

Synvista Therapeutics, Inc.  
Form 10-Q  
November 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 September 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 November 1, 2008, 2,586,326 shares of the registrant's Common Stock were outstanding.

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The Exhibit Index is on page 28

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**SYNVISTA THERAPEUTICS, INC.**

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***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.

***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 Article 8 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 nine months ended September 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.

Our condensed consolidated financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have not made any adjustments to the condensed consolidated financial statements as a result of the outcome of the uncertainty described above. Accordingly, the value of the Company in liquidation may be different from the amounts set forth in our condensed consolidated financial statements.

Our ability to continue operations will depend on our ability to continue to raise capital immediately in order to fund the operation of our business and the development and commercialization of our products. Failure to raise additional capital may result in substantial adverse circumstances, including delisting of our common stock from the American Stock Exchange, which could substantially decrease the liquidity and value of such shares, or ultimately result in our liquidation.

***Note regarding Rights of Holders of Series B Preferred Stock***

The holders of our 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 preferential payment in the event of a liquidation of the Company, which means that holders of the Series B preferred stock would 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 receive no value for their shares upon such a sale or liquidation. Given these rights of the Preferred Stock, we cannot assure you

that the proceeds from any sale or liquidation would be sufficient to provide for any value whatsoever to be paid to our common stockholders.

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. As of September 30, 2008, the amount of the accrued dividend on our outstanding shares of Series B preferred stock was \$2,375,000. If the holders of Series B preferred stock were to elect to require the payment of these accrued dividends in cash, this would severely reduce the Company's liquidity, and could force the Company to promptly cease its operations or to curtail them drastically in order to make the required payments. We cannot assure you as to when, if ever, the holders of Preferred Stock will demand the payment of these dividends in cash, nor can we assure you that we will have adequate cash to make such payments if and when the demand is made.

Holders of the Series B Preferred Stock also have significant rights with respect to specific 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 take the following actions, among others:

- incur debt in excess of \$2,000,000;
- authorize the sale of securities at a price per share less than the price per share that the Series B preferred stock was sold under the Series B Purchase Agreement;
- create any new classes or series of stock with rights senior to the common stock;
- 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 capital stock of the Company other than the Series B preferred stock;
- purchase or redeem any securities;
- liquidate, dissolve or wind-up;
- merge with another entity;
- sell or dispose of any of our assets, including the sale or license of intellectual property;
- amend any portion of our Certificate of Incorporation or Bylaws;
- 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, as amended; 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 the best interests of the Company. Our failure to obtain approval for such actions could result in a material adverse effect on our business and results of operations.

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

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

	September 30, 2008	December 31, 2007 (Note 1)
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 7,957,321	\$ 15,646,225
Other current assets	438,883	234,338
Total current assets	8,396,204	15,880,563
Property and equipment, net	25,132	17,096
Other assets	325,520	807,646
Total assets	\$ 8,746,856	\$ 16,705,305
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 761,052	\$ 1,503,355
Accrued expenses	1,033,265	458,731
Preferred stock dividends payable	2,375,000	875,000
Total current liabilities	4,169,317	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 September 30, 2008 and December 31, 2007	100,000	100,000
Common stock, \$.01 par value; 150,000,000 shares authorized at September 30, 2008 and 300,000,000 shares authorized at December 31, 2007; 2,586,326 shares issued and outstanding at September 30, 2008 and 2,586,377 issued and outstanding at December 31, 2007	25,863	25,864
Additional paid-in capital	282,551,470	276,834,875
Accumulated deficit	(278,099,794)	(263,092,520)
Total stockholders' equity	4,577,539	13,868,219

Total liabilities and stockholders' equity	\$	8,746,856	\$	16,705,305
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The accompanying notes are an integral part of these unaudited financial statements.



