### *License and Other Revenue*

Total license and other revenue for the six months ended June 30, 2008 and 2007, was \$54,000 and \$50,000, respectively, inclusive of \$50,000 received from a licensing agreement with Avon Products, Inc., which we entered into in June 2005. In 2008, we also received \$2,000 from a royalty agreement with ARUP Laboratories, which was entered into in June 2004.

#### *Other Income/Expense*

Investment income for the six months ended June 30, 2008 and 2007, was \$210,000 and \$63,000, respectively. Income was derived from interest earned on cash and cash equivalents and short-term investments. The increase in investment income was due to higher cash balances as a result of our preferred stock financing in July 2007.

Our interest expense was \$3,000 for the six months ended June 30, 2008, compared to \$5,235,000 for the period ended June 30, 2007. The decrease was the result of interest expense relating to our private debt financing completed in January 2007.

We recognized \$400,000 of other expense in June 2008, as a result of the write-off of our investment in Oxis International common stock.

### *Operating Expenses*

Total operating expenses were \$5,389,000 for the six months ended June 30, 2008, compared to \$4,041,000 for the six months ended June 30, 2007, and consisted primarily of research and development expenses and general and administrative expenses in 2008 and 2007. Research and development expenses normally include third-party expenses associated with pre-clinical, clinical, and diagnostic studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses, and facility expenses.



### *Research and Development*

Research and development expenses were \$3,390,000 for the six months ended June 30, 2008, as compared to \$2,401,000 for the same period in 2007, an increase of \$989,000 or 41%. This increase was attributed to higher personnel-related costs and higher research study costs offset by \$800,000 of lower license fees.

For the six months ended June 30, 2008, personnel-related research and development costs totaled \$453,000, compared to \$156,000 for the same period in 2007, an increase of \$297,000, or 190%. This increase was primarily driven by the hiring of additional personnel within the Clinical, Pre-Clinical, and Diagnostic departments.

For the six months ended June 30, 2008, research study costs totaled \$2,876,000, compared to \$2,205,000 for the same period in 2007, an increase of \$671,000, or 30%. In 2008, research study costs included \$1,456,000 of clinical trial costs, \$404,000 of manufacturing and storage expenses, \$394,000 of third party consulting costs, \$218,000 of sponsored research and research funding, \$215,000 of patent expense, \$75,000 of product liability insurance, \$52,000 of regulatory costs, and \$40,000 of license fees. Comparatively, in 2007, research study costs consisted of \$811,000 of clinical trial costs, \$800,000 of license fees, \$366,000 of patent expense, and \$180,000 of third party consulting costs.

### *General and Administrative*

General and administrative expenses were \$1,857,000 for the six months ended June 30, 2008, as compared to \$1,640,000 for the same period in 2007, for an increase of \$217,000, or 13%. The increase in 2008 was primarily related to higher personnel-related expenses by \$296,000, an increase in investor relations costs of \$89,000, higher franchise taxes of \$56,000, higher repairs and maintenance costs by \$37,000, and an increase in fees relating to Sarbanes-Oxley compliance of \$31,000. These increases were partially offset by lower administrative and consulting expenses of \$120,000 and \$78,000, respectively, as well as lower legal costs by \$41,000, facility costs by \$26,000, and insurance costs by \$25,000.

### *Selling and Marketing*

In the second quarter of 2008, we began commercial planning surrounding our haptoglobin diagnostic kits. Selling and marketing expenses for the six months ended June 30, 2008, were \$142,000, inclusive of \$89,000 of personnel-related expenses, and \$28,000 of medical education related expenses. There were no such expenses during the comparable period in 2007.

### *Net Loss*

We had net losses of \$5,528,000 and \$9,164,000 in the six months ended June 30, 2008 and 2007, respectively. We had net losses applicable to common stockholders for the six months ended June 30, 2008 and 2007, of \$9,933,000 and \$9,164,000, inclusive of preferred stock dividends of \$4,404,000 and \$0 for the six months ended June 30, 2008 and 2007, respectively.

### **Liquidity and Capital Resources**

We had cash and cash equivalents at June 30, 2008, of \$10,098,000, compared to \$15,646,000 at December 31, 2007. The decrease is primarily attributable to \$5,540,000 of net cash used in operating activities. At June 30, 2008, we had working capital of \$7,394,000.

We do not have any approved products and currently derive cash from sales of our securities, sales of our New Jersey state net operating loss carryforwards and interest on cash and cash equivalents. We are highly susceptible to conditions in the global financial markets and in the pharmaceutical industry. Positive and negative movement in

those markets will continue to pose opportunities and challenges to us. Previous downturns in the market valuations of biotechnology companies and of the equity markets more generally have restricted our ability to raise additional capital on favorable terms.



In August 2007, we entered into a share purchase agreement for the purchase of \$500,000 of newly issued shares of Oxis International Limited (“Oxis”) common stock at a premium over the then current market price. It is our understanding that Oxis held some value as of June 30, 2008, but it is our position that we will not recoup our investment in Oxis. On June 19, 2008, Oxis received a Notice of Disposition of Collateral from certain debenture holders. Our investment in Oxis was written off as of June 30, 2008. This security was restricted for sale until the early part of February 2009.

