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

## FORM 10-Q

X	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)	OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly peri	iod ended September 30, 2008
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)	OF THE EXCHANGE ACT OF 1934
	Commission fi	ile number: 000-51476
		OLOGY HOLDINGS, INC. rant as specified in its charter)
	<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	20-2903526 (I.R.S. Employer Identification Number)
	East Setauk	oute 25A, No. 2 et, New York 11733 ncipal executive offices)
	· ·	1) 942-7959 e number, including area code)
		t applicable ormer fiscal year, if changed since last report)
		filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 s), and (2) has been subject to such filing requirements for the past 90 days. Yes $\boxtimes$ No $\square$
Indicate by o	check mark whether the registrant is a large accelerated filer, an accelera	ated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Large accele Non-acceler	erated filer □ ated filer □	Accelerated filer □ Smaller reporting company ⊠
Indicate by o	check mark whether the registrant is a shell company (as defined in Rule	12b-2 of the Exchange Act). Yes □ No ⊠
As of Octob	er 31, 2008, the Company had 27,932,178 shares of common stock, \$0.0	0001 par value, issued and outstanding.
Documents i	incorporated by reference: None	
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## LIXTE BIOTECHNOLOGY HOLDINGS, INC.

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#### Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. For example, statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend," anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, available cash, research results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 10f this Quarterly Report on Form 10-Q.

(a development stage company)

## CONDENSED CONSOLIDATED BALANCE SHEETS

	Sej	September 30, 2008 (Unaudited)		December 31, 2007	
	J)				
ASSETS					
Current assets:					
Cash and cash equivalents	\$	23,784	\$	508,070	
Advances on research and development contract services		50,000		88,180	
Prepaid expenses		25,454		32,117	
Total current assets		99,238		628,367	
Office equipment, net of accumulated depreciation of \$1,640 at September 30, 2008 and \$1,167 at December 31, 2007		269		742	
Total assets	\$	99,507	\$	629,109	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)					
Current liabilities:					
Accounts payable and accrued expenses	\$	101,021	\$	73,741	
Liquidated damages payable under registration rights agreement		74,000		74,000	
Research and development contract liabilities		_		11,725	
Due to stockholder		92,717		92,717	
Total current liabilities		267,738		252,183	
Commitments and contingencies					
Stockholders' equity (deficiency):					
Preferred stock, \$0.0001 par value					
authorized - 10,000,000 shares; issued - none					
Common stock, \$0.0001 par value authorized - 100,000,000 shares;		_		_	
issued and outstanding - 27,932,178 shares at September 30, 2008 and					
27,832,178 shares at December 31, 2007		2,793		2,783	
Additional paid-in capital		3,065,400		2,600,839	
Deficit accumulated during the development stage		(3,236,424)		(2,226,696)	
Total stockholders' equity (deficiency)		(168,231)		376,926	
Total liabilities and stockholders' equity (deficiency)	\$	99,507	\$	629,109	

See accompanying notes to condensed consolidated financial statements.

(a development stage company)

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

Period from

	_	Three Mont Septembe		Nine Months Ended September 30,		August 9, 2005 (Inception) to September 30, 2008	
		2008 2007 2008 2007			(Cumulative)		
Revenues	\$	_ 8	<u> </u>	<u> </u>	\$ —	\$ —	
Costs and expenses:							
General and administrative, including \$254,915 and \$773,356 of stock-based expense during the three months ended September 30, 2008 and 2007, respectively, \$319,709 and \$791,064 of stock-based expense during the nine months ended September 30, 2008 and 2007, respectively, and \$1,307,553 of stock-based expense for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative)		323,514	819,490	541,385	1,018,735	1,993,306	
Depreciation		155	148	473	444	1,640	
Research and development costs, including \$61,493 and \$4,918 of stock-based expense during the three months ended September 30, 2008 and 2007, respectively, \$144,862 and \$35,918 of stock-based expense during the nine months ended September 30, 2008 and 2007, respectively, and \$195,698 of stock based expense for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative)		172,818	102,178	471,051 —	339,769	1,143,106 50,000	
Total costs and expenses		496,487	921,816	1,012,909	1,358,948	3,188,052	
		(496,487)	(921,816)	(1,012,909)	(1,358,948)		
Interest income		342	862	3,181	9,169	25,628	
Liquidated damages under registration rights agreement		_	_	_	_	(74,000	
Net loss	\$	(496,145)	\$ (920,954)	\$ (1,009,728)	\$ (1,349,779)	\$ (3,236,424)	
Net loss per common share -	\$	(0.02) \$	\$ (0.03) \$	\$ (0.04)	\$ (0.05)		
basic and diluted							

(a development stage company)

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

## Period from August 9, 2005 (Inception) to September 30, 2008

	Commo	n Stock	Additional Paid-in	Deficit Accumulated During the Development	Total Stockholders' Equity	
	Shares	Amount	Capital	Stage	(Deficiency)	
Balance, August 9, 2005 (inception)	_	\$	\$	\$ -	s —	
Shares issued to founding stockholder Net loss for the period August 9, 2005 (inception) to December 31, 2005	19,021,786	1,902	(402)		1,500	
	10.021.706			(16,124)	(16,124)	
Balance, December 31, 2005 Shares issued in connection with reverse merger transaction	19,021,786 4,005,177	1,902 401	(402) 62,099	(16,124)	(14,624) 62,500	
Shares issued in private placement, net of offering costs of \$214,517	3,555,220	355	969,017	_	969,372	
Stock-based compensation	_	_	97,400	_	97,400	
Net loss for the year				(562,084)	(562,084)	
Balance, December 31, 2006	26,582,183	2,658	1,128,114	(578,208)	552,564	
Shares issued in private placement, net of offering costs of \$118,680	999,995	100	531,220	_	531,320	
Stock-based compensation	250,000	25	890,669	_	890,694	
Stock-based research and development costs	_	_	50,836	_	50,836	
Net loss for the year				(1,648,488)	(1,648,488)	
Balance, December 31, 2007	27,832,178	2,783	2,600,839	(2,226,696)	376,926	
Stock-based compensation	_	_	319,709	_	319,709	
Stock-based research and development costs	100,000	10	144,852	_	144,862	
Net loss for the nine months ended September 30, 2008				(1,009,728)	(1,009,728)	
Balance, September 30, 2008 (unaudited)	27,932,178	\$ 2,793	\$ 3,065,400	\$ (3,236,424)	\$ (168,231)	

See accompanying notes to condensed consolidated financial statements.

(a development stage company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

Period from August 9,

2005 (Inception) to **Nine Months Ended** September 30, September 30, 2008 2008 2007 (Cumulative) Cash flows from operating activities \$ (1,009,728) \$ (1,349,779) \$ Net loss (3,236,424)Adjustments to reconcile net loss to net cash used in operating activities: 473 444 Depreciation 1,640 Stock-based compensation 319,709 791,064 1,307,553 Stock-based research and development costs 144,862 35,918 195,698 Changes in operating assets and liabilities: (Increase) decrease in -Advances on research and development contract services 38,180 (74,963)(50,000)Prepaid expenses 6,663 (2,463)(25,454)Increase (decrease) in -Accounts payable and accrued expenses 27,280 6,145 101,021 Research and development contract liabilities (11,725)38,335 Liquidated damages payable under registration rights Agreement 74,000 Net cash used in operating activities (1,631,966) (484,286)(555,299)Cash flows from investing activities Purchase of office equipment (1,909)(272)Net cash used in investing activities (272)(1,909)Cash flows from financing activities Proceeds from sale of common stock to consulting firm 250 Proceeds from sale of common stock to founder 1,500 Cash acquired in reverse merger transaction 62,500 Gross proceeds from sale of common stock 1,833,889 Payment of private placement offering costs (333,197)Advances from stockholder 92,717 Net cash provided by financing activities 1,657,659 Net increase (decrease) in cash (484,286)(555,571) 23,784 Cash at beginning of period 508,070 679,640 Cash at end of period 23,784 124,069 23,784

(continued)

(a development stage company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (continued)

	 Nine Mont Septem			Period f August 9, (Incepti to Septem 30, 20	2005 on) ber
	 2008	2007		(Cumula	tive)
Supplemental disclosures of cash flow information:					
Cash paid for -					
Interest	\$ <u> </u>	\$		\$	<u> </u>
Income taxes	\$ 	\$		\$	
Supplemental schedule of non-cash financing activities:					
Receivable from sale of common stock to consulting firm	\$ 	\$	250	\$	250

See accompanying notes to condensed consolidated financial statements.

(a development stage company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Three Months and Nine Months Ended September 30, 2008 and 2007 (Unaudited)

#### 1. Organization and Business Operations

#### Organization

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation ("Lixte"), completed a reverse merger transaction with SRKP 7, Inc. ("SRKP"), a non-trading public "shell" company, whereby Lixte became a wholly-owned subsidiary of SRKP. For financial reporting purposes, Lixte was considered the accounting acquirer in the merger and the merger was accounted for as a reverse merger. Accordingly, the historical financial statements presented herein are those of Lixte and do not include the historical financial results of SRKP. The stockholders' equity section of SRKP has been retroactively restated for all periods presented to reflect the accounting effect of the reverse merger transaction. All costs associated with the reverse merger transaction were expensed as incurred.

Lixte was incorporated in Delaware on August 9, 2005 to capitalize on opportunities to develop low cost, specific and sensitive tests for the early detection of cancers to better estimate prognosis, to monitor treatment response, and to reveal targets for development of more effective treatments.