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
License and other revenue	\$ 772	\$ 1,066	\$ 54,729	\$ 51,066
Operating expenses:				
Research and development	1,717,984	2,264,503	5,107,974	4,665,580
General and administrative	990,082	894,469	2,847,444	2,534,847
Selling and marketing	220,995	-	362,853	-
Total operating expenses	2,929,061	3,158,972	8,318,271	7,200,427
Loss from operations	(2,928,289)	(3,157,906)	(8,263,542)	(7,149,361)
Investment income	52,969	194,692	262,734	257,738
Interest expense	(2,224)	(1,402,515)	(5,232)	(6,637,831)
Other income/(expense)	5,000	-	(395,000)	-
Net loss	(2,872,544)	(4,365,729)	(8,401,040)	(13,529,454)
Preferred stock dividends - Series B	500,000	375,000	1,500,000	375,000
Deemed dividends to Series B preferred stockholders on beneficial conversion feature	1,702,078	1,244,993	5,106,234	1,244,993
Net loss applicable to common shares	\$ (5,074,622)	\$ (5,985,722)	\$ (15,007,274)	\$ (15,149,447)
Net loss per common share:				
Basic and diluted	\$ (1.96)	\$ (2.31)	\$ (5.80)	\$ (5.86)
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 financial statements.

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

	Nine months ended September 30, 2008						Total Stockholders' Equity
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	
	Shares	Amount	Shares	Amount			
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	—	—	—	—		(8,401,040)	(8,401,040)
Fractional shares	—	—	(51)	(1)	1	—	—
Deemed dividends to Series B preferred stockholders on beneficial conversion feature	—	—	—	—	5,106,234	(5,106,234)	—
Series B preferred stock dividend payable	—	—	—	—		(1,500,000)	(1,500,000)
Stock-based compensation	—	—	—	—	594,002	—	594,002
Options issued for consulting services	—	—	—	—	4,014	—	4,014
Compensation costs related to restricted stock	—	—	—	—	12,344	—	12,344
Balances, September 30, 2008	10,000,000	\$ 100,000	2,586,326	\$ 25,863	\$ 282,551,470	\$ (278,099,794)	\$ 4,577,539

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
Cash flows from operating activities:		
Net loss	\$ (8,401,040)	\$ \$(13,529,454)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	594,002	169,180
Options issued for consulting services	4,014	2,732
Compensation costs related to restricted stock	12,344	58,741
Non-cash interest expense	—	164,384
Amortization of debt discount	—	6,000,000
Amortization of deferred financing costs	—	466,413
Depreciation and amortization	9,758	7,567
Write-off of investment in Oxis stock	400,000	—
Changes in operating assets and liabilities:		
Other current assets	(204,545)	(36,386)
Other assets	82,126	66,867
Accounts payable and accrued expenses	(167,769)	331,391
Net cash used in operating activities	(7,671,110)	(6,298,565)
Cash flows from investing activities:		
Capital expenditures	(17,794)	(13,548)
Payments for securities purchased under the Oxis agreement	—	(400,000)
Net cash used in investing activities	(17,794)	(413,548)
Cash flows from financing activities:		
Proceeds from debt financing	—	6,000,000
Proceeds from issuance of preferred stock	—	18,835,616
Payments for private placement costs	—	(1,837,954)
Payments for debt financing costs	—	(466,413)
Net cash provided by financing activities	—	22,531,249
Net increase/(decrease) in cash and cash equivalents	(7,688,904)	15,819,136
Cash and cash equivalents, beginning of period	15,646,225	1,478,780
Cash and cash equivalents, end of period	\$ 7,957,321	\$ 17,297,916
Supplemental disclosures of non-cash investing and financing activities:		
Deemed dividends to Series B preferred stockholders on beneficial conversion	\$ 5,106,234	\$ 1,244,993
Series B stock dividends payable	\$ 1,500,000	\$ 375,000
Warrants issued and embedded conversion feature associated with debt financing	\$ —	\$ 6,000,000
Beneficial conversion feature on convertible Series B preferred stock	\$ —	\$ 13,616,625
Preferred stock issued pursuant to conversion of debt and accrued interest	\$ —	\$ 6,164,384
Fair value of warrants issued to placement agents for private placement allocable to private placement	\$ —	\$ 1,619,256

The accompanying notes are an integral part of these unaudited 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 Article 8 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 nine months ended September 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.

**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 \$278,099,794 as of September 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 September 30, 2008, the Company had working capital of \$4,226,887, including \$7,957,321 of cash and cash equivalents. The Company's net cash used in operating activities for the nine months ended September 30, 2008 was \$7,671,110 and for the year ended December 31, 2007 was \$7,946,700.