On July 25, 2007, institutional investors purchased \$25,000,000 of newly created Series B Preferred Stock and warrants to purchase shares of Series B Preferred Stock. At the closing of the financing, we issued 10,000,000 shares of our Series B Preferred Stock and warrants to purchase 2,500,000 shares of Series B Preferred Stock. The Series B Preferred Stock accrues dividends at a rate of 8% per year on the original issue price of \$2.50 per share for a period of five years from the date on which the shares of Series B Preferred Stock were issued. The warrants are exercisable for a period of five years commencing on July 25, 2007 at an exercise price of \$2.50 per share.

We expect to utilize cash and cash equivalents to fund our operating activities, including continued development of SYI-2074 and alagebrium and development of a diagnostic kit. Based on our projected spending levels, the remaining cost of our current trials and the development of such a diagnostic kit, which are expected to continue into 2009, exclusive of our internal costs, is estimated to be \$4,000,000. The cost includes executed, but cancelable, agreements with outside organizations. The amount and timing of our future capital requirements will depend on numerous factors, including the progress and timing of our research and development programs, the number and characteristics of product candidates that we pursue, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any. We expect to have sufficient cash and cash equivalents to satisfy our working capital requirements into the first quarter of 2009. The Company may be required to pay accrued dividends on its preferred stock, totaling \$1,875,000 as of June 30 in cash, rather than in stock, at the request of the Preferred Stock holders. While this would reduce the Company’s liquidity, the Company believes that its ability to adjust spending levels in a number of programs will permit its continued operations into the first quarter of 2009, regardless of the form of dividend payment elected by the holders of our Series B preferred stock.

We will require, over the longer term, substantial additional funding to continue development and commercialization of SYI-2074, alagebrium and our other product candidates and to continue our operations. We believe that satisfying these capital requirements over the long term will require successful commercialization of our product candidates. However, it is uncertain whether any product candidates will be approved or will be commercially successful.

Selling securities to satisfy our capital requirements may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles. There can be no assurances that such funding will be available at all or on terms acceptable to us. If funds are obtained through arrangements with collaborative partners or others, we may be required to relinquish rights to our technologies or product candidates and alter our plans for the development of our product candidates. If we are unable to obtain the necessary funding, we may be forced to cease operations. There can be no assurance that the products or technologies that we are currently developing will result in revenues to us or any meaningful return on investment to our stockholders.

### **Critical Accounting Policies**

As of the date of the filing of this quarterly report, we believe there have been no material changes to our critical accounting policies and estimates during the six months ended June 30, 2008.

### ***Forward-Looking Statements and Cautionary Statements***

Statements in this Form 10-Q that are not statements or descriptions of historical facts are "forward-looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended, 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" 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. 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 Form 10-Q.

The forward-looking statements represent our judgments and expectations as of the date of this Report. We assume no obligation to update any such forward-looking statements.

### **ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.**

Our exposure to market risk for changes in interest rates relates primarily to our investment in marketable securities. We do not use derivative financial instruments in our investments. All of our investments reside in money market accounts. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this Item.

### **ITEM 4T. Controls and Procedures.**

a) *Evaluation of Disclosure Controls and Procedures.* Our management has evaluated, with the participation of our Chief Executive Officer and our Director of Finance and Administration, Principal Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, the Chief Executive Officer and the Director of Finance and Administration, Principal Financial Officer have concluded that as of the end of such fiscal quarter, our current disclosure controls and procedures as of that date were effective to ensure that information required to be disclosed in the reports filed under the Exchange Act was recorded, processed, summarized and reported on an accurate and timely basis.

b) *Changes in Internal Control Over Financial Reporting.* There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1A. Risk Factors.

#### Risks Related To Our Business

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

As of June 30, 2008, we had cash and cash equivalents on hand of \$10,097,972. 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 programs, 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. As of June 30, 2008, the amount of the accrued dividend on our outstanding shares of Series B preferred stock was \$1,875,000. Accordingly, 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.

### ITEM 6. Exhibits.

#### Exhibits

See the "Exhibit Index" on page 21 for exhibits required to be filed with this Quarterly Report on Form 10-Q.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 14, 2008

**SYNVISTA THERAPEUTICS, INC.**

By: /s/ Noah Berkowitz, M.D., Ph.D.

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Noah Berkowitz, M.D., Ph.D.  
President and Chief Executive Officer  
(principal executive officer)

By: /s/ Wendy A. Milici

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Wendy A. Milici  
(principal financial officer)

By: /s/ Alex D'Amico

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Alex D'Amico  
(principal accounting officer)

**EXHIBIT INDEX**

Exhibit No.	Description of Exhibit
3.1	Restated Certificate of Incorporation, as amended, of Synvista Therapeutics, Inc.
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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