Unless the context indicates otherwise, SRKP and Lixte are hereinafter referred to as the "Company". On December 7, 2006, the Company amended its Certificate of Incorporation to change its name from SRKP 7, Inc. to Lixte Biotechnology Holdings, Inc. ("Holdings").

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

The condensed consolidated financial statements at September 30, 2008, for the three months and nine months ended September 30, 2008 and 2007, and for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative), are unaudited. In the opinion of management, all adjustments (including normal recurring adjustments) have been made that are necessary to present fairly the financial position of the Company as of September 30, 2008, the results of its operations for the three months and nine months ended September 30, 2008 and 2007, and for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative), and its cash flows for the nine months ended September 30, 2008 and 2007, and for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative). Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The condensed consolidated balance sheet at December 31, 2007 has been derived from the Company's audited financial statements as of that date.

The statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the financial statements and other information included in the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007, as filed with the Securities and Exchange Commission.

The Company is considered a "development stage company" as defined in SFAS No. 7, "Accounting and Reporting by Development Stage Enterprises", as it has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations. The Company has selected December 31 as its fiscal year end.

#### **Operations**

The Company is developing new treatments for several human cancers for which better treatments are urgently needed. The primary focus is on the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM"). The Company, however, has expanded the scope of its drug development program to other cancers of neural tissue (nerve and brain), including medulloblastoma, the most common brain tumor of children, and neuroblastoma, the most common cancer of children, and to several of the most common cancers. The expansion of the scope of the program is based on documentation that each of two distinct types of drugs being developed by the Company inhibits the growth of cell lines of GBM, medulloblastoma, neuroblastoma, and pancreatic cancer in animal models of these diseases and is also active against breast, colon, lung, prostate, ovary, stomach and liver cancer and the major types of leukemias in cell culture. The Company has also recently shown that certain of its compounds are active against fungi that cause life-threatening diseases and other compounds are active against fungi responsible for the majority of skin and nail infections. In addition, the Company found that still other of its compounds affect biochemical pathways such that they may be potentially useful for the treatment of common neurodegenerative diseases such as Alzheimer's disease. These non-cancer applications are under evaluation in collaboration with outside experts.

The research on brain tumors is being conducted with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") under a Cooperative Research and Development Agreement ("CRADA") initiated on March 22, 2006. The research at NINDS is led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang is aided by two senior research technicians supported by the Company under the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the steps needed to gain Food and Drug Administration ("FDA") approval for clinical trials.

Patent applications on work done under the CRADA are jointly owned by NIH and Lixte. NIH co-inventors assign their rights to NIH. Under the CRADA, Lixte is entitled to negotiate an exclusive license from NIH to all claims in these patent applications. The Company and NIH concluded negotiations and executed an exclusive license on seven patent filings effective September 19, 2008. The Company has also filed patent applications for intellectual property owned solely by the Company. These applications concern two series of new anti-cancer agents referred to as the LB-100 series and the LB-200 series. The applications include identification of the structure of molecules, their synthesis, and their anti-cancer, anti-fungal, and potential neuroprotective activities. In February 2008, the Company converted provisional patent applications relating to the nature and activity of the LB-100 series of drugs with the filing of a U.S. non-provisional and a PCT patent application and is in the process of converting provisional patent applications for the LB-200 series.

The Company filed five patent applications on August 1, 2008. Two of these filings deal with applications filed earlier jointly with NIH for work done under the CRADA: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers; and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

During 2007, the Company also documented that some of its compounds have activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS and those having bone marrow transplantations. This finding extends the potential use of some of Lixte's compounds to the large and important field of therapy of life-threatening mycotic infections.

On April 23, 2008, the Company announced that its CRADA collaborators, Dr. Jie Lu and Dr. Zhengping Zhuang of the Surgical Neurology Branch, NINDS, reported the activity of compound, LB-100, against human glioblastoma multiforme cells in a mouse model of cancer at the Annual Meeting of the American Association of Cancer Research. On August 8, 2008, the Company announced that lead compounds from both the LB-100 and LB-200 series inhibit human pancreatic cancer cells growing in mice. The pancreatic cancer studies are early and there is no evidence that these drugs are able to eliminate pancreatic cancers but rather may slow their growth.

The Company expects that its products will derive directly from the intellectual property generated by its research. Progress to date has borne out this expectation. The development of lead compounds with different mechanisms of action that have now been shown to have activity against brain tumors and several other more common cancers as well as serious fungal infections, originated from the discovery of a biomarker most prominent in GBM. The Company continues to use biomarker discovery to provide insights as to the potential biochemical vulnerabilities of cancers expressing the biomarker.

#### Going Concern

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date.

The Company's ability to continue as a going concern is dependent upon its ability to develop additional sources of capital and to ultimately achieve profitable operations. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At September 30, 2008, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2008 is related to the Company's formation, capital raising efforts and initial research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company's cash requirements were funded by advances from Lixte's founder.

Because the Company is currently engaged in research at an early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating revenues. As such, the Company's business is unlikely to generate any revenue in the next several years and may never do so. Even if the Company is able to generate revenues in the future through licensing its technologies or through product sales, there can be no assurance that the Company will be able to generate a profit.

The Company does not have sufficient resources to fund its operations, including the Company's research activities with respect to its intellectual property, for the next twelve months. In addition, the Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company needs to raise additional funds in order to satisfy its future working capital requirements.

The Company estimates that it will require additional funding of approximately \$2,000,000 for the remainder of 2008 and 2009 to fund operations and continuing drug discovery and to bring two drugs through the pre-clinical evaluation process needed for submission of an Investigational New Drug ("IND") application. The Company is currently attempting to complete a \$2,000,000 private placement of its securities during 2008, although there can be no assurances that the Company will be successful in this regard. Pursuant to an unsecured demand promissory note bearing interest at the rate of 5% per annum, the Company borrowed \$100,000 from one of its consultants during October 2008 to fund short-term cash requirements while it attempts to complete the \$2,000,000 private placement of its securities. In view of the Company's limited cash position, failure to complete the private placement offering would result in the Company being unable to repay the loan. Additionally, the amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

Current market conditions present uncertainty as to the Company's ability to secure additional funds, as well as its ability to reach profitability. There can be no assurances that the Company will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to the Company's ability to achieve positive earnings and cash flows from operations. Continued negative cash flows and lack of liquidity create significant uncertainty about the Company's ability to fully implement its operating plan, as a result of which the Company may have to reduce the scope of its planned operations. If cash resources are insufficient to satisfy the Company's liquidity requirements, the Company would be required to scale back or discontinue its technology and product development programs, or obtain funds, if available, through strategic alliances that may require the Company to relinquish rights to certain of its technologies products, or to discontinue its operations entirely.

#### 2. Summary of Significant Accounting Policies

#### Principles of Consolidation

The accompanying consolidated financial statements include the financial statements of Holdings and its wholly-owned subsidiary, Lixte. All intercompany balances and transactions have been eliminated in consolidation.

#### Cash and Cash Equivalents and Concentrations

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. At times, such cash and cash equivalents may exceed federally insured limits. The Company has not experienced a loss in such accounts to date. The Company maintains its accounts with financial institutions with high credit ratings.

#### Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of fees paid to consultants and outside service providers, patent fees and costs, royalty costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Amounts due, pursuant to contractual commitments, on research and development contracts with third parties are recorded as a liability, with the related amount of such contracts recorded as advances on research and development contract services on the Company's balance sheet. Such advances on research and development contract services are expensed over their life on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The Company accounts for its research and development contracts in accordance with EITF 07-3.

The funds paid to NINDS of the NIH, pursuant to the CRADA effective March 22, 2006, as amended, represented an advance on research and development costs and therefore had future economic benefit. As such, such costs were being charged to expense when they were actually expended by the provider, which is, effectively, as they performed the research activities that they were contractually committed to provide. Absent information that would indicate that a different expensing schedule was more appropriate (such as, for example, from the achievement of performance milestones or the completion of contract work), such advances were expensed over the contractual service term on a straight-line basis, which reflected a reasonable estimate of when the underlying research and development costs were being incurred.

#### Patent Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal fees, are expensed as incurred. Patent costs were \$53,075 and \$20,340 for the three months ended September 30, 2008 and 2007, respectively, \$127,299 and \$66,931 for the nine months ended September 30, 2008 and 2007, respectively, and \$288,208 for the period from August 9, 2005 (inception) to September 30, 2008 (cumulative). Patent costs are included in research and development costs in the Company's statement of operations.

#### Income Taxes

The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), which establishes financial accounting and reporting standards for the effects of income taxes that result from an enterprise's activities during the current and preceding years. SFAS No. 109 requires an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

For federal income tax purposes, substantially all expenses, except for interest, taxes, and research and development, are deemed start-up and organization costs and must be deferred until the Company commences business operations at which time they may be written off over a 180-month period. The Company has elected to deduct research and development costs currently.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

For federal income tax purposes, net operating losses can be carried forward for a period of 20 years until they are either utilized or until they expire.

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109" ("FIN 48"), which provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. A tax benefit from an uncertain position may be recognized only if it is "more likely than not" that the position is sustainable based on its technical merits. The Company adopted the provisions of FIN 48 on January 1, 2007.

#### Stock-Based Compensation

The Company accounts for share-based payments pursuant to SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), a revision to SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 123R requires that the Company measure the cost of employee services received in exchange for equity awards based on the grant date fair value of the awards, with the cost to be recognized as compensation expense in the Company's financial statements over the vesting period of the awards.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110 ("SAB 110"), which expresses the views of the staff regarding the use of a "simplified" method, as discussed in Staff Accounting Bulletin No. 107, in developing an estimate of expected term of "plain vanilla" share options in accordance with SFAS No. 123R. The staff indicated that it will accept a company's election to use the simplified method, regardless of whether the company has sufficient information to make more refined estimates of expected term. SAB 110 was effective January 1, 2008, and did not have a significant impact on the Company's consolidated financial statements.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with EITF No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and EITF 00-18, "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than Employees", whereas the value of the stock compensation is based upon the measurement date as determined at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete. In accordance with EITF 96-18, options granted to Scientific Advisory Board committee members and outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the then current value on the date of vesting.