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 is 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. Based on the projected spending levels for the Company, it does not currently have adequate cash and cash equivalents to complete its clinical trials and/or the development of its diagnostic test kits and, therefore, urgently requires additional funding in order to continue operations. The Company is actively pursuing fund-raising possibilities through the sale of its equity securities. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated levels, Synvista will not have the ability to continue as a going concern after the first quarter of 2009. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities, we will be required to significantly reduce or curtail our research and product development activities, to sell or out-license our assets and may be required to curtail our other operations significantly or cease operations altogether. We have the intent and ability to quickly and significantly reduce the cash expenditure rate, if necessary, as we have limited fixed commitments, which include executed, but cancelable, agreements with outside organizations.

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 \$2,375,000 as of September 30, 2008, in cash rather than in shares of its Series B preferred stock. If the holders of Series B preferred stock were to elect to require the payment of these accrued dividends in cash, this would severely reduce the Company's liquidity, and could force the Company to promptly cease its operations or to curtail them drastically in order to make the required payments. The Company believes that its ability to adjust spending levels quickly 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 will require substantial new funding in early 2009 in order to continue the 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. 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.

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:

	Nine months ended September 30	
	2008	2007
Expected volatility	112%	148%
Dividend yield	—	—
Expected term (in years)	6.57	6.12
Risk-free interest rate	4.25%	4.88%

The weighted average grant date fair value of options granted during the first nine months of 2008 was \$1.58 as determined by the Black-Scholes option valuation model using the assumptions listed in the chart above.

Options granted to consultants and other non-employees are accounted for in accordance with Emerging Issues 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. For the nine-months ended September 30, 2008 and September 30, 2007, the Company recognized research and development consulting expenses of \$4,014 and \$2,732, respectively.

For the three and nine month periods ended September 30, 2008, the Company recognized share-based employee compensation cost of \$177,037 and \$594,002, respectively and for the three and nine month periods ended September 30, 2007, the Company recognized share-based employee compensation cost of approximately \$84,618 and \$169,180 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 September 30, 2008, the total compensation cost related to non-vested option awards not yet recognized is \$1,195,898. The weighted-average period over which this cost is expected to be recognized is approximately 2.2 years.



A summary of the status of the Company's stock options outstanding as of September 30, 2008 and changes during the nine 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	76,000	1.88		
Exercised	-			
Cancelled	(25,265)	108.20		
Outstanding at September 30, 2008	927,441	12.33	8.17	\$ —
Options exercisable at September 30, 2008	334,091	29.30	6.55	\$ —

#### *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 nine month period ended September 30, 2008, and 2,148 shares vested during the period. The total fair value of shares vested during the period was \$16,110.

There were 19,200 shares of restricted stock granted during the year ended December 31, 2006, of which 6,400 were forfeited and 8,520 vested in prior periods. Of the 10,668 total shares of restricted stock that vested, the vesting of 4,280 shares had been accelerated by the Board of Directors. The total fair value of all shares vested is \$80,010.

The Company recognized compensation cost of \$7,008 and \$12,344 for the three and nine months ended September 30, 2008, respectively, which was recorded as general and administrative expense in the condensed consolidated statement of operations.

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

Nonvested Shares	Shares	Weighted average grant date fair value
Nonvested at January 1, 2008	4,280	\$ 7.50
Granted	—	—
Vested	2,148	7.50
Forfeited	—	—
Nonvested at September 30, 2008	2,132	7.50

As of September 30, 2008, there was \$4,279 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 0.80 years.

#### 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 September 30, 2008 and 2007, was 14,412,421 and 13,770,766 shares, respectively.

	September 30, 2008	2007
Preferred Stock	10,000,000	10,000,000
Restricted Stock	12,800	12,800
Warrants	3,530,716	3,551,640
Options	868,905	206,326
Potentially dilutive shares excluded from calculation	14,412,421	13,770,766

#### 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 November 1, 2008, the holders of the Series B Preferred Stock have not designated their dividends as payable either in cash or preferred stock.