#### Earnings Per Share

The Company computes earnings per share ("EPS") in accordance with SFAS No. 128, "Earnings per Share" and SEC Staff Accounting Bulletin No. 98. SFAS No. 128 requires companies with complex capital structures to present basic and diluted EPS. Basic EPS is measured as the income (loss) available to common shareholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., warrants and options) as if they had been converted at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share are the same for all periods presented because all warrants and stock options outstanding are anti-dilutive. The 19,021,786 shares of common stock issued to the founder of Lixte in conjunction with the closing of the reverse merger transaction on June 30, 2006 have been presented as outstanding for all periods presented.

At September 30, 2008 and December 31, 2007, the Company had securities outstanding entitling the holder thereof to acquire shares of common stock as follows:

	September 30, 2008	December 31, 2007		
Warrants	546,626	546,626		
Stock options	2,240,000	2,090,000		
Total	2,786,626	2,636,626		

#### Equipment

Equipment is recorded at cost. Depreciation expense is provided on a straight-line basis using estimated useful lives of 3 years. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the property accounts are relieved of costs and accumulated depreciation and any resulting gain or loss is credited or charged to operations.

#### Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, prepaid expenses, accounts payable, accrued expenses and due to stockholder approximate their respective fair values due to the short-term nature of these items.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

## Reclassification

Certain reclassifications have been made to prior period balances to conform to the September 30, 2008 presentation. Such reclassifications did not have any effect on results of operations.

### Adoption of New Accounting Policies

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"), which establishes a formal framework for measuring fair value under Generally Accepted Accounting Principles ("GAAP"). SFAS No. 157 defines and codifies the many definitions of fair value included among various other authoritative literature, clarifies and, in some instances, expands on the guidance for implementing fair value measurements, and increases the level of disclosure required for fair value measurements. Although SFAS No. 157 applies to and amends the provisions of existing FASB and American Institute of Certified Public Accountants ("AICPA") pronouncements, it does not, of itself, require any new fair value measurements, nor does it establish valuation standards. SFAS No. 157 applies to all other accounting pronouncements requiring or permitting fair value measurements, except for: SFAS No. 123R, share-based payment and related pronouncements, the practicability exceptions to fair value determinations allowed by various other authoritative pronouncements, and AICPA Statements of Position 97-2 and 98-9 that deal with software revenue recognition. The Company adopted SFAS No. 157 on January 1, 2008.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"), which provides companies with an option to report selected financial assets and liabilities at fair value. SFAS No. 159's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate companies not between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. SFAS No. 159 also requires companies to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. The Company adopted SFAS No. 159 on January 1, 2008.

The adoption of SFAS No. 157 and SFAS No. 159 on January 1, 2008 did not have any effect on the Company's consolidated financial statement presentation or disclosures.

#### Recent Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"), which requires an acquirer to recognize in its financial statements as of the acquisition date (i) the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, measured at their fair values on the acquisition date, and (ii) goodwill as the excess of the consideration transferred plus the fair value of any noncontrolling interest in the acquiree at the acquisition date over the fair values of the identifiable net assets acquired. Acquisition-related costs, which are the costs an acquirer incurs to effect a business combination, will be accounted for as expenses in the periods in which the costs are incurred and the services are received, except that costs to issue debt or equity securities will be recognized in accordance with other applicable GAAP. SFAS No. 141(R) makes significant amendments to other Statements and other authoritative guidance to provide additional guidance or to conform the guidance in that literature to that provided in SFAS No. 141(R). SFAS No. 141(R) also provides guidance as to what information is to be disclosed to enable users of financial statements to evaluate the nature and financial effects of a business combination. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. Early adoption is prohibited. The adoption of SFAS No. 141(R) will affect how the Company accounts for a business combination concluded after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51" ("SFAS No. 160"), which revises the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require (i) the ownership interests in subsidiaries held by parties other than the parent be clearly identified, labeled, and presented in the consolidated statement of financial position within equity, but separate from the parent's equity, (ii) the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented on the face of the consolidated statement of income, (iii) changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently as equity transactions, (iv) when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be initially measured at fair value, with the gain or loss on the deconsolidation of the subsidiary being measured using the fair value of any noncontrolling equity investment rather than the carrying amount of that retained investment, and (v) entities provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 amends FASB No. 128 to provide that the calculation of earnings per share amounts in the consolidated financial statements will continue to be based on the amounts attributable to the parent. SFAS No. 160 is effective for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Early adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the p

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133" ("SFAS No. 161"). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). The objective of SFAS No. 161 is to provide users of financial statements with an enhanced understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 applies to all derivative financial instruments, including bifurcated derivative instruments (and nonderivative instruments that are designed and qualify as hedging instruments pursuant to paragraphs 37 and 42 of SFAS No. 133) and related hedged items accounted for under SFAS No. 133 and its related interpretations. SFAS No. 161 also amends certain provisions of SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS No. 161 will have any impact on its consolidated financial statement presentation or disclosures.

#### 3. Share Exchange Agreement and Private Placement

#### Share Exchange Agreement

On June 30, 2006, pursuant to a Share Exchange Agreement dated as of June 8, 2006 (the "Share Exchange Agreement") by and among Holdings, Dr. John S. Kovach ("Seller") and Lixte, Holdings issued 19,021,786 shares of its common stock in exchange for all of the issued and outstanding shares of Lixte (the "Exchange"). Previously, on October 3, 2005, Lixte had issued 1,500 shares of its no par value common stock to its founder for \$1,500, which constituted all of the issued and outstanding shares of Lixte prior to the Exchange. As a result of the Exchange, Lixte became a wholly-owned subsidiary of Holdings.

Pursuant to the Exchange, Holdings issued to the Seller 19,021,786 shares of its common stock. Holdings had a total of 25,000,832 shares of common stock issued and outstanding after giving effect to the Exchange and the 1,973,869 shares of common stock issued in the initial closing of the private placement.

As a result of the Exchange and the shares of common stock issued in the initial closing of the private placement, on June 30, 2006, the stockholders of the Company immediately prior to the Exchange owned 4,005,177 shares of common stock, equivalent to approximately 16% of the issued and outstanding shares of the Company's common stock, and the former stockholder of Lixte acquired control of the Company.

The Share Exchange Agreement was determined through arms-length negotiations between Holdings, the Seller and Lixte. In connection with the Exchange, the Company paid WestPark Capital, Inc. an aggregate cash fee of \$50,000.

#### **Private Placements**

On June 30, 2006, concurrently with the closing of the Exchange, the Company sold an aggregate of 1,973,869 shares of its common stock to accredited investors in an initial closing of a private placement at a per share price of \$0.333, resulting in aggregate gross proceeds to the Company of \$657,299. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.333 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.333 per share. A total of 236,864 warrants were issued. Net cash proceeds to the Company, after the deduction of all private placement offering costs and expenses, were \$522,939.

On July 27, 2006, the Company sold an aggregate of 1,581,351 shares of its common stock to accredited investors in a second closing of the private placement at a per share price of \$0.333 resulting in aggregate gross proceeds to the Company of \$526,590. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.333 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.333 per share. A total of 189,762 warrants were issued. Net cash proceeds to the Company were \$446,433.

In conjunction with the private placement of common stock, the Company issued a total of 426,626 five-year warrants to WestPark Capital, Inc. exercisable at the per share price of the common stock sold in the private placement (\$0.333 per share). The warrants issued to WestPark Capital, Inc. do not contain any price anti-dilution provisions. However, such warrants contain cashless exercise provisions and demand registration rights, but the warrant holder has agreed to waive any claims to monetary damages or financial penalties for any failure by the Company to comply with such registration requirements. Based on the foregoing, the warrants have been accounted for as equity.

The fair value of the warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$132,254 (\$0.31 per share) using the following Black-Scholes input variables: stock price on date of grant - \$0.333; exercise price - \$0.333; expected life - 5 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%.

As part of the Company's private placement of its securities completed on July 27, 2006, the Company entered into a registration rights agreement with the purchasers, whereby the Company agreed to register the shares of common stock sold in the private placement, and to maintain the effectiveness of such registration statement, subject to certain conditions. The agreement required the Company to file a registration statement within 45 days of the closing of the private placement and to have the registration statement declared effective within 120 days of the closing of the private placement. On September 8, 2006, the Company filed a registration statement on Form SB-2 to register 3,555,220 shares of the common stock sold in the private placement. Since the registration statement was not declared effective by the Securities and Exchange Commission within 120 days of the closing of the private placement, the Company was required to pay each investor prorated liquidated damages equal to 1.0% of the amount raised per month, payable monthly in cash.

In accordance with EITF 00-19-2, "Accounting for Registration Payment Arrangements", on the date of the closing of the private placement, the Company believed it would meet the deadlines under the registration rights agreement with respect to filing a registration statement and having it declared effective by the Securities and Exchange Commission. As a result, the Company did not record any liabilities associated with the registration rights agreement at June 30, 2006. At December 31, 2006, the Company determined that the registration statement covering the shares sold in the private placement would not be declared effective within the requisite time frame and therefore accrued six months liquidated damages under the registration rights agreement aggregating approximately \$74,000, which has been presented as a current liability at September 30, 2008 and December 31, 2007. The Company's registration statement on Form SB-2 was declared effective by the Securities and Exchange Commission on May 14, 2007. At September 30, 2008, the registration penalty to the investors had not been paid.

On December 12, 2007, the Company sold an aggregate of 999,995 shares of its common stock to accredited investors in a second private placement at a per share price of \$0.65, resulting in aggregate gross proceeds to the Company of \$650,000. The Company paid to WestPark Capital, Inc., as placement agent, a commission of 10% and a non-accountable fee of 4% of the gross proceeds of the private placement and issued five-year warrants to purchase common stock equal to (a) 10% of the number of shares sold in the private placement exercisable at \$0.65 per share and (b) an additional 2% of the number of shares sold in the private placement also exercisable at \$0.65 per share. Net cash proceeds to the Company were \$531,320.

In conjunction with the second private placement of common stock, the Company issued a total of 120,000 five-year warrants to WestPark Capital, Inc. exercisable at the per share price of the common stock sold in the private placement (\$0.65 per share). The warrants issued to WestPark Capital, Inc. do not contain any price anti-dilution provisions. However, such warrants contain cashless exercise provisions and demand registration rights, but the warrant holder has agreed to waive any claims to monetary damages or financial penalties for any failure by the Company to comply with such registration requirements. Based on the foregoing, the warrants have been accounted for as equity.

The fair value of the warrants, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$115,200 (\$0.96 per share) using the following Black-Scholes input variables: stock price on date of grant - \$1.10; exercise price - \$0.65; expected life - 5 years; expected volatility - 118.6%; expected dividend yield - 0%; risk-free interest rate - 4%.

As part of the Company's second private placement of its securities completed on December 12, 2007, the Company entered into a registration rights agreement with the purchasers, whereby the Company agreed to register the shares of common stock sold in the second private placement at its sole cost and expense. The registration rights agreement terminates at such time as the common shares may be sold in market transactions without regard to any volume limitations. The registration rights agreement requires the Company to file a registration statement within 75 days of receipt of written demand from holders who represent at least 50% of the common shares issued pursuant to the second private placement, provided that no demand shall be made for less than 500,000 shares, and to use its best efforts to cause such registration statement to become and remain effective for the requisite period. The registration rights agreement also provides for unlimited piggyback registration rights. The registration rights agreement does not provide for any penalties in the event that the Company is unable to comply with its terms.

The Company's common stock was listed for trading on the OTC Bulletin Board commencing September 24, 2007.

#### 4. Related Party Transactions

Prior to June 30, 2006, Lixte's founding stockholder and Chief Executive Officer, Dr. John Kovach, had periodically made advances to the Company to meet operating expenses. Such advances are non-interest-bearing and are due on demand. At September 30, 2008 and December 31, 2007, stockholder advances totaled \$92,717.

The Company's office facilities have been provided without charge by Dr. Kovach. Such costs were not material to the financial statements and, accordingly, have not been reflected therein.

Dr. Kovach did not receive any compensation from the Company during the three months and nine months ended September 30, 2008 and 2007, and for the period from August 9, 2005 (inception) through September 30, 2008 (cumulative), in view of the Company's development stage status and limited resources. Any future compensation arrangements will be subject to the approval of the Board of Directors.

Dr. Kovach is involved in other business activities and may, in the future, become involved in other business opportunities that become available. Accordingly, he may face a conflict in selecting between the Company and his other business interests. The Company has not yet formulated a policy for the resolution of such potential conflicts.

#### 5. Common Stock and Preferred Stock

The Company's Certificate of Incorporation provides for authorized capital of 110,000,000 shares, of which 100,000,000 shares are common stock with a par value of \$0.0001 per share and 10,000,000 shares are preferred stock with a par value of \$0.0001 per share.

The Company is authorized to issue 10,000,000 shares of preferred stock with such designations, voting and other rights and preferences, as may be determined from time to time by the Board of Directors.

#### 6. Stock Options and Warrants

On June 30, 2006, effective with the closing of the Exchange, the Company granted to Dr. Philip Palmedo, an outside director of the Company, stock options to purchase an aggregate of 200,000 shares of common stock, exercisable for a period of five years at \$0.333 per share, with one-third of the options (66,666 shares) vesting immediately upon joining the Board and one-third vesting annually on each of June 30, 2007 and 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$62,000 (\$0.31 per share), of which \$20,666 was charged to operations on June 30, 2006, and the remaining \$41,334 was charged to operations ratably from July 1, 2006 through June 30, 2008. During the three months and nine months ended September 30, 2007, the Company recorded a charge to operations of \$5,167 and \$15,501 with respect to these options. During the three months and nine months ended September 30, 2008, the Company recorded a charge to operations of \$-0-and \$10,332, respectively, with respect to these options.

On June 30, 2006, effective with the closing of the Exchange, the Company also granted to Dr. Palmedo additional stock options to purchase 190,000 shares of common stock exercisable for a period of five years at \$0.333 per share for services rendered in developing the business plan for Lixte, all of which were fully vested upon issuance. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$58,900 (\$0.31 per share), and was charged to operations at June 30, 2006.

On June 30, 2006, effective with the closing of the Exchange, the Company granted to certain members of its Scientific Advisory Committee stock options to purchase an aggregate of 100,000 shares of common stock exercisable for a period of five years at \$0.333 per share, with one-half of the options vesting annually on each of June 30, 2007 and June 30, 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was charged to operations ratably from July 1, 2006 through June 30, 2008. During the three months and nine months ended September 30, 2007, the Company recorded a charge to operations of \$12,316 and \$19,692, respectively, with respect to these options. During the three months and nine months ended September 30, 2008, the Company recorded a charge (credit) to operations of \$-0- and \$(3,336), respectively, with respect to these options.

On June 30, 2006, the fair value of the aforementioned stock options was initially calculated using the following Black-Scholes input variables: stock price - \$0.333; exercise price - \$0.333; expected life - 5 to 7 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%. On June 30, 2007, the Black-Scholes input variables utilized to determine the fair value of the aforementioned stock options were stock price - \$0.333; exercise price - \$0.333; expected life - 4 to 6 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 4.5%. On June 30, 2008, the fair value of the aforementioned stock options was calculated using the following Black-Scholes input variables: stock price - \$0.30; exercise price - \$0.333; expected life - 3 to 5 years; expected volatility - 154.5%; expected dividend yield - 0%; risk-free interest rate - 3.28%.

In August 2008, a member of the Scientific Advisory Committee resigned from his position and waived his right to his vested stock option to purchase 50,000 shares of common stock.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provides for the granting of awards, consisting of common stock options, stock appreciation rights, performance shares, or restricted shares of common stock, to employees and independent contractors, for up to 2,500,000 shares of the Company's common stock, under terms and condition, as determined by the Company's Board of Directors.

On September 12, 2007, in conjunction with his appointment as a director of the Company, the Company granted to Dr. Stephen Carter stock options to purchase an aggregate of 200,000 shares of common stock under the 2007 Plan, exercisable for a period of five years from vesting date at \$0.333 per share, with one-half (100,000 shares) vesting annually on each of September 12, 2008 and 2009. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$204,000 (\$1.02 per share), and is being charged to operations ratably from September 12, 2007 through September 12, 2009. During the three months ended September 30, 2008 and 2007, the Company recorded a charge to operations of \$25,653 and \$5,016, respectively, with respect to these options. During the nine months ended September 30, 2008 and 2007, the Company recorded a charge to operations of \$76,375 and \$5,016, respectively, with respect to these options.

On September 12, 2007, the Company entered into a consulting agreement with Gil Schwartzberg, pursuant to which the Company granted to Mr. Schwartzberg stock options to purchase an aggregate of 1,000,000 shares of common stock, exercisable for a period of four years from the vesting date at \$1.00 per share, with one-half of the options (500,000 shares) vesting immediately and one-half (500,000 shares) vesting on September 12, 2008. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$945,000 (\$0.945 per share), of which \$465,000 was attributed to the fully-vested options and was thus charged to operations on September 12, 2007. The remaining portion of the fair value of these options was charged to operations ratably from September 12, 2007 through September 12, 2008. On September 12, 2008, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$325,000 (\$0.65 per share), which resulted in a charge to operations of \$229,262 and \$236,338 during the three months and nine months ended September 30, 2008, respectively. During the three months and nine months ended September 30, 2007, the Company recorded a charge to operations of \$23,607 with respect to these options.

On September 12, 2007, the Company entered into a consulting agreement with Francis Johnson, a co-owner of Chem-Master International, Inc., and granted to Professor Johnson stock options to purchase an aggregate of 300,000 shares of common stock, exercisable for a period of four years from the vesting date at \$0.333 per share, with one-third (100,000 shares) vesting annually on each of September 12, 2008, 2009 and 2010. The fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$300,000 (\$1.00 per share), and is being charged to operations ratably from September 12, 2007 through September 12, 2010. On September 12, 2008 and September 30, 2008, the fair value of these options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$195,000 (\$0.65 per share) and \$150,000 (\$0.50 per share), respectively, which resulted in a charge to operations of \$45,925 and \$47,630 during the three months and nine months ended September 30, 2008, respectively. During the three months and nine months ended September 30, 2007, the Company recorded a charge to operations of \$4,918 with respect to these options.