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

### 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 primarily focused on fund-raising activities and exploring strategic relationships to support our development programs. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities or the out-license of our technology, or if the level of cash and cash equivalents falls below anticipated levels, we may be required to significantly curtail the research, product development, preclinical testing and clinical trials of our product candidates or cease our operations altogether.

We are developing a diagnostic test to identify the subset of patients with diabetes who are at increased risk for cardiovascular disease. The technology underlying this test 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 haptoglobin, which is a protein found in the blood. This diagnostic test may be useful in determining a patient's risk for adverse cardiovascular events. It may also be useful to identify a subset of diabetic patients in whom daily use of vitamin E could potentially reduce the rate of heart attack. We are evaluating arrangements that would allow our technology or intellectual property to be used by commercial enterprises for the aforementioned purposes and would be further developed and validated by a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments, or CLIA, and offered as a testing service. Further, we are developing a kit for use in determining cardiovascular disease risk in diabetic patients that will be submitted to the U.S. Food and Drug Administration for premarket clearance under the 510(k) pathway. Any successful commercialization of such a kit, if cleared, 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 was developed by MicroCoat GmbH of Bernried, Germany, using our proprietary reagents, and 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, which was 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.

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SYI-2074 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. It had completed more than 50% enrollment at the end of the third quarter of 2008. 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 75% 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 which began in the third quarter of 2008.

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 formation 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 \$278,099,794 as of September 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 continue as a going concern and 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" and in this report under the heading "Part II - Item 1A - Risk Factors."

## **Results of Operations**

### **Three Months ended September 30, 2008 and 2007**

#### *License and Other Revenue*

Total license and other revenue for the three months ended September 30, 2008 and 2007, was \$1,000 and \$1,000, respectively, attributable to royalty revenue received from ARUP Laboratories as a result of a royalty agreement entered into in September 2004.

#### *Other Income/Expense*

Investment income for the three months ended September 30, 2008 and 2007, was \$53,000 and \$195,000, respectively. Income was derived from interest earned on cash and cash equivalents and short-term investments. The decrease in investment income was due to lower cash balances during the current year. In 2007, there was a higher cash balance as a result of our preferred stock financing in July 2007.

Our interest expense was \$2,000 for the three months ended September 30, 2008, compared to \$1,403,000 for the period ended September 30, 2007. The decrease was the result of interest expense relating to our private debt financing completed in January 2007.

#### *Operating Expenses*

Total operating expenses were \$2,929,000 for the three months ended September 30, 2008, compared to \$3,159,000 for the three months ended September 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.

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### *Research and Development*

Research and development expenses were \$1,718,000 for the three months ended September 30, 2008, as compared to \$2,265,000 for the same period in 2007, a decrease of \$547,000, or 24%. This decrease was due to lower research study costs resulting from the discontinuation of SYI-2074 Trials 201 and 203 in June 2008. In addition, research study costs were higher in 2007 due to the increased spending on clinical trials after the July 2007 financing. The lower study costs were partially offset by higher personnel-related costs.

For the three months ended September 30, 2008, personnel-related research and development costs totaled \$226,000, compared to \$78,000 for the same period in 2007, an increase of \$148,000, or 190%. This increase was primarily driven by the hiring of additional personnel within the Clinical, Pre-Clinical, and Diagnostic departments.

For the three months ended September 30, 2008, the total amount spent on research study costs was \$1,467,000, inclusive of \$858,000 of clinical trial costs, \$195,000 of manufacturing and storage expenses, \$119,000 of third party consulting costs, \$111,000 of patent expenses, \$100,000 of license fees, \$49,000 of product liability insurance, and \$11,000 of regulatory costs. For the same period in 2007, we incurred \$1,794,000 of clinical trial expenses, \$181,000 of third party consulting expenses, \$157,000 of patent expenses, and \$41,000 of product liability insurance.

### *General and Administrative*

General and administrative expenses were \$990,000 for the three months ended September 30, 2008, as compared to \$894,000 for the same period in 2007, for an increase of \$96,000 or 11%. The increase in 2008 was related to the following: higher Board of Directors expense of \$37,000 due to the addition of a new Board member, an increase in administrative expenses of \$37,000, an increase in investor relations costs of \$31,000, higher legal costs of \$27,000, and an increase in repairs and maintenance expense of \$13,000. These increases were partially offset by lower consulting expenses of \$24,000 and lower facilities costs of \$17,000.