On September 12, 2007, the fair value of the aforementioned stock options was initially calculated using the following Black-Scholes input variables: stock price - \$1.05; exercise price - \$0.333 to \$1.00; expected life - 4 to 6 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 5%. On September 12, 2008, the fair value of the aforementioned stock options was calculated (for stock options revalued pursuant to EITF 98-16) using the following Black-Scholes input variables: stock price - \$0.65; exercise price - \$0.333 to \$1.00; expected life - 4 years; expected volatility - 275.7%; expected dividend yield - 0%; risk-free interest rate - 2.48%. On September 30, 2008, the fair value of the aforementioned stock options was calculated (for stock options revalued pursuant to EITF 98-16) using the following Black-Scholes input variables: stock price - \$0.50; exercise price - \$0.333; expected life - 4.98 years; expected volatility - 275.7%; expected dividend yield - 0%; risk-free interest rate - 2.48%. As the Company's common stock commenced trading on September 24, 2007, the Company was able to utilize such trading date to generate revised volatility factors at September 12, 2008 and September 30, 2008.

Additional information with respect to common stock warrants and stock options issued is provided at Notes 3 and 7.

#### 7. Commitments and Contingencies

Effective March 22, 2006, Lixte entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA was for a term of 42 months from the effective date and could be unilaterally terminated by either party by providing written notice within sixty days. The CRADA provided for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for glioma cell differentiation. The CRADA also provided that NINDS and Lixte would conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, Lixte agreed to provide funds under the CRADA in the amount of \$200,000 per year to fund two technical assistants for the technical, statistical and administrative support for the research activities, as well as to pay for supplies and travel expenses. The first \$200,000 was due within 180 days of the effective date and was paid in full on July 6, 2006. The second \$200,000 was paid in full on June 29, 2007. In June 2008, the CRADA was extended to September 30, 2009, with no additional funding required for the period between July 1, 2008 and September 30, 2008. However, for the period from October 1, 2008 through September 30, 2009, the Company has agreed to provide additional funding under the CRADA of \$200,000, to be paid in four quarterly installments of \$50,000 commencing on October 1, 2008. The first installment of \$50,000 was paid on September 29, 2008.

On January 5, 2007, Lixte entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which Lixte retained the University to provide to it certain samples of primary cancer tissue and related biological fluids to be obtained from patients afflicted with specified types of cancer. The University also agreed to provide certain information relating to such patients. Lixte agreed to pay the University 72,000 Euros in two equal installments. The first installment of 36,000 Euros (\$48,902) was paid on March 7, 2007. On January 12, 2008, Lixte terminated the Services Agreement in accordance with its terms, as a result of which payment of the second installment of 36,000 Euros was cancelled. The University agreed to deliver 50% of the aforementioned samples under the terminated Services Agreement.

On February 5, 2007, Lixte entered into a two-year agreement (the "Chem-Master Agreement") with Chem-Master International, Inc. ("Chem-Master"), a company co-owned by Francis Johnson, a consultant to the Company, pursuant to which Lixte engaged Chem-Master to synthesize a compound designated as "LB-1", and any other compound synthesized by Chem-Master pursuant to Lixte's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, Lixte agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. The fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$31,000 (\$0.31 per share) using the following Black-Scholes input variables: stock price on date of grant - \$0.333; exercise price - \$0.333; expected life - 5 years; expected volatility - 150%; expected dividend yield - 0%; risk-free interest rate - 4.5%. The \$31,000 fair value was charged to operations as research and development costs during the year ended December 31, 2007, since the option was fully vested and non-forfeitable on the date of issuance. Lixte has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On February 5, 2009, provided that the Chem-Master Agreement has not been terminated prior to such date, the Company has agreed to grant Chem-Master a second five-year option to purchase an additional 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. As of September 30, 2008, the Company determined that it was likely that this option would be issued. Accordingly, the fair value of the option (initially calculated as \$50,000) will be reflected as a charge to operations for the period

On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as "LB-3". Pursuant to the amendment, the Company issued 100,000 shares of its restricted common stock, valued at \$75,000, and granted an option to purchase 200,000 shares of common stock. The option is exercisable for a period of two years from the vesting date at \$1.65 per share, with one-half (100,000 shares) vesting on August 1, 2009, and one-half (100,000 shares) vesting on February 1, 2011. The fair value of this option, as calculated pursuant to the Black-Scholes option-pricing model, was initially determined to be \$96,000 (\$0.48 per share) using the following Black-Scholes input variables: stock price on date of grant - \$0.75; exercise price - \$1.65; expected life - 5 years; expected volatility - 120.1%; expected dividend yield - 0%; risk-free interest rate - 3.09%.

The fair value of the restricted common stock issued was charged to operations as research and development costs on January 29, 2008. On September 30, 2008, the fair value of the aforementioned stock options was determined to be \$100,000 (\$0.50 per share) calculated using the following Black-Scholes input variables: stock price - \$0.50; exercise price - \$1.65; expected life - 4.34 years; expected volatility - 275.7%; expected dividend yield - 0%; risk-free interest rate - 2.48%, which resulted in a charge to operations of \$15,568 and \$22,232 during the three months and nine months ended September 30, 2008, respectively.

On September 12, 2007, the Company entered into two consulting agreements for financial and scientific services. Compensation related to these agreements was primarily in the form of stock options (see Note 6).

On September 20, 2007, the Company entered into a one-year consulting agreement (the "Mirador Agreement") with Mirador Consulting, Inc. ("Mirador"), pursuant to which Mirador was to provide the Company with various financial services. Pursuant to the Mirador Agreement, the Company agreed to pay Mirador \$5,000 per month and also agreed to sell Mirador 250,000 shares of the Company's restricted common stock for \$250 (\$0.001 per share). The fair value of this transaction was determined to be in excess of the purchase price by \$262,250 (\$1.049 per share), reflecting the difference between the \$0.001 purchase price and the \$1.05 price per share as quoted on the OTC Bulletin Board on the transaction date, and was charged to operations as stock-based compensation during the year ended December 31, 2007, since the shares were fully vested and non-forfeitable on the date of issuance. The Company made payments under the Mirador Agreement aggregating \$10,000 during 2007. The Mirador Agreement was amended in February 2008, pursuant to which Mirador agreed to forgive all accrued but unpaid monthly fees through February 29, 2008, and the Company agreed to pay Mirador a fee of \$2,000 per month for the remaining six months of the Mirador Agreement.

In September 2008, the Company engaged an internet-based investor information service to enhance awareness of the Company's progress in developing a portfolio of pharmacological agents at an initial cost of \$2,500, plus \$500 per month for a period of twelve months.

Effective as of September 19, 2008, Lixte entered into an agreement with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The agreement provides for an initial payment of \$25,000 to NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The agreement also provides for the Company to pay specified royalties based on (i) net sales by the Company and its sublicensees, (ii) the achievement of certain clinical benchmarks, and (iii) the granting of sublicenses. The Company recorded the initial \$25,000 obligation as a charge to research and development costs at September 30, 2008.

#### 8. Subsequent Events

On October 3, 2008, pursuant to an unsecured demand promissory note bearing interest at the rate of 5% per annum, the Company borrowed \$100,000 from Gil Schwartzberg, one of its consultants (see Note 6), to fund short-term cash requirements.

During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The Company agreed to pay a fee not to exceed \$50,000 over a four-month period for such services.

On October 7, 2008, the Company appointed Dr. Mel Sorensen to its Board of Directors. Dr. Sorenson is a medical oncologist with extensive experience in cancer drug development, first at the National Cancer Institute, then at Bayer and Glaxo Smith Kline, before becoming President and CEO of a new cancer therapeutics company, Ascenta Therapeutics, in 2004. Dr. Sorenson will be paid an annual consulting fee of \$40,000, payable in quarterly installments over a one year period commencing October 7, 2008, to assist the Company in identifying a strategic partner. Dr. Sorenson was also granted a stock option to purchase 200,000 shares of the Company's common stock, exercisable at \$0.50 per share for a period of five years from each tranche's vesting date. The option vests as to 25,000 shares on January 1, 2009, and a further 25,000 shares on the first day of each subsequent calendar quarter until all of the shares are vested.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

On June 30, 2006, Lixte Biotechnology, Inc., a privately-held Delaware corporation ("Lixte"), completed a reverse merger transaction with SRKP 7, Inc. ("SRKP"), a non-trading public "shell" company, whereby Lixte became a wholly-owned subsidiary of SRKP. For financial reporting purposes, Lixte was considered the accounting acquirer in the merger and the merger was accounted for as a reverse merger. Accordingly, the historical financial statements presented herein are those of Lixte and do not include the historical financial results of SRKP. The stockholders' equity section of SRKP has been retroactively restated for all periods presented to reflect the accounting effect of the reverse merger transaction. All costs associated with the reverse merger transaction were expensed as incurred.

Lixte was incorporated in Delaware on August 9, 2005 to capitalize on opportunities to develop low cost, specific and sensitive tests for the early detection of cancers to better estimate prognosis, to monitor treatment response, and to reveal targets for development of more effective treatments.

Unless the context indicates otherwise, SRKP and Lixte are hereinafter referred to as the "Company". On December 7, 2006, the Company amended its Certificate of Incorporation to change its name from SRKP 7, Inc. to Lixte Biotechnology Holdings, Inc. ("Holdings").

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date. The Company's ability to continue as a going concern is dependent upon its ability to develop additional sources of capital and to ultimately achieve profitable operations. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties (see "Liquidity and Capital Resources - September 30, 2008 - Going Concern").

#### **Recent Developments**

On April 23, 2008, Dr. Jie Lu and Dr. Zhengping Zhuang of the Surgical Neurology Branch, National Institute of Neurological Disorders and Stroke, National Institutes of Health, reported at the Annual Meeting of the American Association of Cancer Research that the Company's lead compound, LB-1, has anti-cancer activity against human glioblastoma multiforme cells in a mouse model of cancer. On August 8, 2008, the Company announced that lead compounds from each of two different types of drugs being developed by it as a potential treatment for specific types of brain cancers have activity against human pancreatic cancers in a mouse model. These are early studies and there is no evidence that these drugs are able to eliminate pancreatic cancers, but rather slow their growth.

On August 1, 2008, five patent applications were filed with regard to the Company's various ongoing research activities. Two of these patent filings deal with applications filed earlier jointly with NIH for work done under the CRADA as follows: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers; and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children), and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The Company agreed to pay a fee not to exceed \$50,000 over a four-month period for such services.

On October 7, 2008, the Company appointed Dr. Mel Sorensen to its Board of Directors. Dr. Sorenson is a medical oncologist with extensive experience in cancer drug development, first at the National Cancer Institute, then at Bayer and Glaxo Smith Kline, before becoming President and CEO of a new cancer therapeutics company, Ascenta Therapeutics. Dr. Sorenson will be paid an annual consulting fee of \$40,000, payable in quarterly installments over a one year period commencing October 7, 2008, to assist the Company in identifying a strategic partner. Dr. Sorenson was also granted a stock option to purchase 200,000 shares of the Company's common stock, exercisable at \$0.50 per share for a period of five years from each tranche's vesting date. The option vests as to 25,000 shares on January 1, 2009, and a further 25,000 shares on the first day of each subsequent calendar quarter until all of the shares are vested.

## **Adoption of New Accounting Policies**

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS No. 157"), which establishes a formal framework for measuring fair value under Generally Accepted Accounting Principles ("GAAP").

SFAS No. 157 defines and codifies the many definitions of fair value included among various other authoritative literature, clarifies and, in some instances, expands on the guidance for implementing fair value measurements, and increases the level of disclosure required for fair value measurements. Although SFAS No. 157 applies to and amends the provisions of existing FASB and American Institute of Certified Public Accountants ("AICPA") pronouncements, it does not, of itself, require any new fair value measurements, nor does it establish valuation standards. SFAS No. 157 applies to all other accounting pronouncements requiring or permitting fair value measurements, except for: SFAS No. 123R, share-based payment and related pronouncements, the practicability exceptions to fair value determinations allowed by various other authoritative pronouncements, and AICPA Statements of Position 97-2 and 98-9 that deal with software revenue recognition. The Company adopted SFAS No. 157 on January 1, 2008.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"), which provides companies with an option to report selected financial assets and liabilities at fair value. SFAS No. 159's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS No. 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. SFAS No. 159 also requires companies to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. SFAS No. 159 does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS No. 157 and SFAS No. 107. The Company adopted SFAS No. 159 on January 1, 2008.

The adoption of SFAS No. 157 and SFAS No. 159 on January 1, 2008 did not have any effect on the Company's consolidated financial statement presentation or disclosures.

#### **Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)"), which requires an acquirer to recognize in its financial statements as of the acquisition date (i) the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, measured at their fair values on the acquisition date, and (ii) goodwill as the excess of the consideration transferred plus the fair value of any noncontrolling interest in the acquiree at the acquisition date over the fair values of the identifiable net assets acquired. Acquisition-related costs, which are the costs an acquirer incurs to effect a business combination, will be accounted for as expenses in the periods in which the costs are incurred and the services are received, except that costs to issue debt or equity securities will be recognized in accordance with other applicable GAAP. SFAS No. 141(R) makes significant amendments to other Statements and other authoritative guidance to provide additional guidance or to conform the guidance in that literature to that provided in SFAS No. 141(R). SFAS No. 141(R) also provides guidance as to what information is to be disclosed to enable users of financial statements to evaluate the nature and financial effects of a business combination. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. Early adoption is prohibited. The adoption of SFAS No. 141(R) will affect how the Company accounts for a business combination concluded after December 31, 2008.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51" ("SFAS No. 160"), which revises the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require (i) the ownership interests in subsidiaries held by parties other than the parent be clearly identified, labeled, and presented in the consolidated statement of financial position within equity, but separate from the parent's equity, (ii) the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented on the face of the consolidated statement of income, (iii) changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently as equity transactions, (iv) when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be initially measured at fair value, with the gain or loss on the deconsolidation of the subsidiary being measured using the fair value of any noncontrolling equity investment rather than the carrying amount of that retained investment, and (v) entities provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 amends FASB No. 128 to provide that the calculation of earnings per share amounts in the consolidated financial statements will continue to be based on the amounts attributable to the parent. SFAS No. 160 is effective for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Early adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the p

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133" ("SFAS No. 161"). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). The objective of SFAS No. 161 is to provide users of financial statements with an enhanced understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 applies to all derivative financial instruments, including bifurcated derivative instruments (and nonderivative instruments that are designed and qualify as hedging instruments pursuant to paragraphs 37 and 42 of SFAS No. 133) and related hedged items accounted for under SFAS No. 133 and its related interpretations. SFAS No. 161 also amends certain provisions of SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS No. 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company does not currently anticipate that the adoption of SFAS No. 161 will have any impact on its consolidated financial statement presentation or disclosures.

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

The Company prepared its consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Management periodically evaluates the estimates and judgments made. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates as a result of different assumptions or conditions.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's consolidated financial statements.

#### **Research and Development**

Research and development costs are expensed as incurred. Research and development expenses consist primarily of fees paid to consultants and outside service providers, patent fees and costs, royalty costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Amounts due, pursuant to contractual commitments, on research and development contracts with third parties are recorded as a liability, with the related amount of such contracts recorded as advances on research and development contract services on the Company's balance sheet. Such advances on research and development contract services are expensed over their life on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The Company accounts for its research and development contracts in accordance with EITF 07-3.

#### **Patent Costs**

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal fees, are expensed as incurred.

#### **Stock-Based Compensation**

The Company accounts for share-based payments pursuant to SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), a revision to SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 123R requires that the Company measure the cost of employee services received in exchange for equity awards based on the grant date fair value of the awards, with the cost to be recognized as compensation expense in the Company's financial statements over the vesting period of the awards.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with EITF No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and EITF 00-18, "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than Employees", whereas the value of the stock compensation is based upon the measurement date as determined at either (a) the date at which a performance commitment is reached or (b) at the date at which the necessary performance to earn the equity instruments is complete. In accordance with EITF 96-18, options granted to Scientific Advisory Board committee members and outside consultants are revalued each reporting period to determine the amount to be recorded as an expense in the respective period. As the options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the then current value on the date of vesting.

#### **Income Taxes**

The Company accounts for income taxes pursuant to SFAS No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), which establishes financial accounting and reporting standards for the effects of income taxes that result from an enterprise's activities during the current and preceding years. SFAS No. 109 requires an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

#### Plan of Operation

#### General Overview of Plans

The Company is concentrating on developing new treatments for the most common and most aggressive type of brain cancer of adults, glioblastoma multiforme ("GBM") and the most common cancer of children, neuroblastoma. The Company has expanded the scope of its anti-cancer investigational activities to include the most common brain tumor of children, medulloblastoma, and also to several other types of more common cancers. This expansion of activity is based on documentation that each of two distinct types of drugs being developed by the Company inhibits the growth of cell lines of breast, colon, lung, prostate, pancreas, ovary, stomach and liver cancer, as well as the major types of leukemias. Activity of lead compounds of both types of drugs was recently demonstrated against human pancreatic cancer cells in a mouse model. Because there is a great need for any kind of effective treatment for pancreatic cancer, this cancer will be studied concomitantly with the primary target of the Company's research program focused on brain cancers.

The research on brain tumors is proceeding in collaboration with the National Institute of Neurological Disorders and Stroke ("NINDS") of the National Institutes of Health ("NIH") under a Cooperative Research and Development Agreement ("CRADA") entered into on March 22, 2006, as amended. The research at NINDS continues to be led by Dr. Zhengping Zhuang, an internationally recognized investigator in the molecular pathology of cancer. Dr. Zhuang is aided by two senior research technicians supported by the Company as part of the CRADA. The goal of the CRADA is to develop more effective drugs for the treatment of GBM through the processes required to gain Food and Drug Administration ("FDA") approval for clinical trials. The CRADA was extended and is presently scheduled to end on September 30, 2009.

The Company filed five patent applications on August 1, 2008. Two of these patent filings deal with applications filed earlier jointly with NIH for work done under the CRADA as follows: (1) a filing entering the regional stage of a PCT application involving the use of certain compounds to treat human tumors expressing a biomarker for brain and other human cancers; and (2) an application for the treatment of the pediatric tumors, medulloblastoma (the most common brain tumor in children) and neuroblastoma (a tumor arising from neural cells outside the brain that is the most common cancer of children). The three new patent applications include: (1) a joint application with NIH identifying a new biomarker for many common human cancers that when targeted by compounds developed by the Company result in inhibition of growth and death of cancer cells; (2) an application by the Company regarding the structure, synthesis and use of a group of new homologs of its LB-1 compounds; and (3) an application by the Company for the use of certain homologs of its drugs as neuroprotective agents with potential application to common neurodegenerative conditions such as Alzheimer's and Parkinson's diseases.

The Company continues to evaluate compounds for activity against several types of fungi that cause serious infections, particularly in immuno-compromised individuals, such as those with HIV-AIDS, and those having bone marrow transplantations. The Company is also exploring indications that its compounds have against strains of fungi that cause the most common fungal infections of the skin and nails. Discussions are in progress with experts in fungal infections regarding the most reliable methods of assessing the potential of new agents for the management of common fungal diseases.