### *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 September 30, 2008, were \$221,000, inclusive of \$62,000 of medical education expenses, \$59,000 of personnel-related expenses, \$38,000 of market research, \$20,000 of expenses relating to conferences and tradeshow, and \$12,000 of advertising and promotion expenses. There were no such expenses during the comparable period in 2007.

### *Net Loss*

We had net losses of \$2,873,000, and \$4,366,000 in the three months ended September 30, 2008 and 2007, respectively. We had net losses applicable to common stockholders for the three months ended September 30, 2008 and 2007, of \$5,075,000 and \$5,986,000, respectively, inclusive of preferred stock dividends and deemed dividends to Series B preferred stockholders of \$2,202,000 and \$1,620,000 for the three months ended September 30, 2008 and 2007, respectively.

### **Nine Months ended September 30, 2008 and 2007**

#### *License and Other Revenue*

Total license and other revenue for the nine months ended September 30, 2008 and 2007, was \$55,000 and \$51,000, respectively, inclusive of \$50,000 received from a licensing agreement with Avon Products, Inc., which we entered into in September 2005. In 2008, we also received \$3,000 from a royalty agreement with ARUP Laboratories, which

was entered into in September 2004. We received \$1,000 in royalty payments from ARUP Laboratories in 2007.

*Other Income/Expense*

Investment income for the nine months ended September 30, 2008 and 2007, was \$263,000 and \$258,000, respectively. Income was derived from interest earned on cash and cash equivalents and short-term investments. There were slightly higher cash balances during the current year as a result of our preferred stock financing in July 2007.

Our interest expense was \$5,000 for the nine months ended September 30, 2008, compared to \$6,638,000 for the period ended September 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 \$8,318,000 for the nine months ended September 30, 2008, compared to \$7,200,000 for the nine months ended September 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 \$5,108,000 for the nine months ended September 30, 2008, as compared to \$4,666,000 for the same period in 2007, an increase of \$442,000 or 9%. This increase was attributed to higher personnel-related costs, partially offset by slightly lower research study costs. Research study costs were higher in 2007 due to the increased spending on clinical trials after the July 2007 financing. In addition, we discontinued SYI-2074 Trials 201 and 203 in June 2008, resulting in lower costs for the 2008 period.

For the nine months ended September 30, 2008, personnel-related research and development costs totaled \$679,000 compared to \$234,000 for the same period in 2007, an increase of \$445,000, or 190%. This increase was primarily driven by the hiring of additional personnel within the Clinical, Pre-Clinical, and Diagnostic departments.

For the nine months ended September 30, 2008, research study costs totaled \$4,343,000, compared to \$4,378,000 for the same period in 2007, a decrease of \$35,000, or 1%. In 2008, research study costs included \$2,314,000 of clinical trial costs, \$599,000 of manufacturing and storage expenses, \$513,000 of third party consulting costs, \$326,000 of patent expenses, \$140,000 of license fees, \$124,000 of product liability insurance, \$118,000 of research funding costs, \$95,000 of sponsored research costs, and \$63,000 of regulatory costs. Comparatively, in 2007, research study costs consisted of \$2,604,000 of clinical trial costs, \$800,000 of license fees, \$524,000 of patent expenses, \$361,000 of third party consulting costs, and \$104,000 of product liability insurance expenses.

*General and Administrative*

General and administrative expenses were \$2,847,000 for the nine months ended September 30, 2008, as compared to \$2,535,000 for the same period in 2007, for an increase of \$312,000, or 12%. The increase in 2008 was related to the following: higher personnel-related expenses of \$289,000, an increase in investor relations costs of \$121,000, higher franchise taxes of \$64,000, higher repairs and maintenance expense of \$40,000, and higher Board of Directors expense of \$38,000 due to the addition of a new Board member. These increases were partially offset by lower consulting and administrative expenses of \$102,000 and \$83,000, respectively, as well as lower facility costs of \$41,000 and lower insurance costs of \$17,000.