The Company expects that its products will derive directly from the intellectual property from its research activities. The development of lead compounds with different mechanisms of action that have activity against brain tumors and other common human cancers, as well as against serious fungal infections, originated from the discovery of a biomarker in GBM. The Company will continue to use discovery and/or recognition of molecular variants characteristic of specific human cancers as a guide to drug discovery and potentially new diagnostic tests. Examples of the productivity of this approach to discovery of new therapeutics are: (1) the recent patent application filing for a new biomarker of several common cancers that when targeted by certain of the Company's drugs results in inhibition of growth and death of cancer cells displaying the marker; and (2) the filing of a patent on certain homologs of one group of compounds as potentially useful for the treatment of neurodegenerative diseases.

#### Plans for the Remainder of 2008

The Company's primary objective is to raise funds to cover ongoing operations and development of its lead compounds for the treatment of brain cancers of adults and neuroblastoma in children and to expand its research to include another devastating human cancer, pancreatic cancer. The Company also wishes to raise sufficient capital to explore, most likely in partnership with a pharmaceutical company, recently discovered activity of some derivatives of its lead drugs for the treatment of fungal diseases and neurodegenerative diseases.

The first goal is to initiate preclinical studies of two of its lead compounds required for submission of an application to the FDA for evaluation in clinical trials. The initial target cancers will be glioblastoma multiforme, neuroblastoma and/or medulloblastoma. The final choice will depend in part upon discussions at a pre-IND meeting with the FDA. Subject to the availability of sufficient resources, the Company will also initiate preclinical evaluation of a second compound.

A second goal is further characterization of the fungal activity of certain homologs of drugs of the LB-200 series. These studies will be done in collaboration with academic partners. If initial activity is confirmed, the Company will assess the interest of pharmaceutical companies with expertise in antibiotic development to license rights to the compounds.

The Company will also screen other homologs of lead compounds of the LB-100 and LB-200 series for neuroprotective activity in laboratory models of brain cell injury. These studies will be conducted in conjunction with a not-for-profit scientific service organization with expertise in this field.

Existing resources will not permit evaluation of activity of the Company's lead drugs against all the common cancers against which the Company's compounds may have anti-cancer activity. Current resources also will not be sufficient to carry out pre-clinical studies necessary to apply to the FDA for approval of drug evaluations in Phase I trials. Accordingly, the Company is seeking to raise approximately \$2,000,000 from the issuance of new debt and/or equity during the latter part of 2008 in order to fund its planned operations in 2009. This funding will allow pre-clinical development of two lead compounds, development of one compound, continued new drug development, and corporate operations through 2009. However, there can be no assurances that the Company will be able to secure such additional financing, or obtain favorable terms on such financing if it is available.

The Company faces several potential challenges in its efforts to achieve commercial success, including raising sufficient capital to fund its business plan, achieving commercially applicable results of its research programs, competition from more established, well-funded companies with competitive technologies, and future competition from companies that are developing new competitive technologies, some of whom are larger companies with greater capital resources than the Company. Because of these challenges, there is substantial uncertainty as to the Company's ability to fund its operations and continue as a going concern (see "Liquidity and Capital Resources - September 30, 2008 - Going Concern" below). Should the Company be unable to raise the required capital on a timely basis, the Company's business plans would be materially adversely affected, and the Company may not be able to continue to conduct operations.

## Plans for 2009

The Company intends to carry out the initiatives begun in late 2008 as described above, and will continue to design and synthesize new compounds that target components of molecular pathways already identified by the Company to be vulnerable to attack by small molecule drugs, and to explore the vulnerability of additional potential new targets. The Company expects to bring one or two lead compounds through approval of an IND and then to partner with an organization experienced in clinical cancer drug development. The partnering organization may be either a clinical branch of NIH or a pharmaceutical company with expertise in the conduct of clinical trials. The Company's present position is to take one or more of its new therapies for the treatment of glioblastoma multiforme and/or treatment of neuroblastoma through pre-clinical evaluation as part of the CRADA with the NIHDS of the NIH. After completing pre-clinical evaluation, the Company will consider partnering with the NIH to conduct a Phase I trial or jointly with the NIH to seek a third party, most probably a large pharmaceutical company, to carry the new therapies into Phase I trials. After completion of Phase I trials, the Company, potentially in partnership with the NIH, would collaborate with the third party to carry new therapies found to be safe for administration to humans in the Phase I trials into Phase II trials.

Phase II trials test the safety and effectiveness, as well as the best estimate of the proper dose of the new therapies, in a group of patients with the same type of cancer at the same stage. For the Company's initial studies, the focus will be brain tumors. The duration of Phase II trials may run from 6 to 24 months. New regimens showing beneficial activity in Phase II trials may then be considered for evaluation in Phase III trials. Phase III trials for the evaluation of new cancer treatments are comparative trials in which the therapeutic benefit of a new regimen is compared to the therapeutic benefit of the best standard regimen in a randomized study.

Whether the Company will participate in or be in a position to participate in any clinical trials will depend upon partnerships and specific licensing agreements. However, in all cases of clinical trial participation, the Company will be subject to FDA regulation. These regulations are specific and form the basis for assessing the potential clinical benefit of new therapeutic regimens while safeguarding the health of patients participating in investigational studies. Even after a drug receives approval from the FDA for sale as a new treatment for a specific disease indication, the sponsors of the drug are subject to reporting potentially adverse effects of the new regimen to the FDA.

Given the progress in identifying two lead compounds with activity in animal models of GBM, the Company is devoting its resources to bring the agents to a point at which an Investigational New Drug ("IND") application can be submitted to the FDA for a Phase I clinical trial. One lead compound (LB-1) is the most advanced in the process and the Company plans to be ready for IND submission by early 2009. The other lead compound (LB-2.5), which inhibits cancer cells by a mechanism distinct from that of LB-1, is anticipated to complete its evaluation by the end of 2009.

On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, pursuant to which Chem-Master was engaged to synthesize certain compounds, and to expressly provide for the expansion of the Company's drug development program, through consultation with the medicinal chemists at Chem-Master. The Company is exploring the synthesis of additional novel anti-cancer drugs. Several targets for anti-cancer drug development are under consideration. When the next group of compounds is developed, it will be designated as "LB-3", as distinguished from the first two classes of compounds that were designated as "LB-1" and "LB-2". This process is currently in the planning stage and no compounds have been made as yet.

During October 2008, Lixte engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins.

#### **Results of Operations**

The Company is a development stage company and had not commenced revenue-generating operations at September 30, 2008.

#### Three Months Ended September 30, 2008 and 2007

General and Administrative Expenses. For the three months ended September 30, 2008, general and administrative expenses were \$323,514, which consisted of stock-based compensation of \$254,915, consulting and professional fees of \$42,811, insurance expense of \$5,955, travel and entertainment of \$6,764, and other operating costs of \$13,069.

For the three months ended September 30, 2007, general and administrative expenses were \$819,493, which consisted of stock-based compensation of \$773,356, consulting and professional fees of \$30,821, insurance expense of \$6,982, travel and entertainment costs of \$1,562, and other operating costs of \$6,772.

Depreciation. For the three months ended September 30, 2008 and 2007, depreciation expense was \$155 and \$148, respectively.

Research and Development Costs. For the three months ended September 30, 2008, research and development costs were \$172,818, including \$61,493 for the vested portion of the fair value of stock options issued to a consultant and a vendor, patent costs of \$53,075, the initial payment of \$25,000 made in connection with the Company's exclusive license agreement with NIH, laboratory supplies of \$14,500, and other costs of \$18,750.

For the three months ended September 30, 2007, research and development costs were \$102,178, including \$4,918 for the vested portion of the fair value of stock options issued to a consultant, patent costs of \$20,340, laboratory supplies of \$13,245, and other costs of \$63,675.

Interest Income. For the three months ended September 30, 2008, interest income was \$342, as compared to interest income of \$862 for the three months ended September 30, 2007.

Net Loss. For the three months ended September 30, 2008, the Company incurred a net loss of \$496,145, as compared to a net loss of \$920,954 for the three months ended September 30, 2007.

#### Nine Months Ended September 30, 2008 and 2007

General and Administrative Expenses. For the nine months ended September 30, 2008, general and administrative expenses were \$541,385, which consisted of stock-based compensation of \$319,709, consulting and professional fees of \$148,596, insurance expense of \$17,866, travel and entertainment costs of \$29,216, and other operating costs of \$25,998.

For the nine months ended September 30, 2007, general and administrative expenses were \$1,018,735, which consisted of stock-based compensation of \$791,064, consulting and professional fees of \$180,085, insurance expense of \$21,357, travel and entertainment costs of \$3,910, and other operating costs of \$26,229.

Depreciation. For the nine months ended September 30, 2008 and 2007, depreciation expense was \$473 and \$444, respectively.

Research and Development Costs. For the nine months ended September 30, 2008, research and development costs were \$471,051, which consisted of the fair value of restricted common stock issued to a vendor of \$75,000, the vested portion of the fair value of stock options issued to a consultant and a vendor of \$69,862, patent costs of \$127,299, the initial payment of \$25,000 made in connection with the Company's exclusive license agreement with NIH, laboratory supplies of \$38,750, and other costs of \$135,140.

For the nine months ended September 30, 2007, research and development costs were \$339,769, which consisted of the vested portion of the fair value of stock options issued to a vendor of \$35,918, patent costs of \$66,931, laboratory supplies of \$23,395, and other costs of \$213,525.

Interest Income. For the nine months ended September 30, 2008, interest income was \$3,181, as compared to interest income of \$9,169 for the nine months ended September 30, 2007.

Net Loss. For the nine months ended September 30, 2008, the Company incurred a net loss of \$1,009,728, as compared to a net loss of \$1,349,779 for the nine months ended September 30, 2007.

#### Liquidity and Capital Resources - September 30, 2008

#### **Going Concern**

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage and has not generated any revenues from operations to date.