### *Selling and Marketing*

In the second quarter of 2008, we began commercial planning surrounding our haptoglobin diagnostic kits. Selling and marketing expenses for the nine months ended September 30, 2008, were \$363,000, inclusive of \$148,000 of personnel-related expenses, \$90,000 of medical education related expenses, \$38,000 of market research, \$33,000 of conferences and tradeshow, and \$12,000 of advertising and promotion. There were no such expenses during the comparable period in 2007.

### *Net Loss*

We had net losses of \$8,401,000 and \$13,529,000 in the nine months ended September 30, 2008 and 2007, respectively. We had net losses applicable to common stockholders for the nine months ended September 30, 2008 and 2007, of \$15,007,000 and \$15,149,000, inclusive of preferred stock dividends and deemed dividends to Series B preferred stockholders of \$6,606,000 and \$1,620,000 for the nine months ended September 30, 2008 and 2007, respectively.

### **Liquidity and Capital Resources**

We had cash and cash equivalents at September 30, 2008, of \$7,957,000, compared to \$15,646,000 at December 31, 2007. The decrease is primarily attributable to \$7,671,000 of net cash used in operating activities. At September 30, 2008, we had working capital of \$4,227,000.

We do not have any approved products and currently derive cash from sales of our securities 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.

We expect to utilize cash and cash equivalents to fund our operating activities, including continued development of SYI-2074, alagebrium and development of our diagnostic test kit. Based on the projected spending levels for the Company, we do not currently have adequate cash and cash equivalents to complete our clinical trials and/or the development of our diagnostic test kits and, therefore, will require additional funding urgently in order to continue operations. The Company is actively pursuing fund-raising possibilities through the sale of its equity securities. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated levels, we will not have the ability to continue as a going concern after the first quarter of 2009. As a result, the Company will continue to monitor its liquidity position and the status of its diagnostic development and clinical trials. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities, we will be required to significantly reduce or curtail our research and product development activities, to sell or out-license our assets, and may be required to curtail our other operations significantly. We have the intent and ability to quickly and significantly reduce the cash expenditure rate, if necessary, as we have limited fixed commitments, which include executed, but cancelable, agreements with outside organizations.

We may be required to pay accrued dividends on our preferred stock, totaling \$2,375,000 as of September 30, 2008 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 quickly 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 investors.

We will require substantial new funding in early 2009 in order to continue the development and commercialization of its product candidates and to continue our operations. The Company believes that satisfying these capital requirements over the long term will require successful commercialization of our product candidates and/or our diagnostic test kits. However, it is uncertain whether any of our products or diagnostic test kits will be approved or will be commercially successful. The amount and timing of the Company's future capital requirements will depend on numerous factors, including the progress of our research and development programs, the exercise by the holders of the Series B preferred stock of their right to receive accrued dividends in the form of cash, 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.



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 will require, in the next few months, substantial additional funding to continue our operations, including the development and commercialization of SYI-2074, alagebrium and our other product candidates. In order to continue funding our capital requirements over the longer term, we will require successful commercialization of our product candidates. However, it is uncertain whether any of our 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 nine months ended September 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 September 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

*If we are unable to obtain sufficient additional funding in the next few months, we may be required to significantly curtail the research, product development, preclinical testing and clinical trials of our product candidates or we may be forced to cease operations altogether.*

The Company is urgently continuing to pursue fund-raising possibilities through the sale of its equity securities. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated levels, the Company will not have the ability to continue as a going concern after the first quarter of 2009. We may also sell or out-license some of our assets in order to generate funds to continue to operate our business. We cannot assure you that we will be able to obtain sufficient financing or to sell sufficient assets in a timely manner or at all, nor that any financing or sale of assets will be available to us on reasonable terms.

The amount and timing of our capital requirements depend on numerous factors, including the timing of resuming our research and development programs, if at all, 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.

In addition, the holders of our Series B preferred stock have the right to receive dividends either in the form of cash or additional shares of Series B preferred stock, at the holders' option. As of September 30, 2008, the amount of the accrued dividend on our outstanding shares of Series B preferred stock was \$2,375,000. 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.

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. If funds are obtained through arrangements with collaborative partners or others, we may be required to relinquish rights to our technologies or product candidates.

***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 and an accruing 8% dividend.***

The holders of our 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 preferential payment in the event of a liquidation of the Company, which means that holders of the Series B preferred stock would 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 receive no value for their shares upon such a sale or liquidation. Given these rights of the Preferred Stock, we cannot assure you that the proceeds from any sale or liquidation would be sufficient to provide for any value whatsoever to be paid to our common stockholders.

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. As of September 30, 2008, the amount of the accrued dividend on our outstanding shares of Series B preferred stock was \$2,375,000. If the holders of Series B preferred stock were to elect to require the payment of these accrued dividends in cash, this would severely reduce the Company's liquidity, and could force the Company to promptly cease its operations or to curtail them drastically in order to make the required payments. We cannot assure you as to when, if ever, the holders of Preferred Stock will demand the payment of these dividends in cash, nor can we assure you that we will have adequate cash to make such payments if and when the demand is made.

Holders of the Series B Preferred Stock also have significant rights with respect to specific 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 take the following actions, among others:

- incur debt in excess of \$2,000,000;
- authorize the sale of securities at a price per share less than the price per share that the Series B preferred stock was sold under the Series B Purchase Agreement;
- create any new classes or series of stock with rights senior to the common stock;
- 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 capital stock of the Company other than the Series B preferred stock;
- purchase or redeem any securities;
- liquidate, dissolve or wind-up;
- merge with another entity;
- sell or dispose of any of our assets, including the sale or license of intellectual property;

- amend any portion of our Certificate of Incorporation or Bylaws;

- 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, as amended; 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 the best interests of the Company. Our failure to obtain approval for such actions could result in a material adverse effect on our business and results of operations.

***Synvista's ability to continue as a going concern is dependent on future financing.***

Our condensed consolidated financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have not made any adjustments to the condensed consolidated financial statements as a result of the outcome of the uncertainty described above. Accordingly, the value of the Company in liquidation may be different from the amounts set forth in our condensed consolidated financial statements.

Our ability to continue operations will depend on our ability to continue to raise capital immediately in order to fund the operation of our business and the development and commercialization of our products. Failure to raise additional capital may result in substantial adverse circumstances, including delisting of our common stock from the American Stock Exchange, which could substantially decrease the liquidity and value of such shares, or ultimately result in our liquidation.



**ITEM 4. Submission of Matters to a Vote of Security-Holders**

The Annual Meeting of Stockholders of the Company (the “Meeting”) was held on July 22, 2008. The following matters were voted upon at the Meeting: (i) an amendment to the Company’s 2005 Stock Plan to reserve up to an additional 940,000 shares of common stock for issuance under the Plan; (ii) an amendment to our Amended and Restated Certificate of Incorporation, in order to decrease the authorized number of shares of common stock (iii) election of Dr. Berkowitz as a Class B Director; (iv) and to ratify the appointment of J.H. Cohn LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2008. There were 10 million shares of Series B preferred that were eligible to vote at the Meeting and they are represented in the count below. Each 2 shares of Series B preferred stock is equal to the vote of 1 share of Common Stock.

(i) The number of votes cast for, against and abstaining from the proposal to approve an amendment to our 2005 Stock Plan to reserve up to an additional 940,000 shares of common stock for issuance under the 2005 Stock Plan, were as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
10,795,716	128,948	1,291	2,071,090

(ii) The number of votes cast for, against and abstaining from the proposal to amend the Company’s Amended and Restated Certificate of Incorporation, in order to decrease the authorized number of shares of preferred stock of the Company, were as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
11,947,599	84,091	39,373	2,071,090

(iii) The number of votes cast for and against the proposal to elect Noah Berkowitz, M.D., Ph.D. as a Class B director to hold office until the 2011 annual meeting and until his successor has been duly elected and qualified, were as follows:

Votes For	Votes Against
11,988,333	82,757

(iv) The number of votes cast for, against and abstaining from the ratification the appointment of J.H. Cohn LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2008, were as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
11,956,935	37,849	76,279	2,071,090

**ITEM 6. Exhibits.**

Exhibits

See the “Exhibit Index” on page 28 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.

**SYNVISTA THERAPEUTICS, INC.**

Date: November 14, 2008

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

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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