The Company's ability to continue as a going concern is dependent upon its ability to develop additional sources of capital and to ultimately achieve profitable operations. The Company's financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At September 30, 2008, the Company had not yet commenced any revenue-generating operations. All activity through September 30, 2008 is related to the Company's formation, capital raising efforts and initial research and development activities. As such, the Company has yet to generate any cash flows from operations, and is dependent on debt and equity funding from both related and unrelated parties to finance its operations. Prior to June 30, 2006, the Company's cash requirements were funded by advances from Lixte's founder.

Because the Company is currently engaged in research at an early stage, it will likely take a significant amount of time to develop any product or intellectual property capable of generating revenues. As such, the Company's business is unlikely to generate any revenue in the next several years and may never do so. Even if the Company is able to generate revenues in the future through licensing its technologies or through product sales, there can be no assurance that the Company will be able to generate a profit.

The Company does not have sufficient resources to fund its operations, including the Company's research activities with respect to its intellectual property, for the next twelve months. In addition, the Company does not have sufficient resources to fully develop and commercialize any products that may arise from its research. Accordingly, the Company needs to raise additional funds in order to satisfy its future working capital requirements.

The Company estimates that it will require additional funding of approximately \$2,000,000 for the remainder of 2008 and 2009 to fund operations and continuing drug discovery and to bring two drugs through the pre-clinical evaluation process needed for submission of an IND application. The Company is currently attempting to complete a \$2,000,000 private placement of its securities during 2008, although there can be no assurances that the Company will be successful in this regard. Pursuant to an unsecured demand promissory note bearing interest at the rate of 5% per annum, the Company borrowed \$100,000 from one of its consultants during October 2008 to fund short-term cash requirements while it attempts to complete the \$2,000,000 private placement of its securities. In view of the Company's limited cash position, failure to complete the private placement offering would result in the Company being unable to repay the loan. Additionally, the amount and timing of future cash requirements will depend on the market's evaluation of the Company's technology and products, if any, and the resources that it devotes to developing and supporting its activities. The Company will need to fund these cash requirements from a combination of additional debt or equity financings, or the sale, licensing or joint venturing of its intellectual properties.

Current market conditions present uncertainty as to the Company's ability to secure additional funds, as well as its ability to reach profitability. There can be no assurances that the Company will be able to secure additional financing, or obtain favorable terms on such financing if it is available, or as to the Company's ability to achieve positive earnings and cash flows from operations. Continued negative cash flows and lack of liquidity create significant uncertainty about the Company's ability to fully implement its operating plan, as a result of which the Company may have to reduce the scope of its planned operations. If cash resources are insufficient to satisfy the Company's liquidity requirements, the Company would be required to scale back or discontinue its technology and product development programs, or obtain funds, if available, through strategic alliances that may require the Company to relinquish rights to certain of its technologies products, or to discontinue its operations entirely.

Operating Activities. For the nine months ended September 30, 2008, operating activities utilized cash of \$484,286, as compared to utilizing cash of \$555,299 for the nine months ended September 30, 2007, primarily as a result of a decrease in advances on research and development contract services in 2008, as compared to amounts spent on research and development contract services in 2007 related to an installment payment made under the CRADA in 2007.

The Company had a working capital deficiency of \$168,500 at September 30, 2008. At December 31, 2007, the Company had working capital of \$376,184, primarily as a result of the sale of the Company's common stock pursuant to a second private placement in December 2007 that generated net proceeds of \$531,320.

Investing Activities. There were no investing activities during the nine months ended September 30, 2008. For the nine months ended September 30, 2007, investing activities utilized cash of \$272 for the purchase of office equipment.

Financing Activities. There were no financing activities during the nine months ended September 30, 2008 and 2007.

#### **Principal Commitments**

At September 30, 2008, the Company did not have any material commitments for capital expenditures. The Company's principal commitments at September 30, 2008 consisted of the liquidated damages payable under the registration rights agreement of \$74,000 and the contractual obligations as summarized below.

Effective March 22, 2006, Lixte entered into a CRADA, as amended, with the NINDS of the NIH. The CRADA is for a term of 42 months from the effective date and may be unilaterally terminated by either party by providing written notice within sixty days. The CRADA provides for the collaboration between the parties in the identification and evaluation of agents that target the Nuclear Receptor CoRepressor (N-CoR) pathway for glioma cell differentiation. The CRADA also provided that NINDS and Lixte will conduct research to determine if expression of N-CoR correlates with prognosis in glioma patients. Pursuant to the CRADA, Lixte agreed to provide funds under the CRADA in the amount of \$200,000 per year to fund two technical assistants for the technical, statistical and administrative support for the research activities, as well as to pay for supplies and travel expenses. The first \$200,000 was due within 180 days of the effective date and was paid in full on July 6, 2006. The second \$200,000 was paid in full on June 29, 2007. In June 2008, the CRADA was extended to September 30, 2009 with no additional funding required for the period between July 1, 2008 and September 30, 2008. However, for the period from October 1, 2008 through September 30, 2009, the Company has agreed to provide additional funding under the CRADA of \$200,000, to be paid in four quarterly installments of \$50,000 commencing on October 1, 2008. The first installment of \$50,000 was paid on September 29, 2008.

On January 5, 2007, Lixte entered into a Services Agreement with The Free State of Bavaria (Germany) represented by the University of Regensburg (the "University") pursuant to which Lixte retained the University to provide to it certain samples of primary cancer tissue and related biological fluids to be obtained from patients afflicted with specified types of cancer. The University also agreed to provide certain information relating to such patients. Lixte agreed to pay the University 72,000 Euros in two equal installments. The first installment of 36,000 Euros (\$48,902) was paid on March 7, 2007. On January 12, 2008, Lixte terminated the Services Agreement in accordance with its terms, as a result of which payment of the second installment of 36,000 Euros was cancelled. The University agreed to deliver 50% of the aforementioned samples under the terminated Services Agreement.

On February 5, 2007, Lixte entered into a two-year agreement (the "Chem-Master Agreement") with Chem-Master International, Inc. ("Chem-Master"), a company co-owned by Francis Johnson, a consultant to the Company, pursuant to which Lixte engaged Chem-Master to synthesize a compound designated as "LB-1", and any other compound synthesized by Chem-Master pursuant to Lixte's request, which have potential use in treating a disease, including, without limitation, cancers such as glioblastomas. Pursuant to the Chem-Master Agreement, Lixte agreed to reimburse Chem-Master for the cost of materials, labor, and expenses for other items used in the synthesis process, and also agreed to grant Chem-Master a five-year option to purchase 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. Lixte has the right to terminate the Chem-Master Agreement at any time during its term upon sixty days prior written notice. On February 5, 2009, provided that the Chem-Master Agreement has not been terminated prior to such date, the Company has agreed to grant Chem-Master a second five-year option to purchase an additional 100,000 shares of the Company's common stock at an exercise price of \$0.333 per share. As of September 30, 2008, the Company determined that it was likely that this option would be issued.

On January 29, 2008, the Chem-Master Agreement was amended to extend its term to February 15, 2014, and to expressly provide for the design and synthesis of a new series of compounds designated as "LB-3". Pursuant to the amendment, the Company issued 100,000 shares of its restricted common stock and granted an option to purchase 200,000 shares of common stock. The option is exercisable for a period of two years from vesting date at \$1.65 per share, with one-half (100,000 shares) vesting on August 1, 2009, and one-half (100,000 shares) vesting on February 1, 2011.

On September 20, 2007, the Company entered into a one-year consulting agreement (the "Mirador Agreement") with Mirador Consulting, Inc. ("Mirador"), pursuant to which Mirador was to provide the Company with various financial services. Pursuant to the Mirador Agreement, the Company agreed to pay Mirador \$5,000 per month and also agreed to sell Mirador 250,000 shares of the Company's restricted common stock for \$250 (\$0.001 per share). The Company made payments under the Mirador Agreement aggregating \$10,000 during 2007. The Mirador Agreement was amended in February 2008, pursuant to which Mirador agreed to forgive all accrued but unpaid monthly fees through February 29, 2008, and the Company agreed to pay Mirador a fee of \$2,000 per month for the remaining six months of the Mirador Agreement.

During September 2008, the Company engaged an internet-based investor information service, to enhance awareness of the Company's progress in developing a portfolio of pharmacological agents at an initial cost of \$2,500, plus \$500 per month for a period of twelve months.

Effective as of September 19, 2008, Lixte entered into an agreement with the NIH providing the Company with an exclusive license for all patents submitted jointly with the NIH under the CRADA. The agreement provides for an initial payment of \$25,000 to NIH within 60 days of September 19, 2008, and for a minimum annual royalty of \$30,000 on January 1 of each calendar year following the year in which the CRADA is terminated. The agreement also provides for the Company to pay specified royalties based on (i) net sales by the Company and its sublicensees, (ii) the achievement of certain clinical benchmarks, and (iii) the granting of sublicenses. The Company recorded the initial \$25,000 obligation as a charge to research and development costs at September 30, 2008.

During October 2008, the Company engaged Southern Research Institute, Birmingham, Alabama, to assess one lead compound from each of two classes of its proprietary pharmacological agents for effects on normal neuronal cells and to determine if the compounds protect normal brain cells from injury in several different models of chemical and traumatic brain injury. The goal is to determine if these agents have promise as potentially useful for the prevention, amelioration or delay of progression of neurodegenerative diseases such as Alzheimer's disease and other neurological diseases or impairments resulting from trauma and/or other diverse or unknown origins. The Company agreed to pay a fee not to exceed \$50,000 over a four-month period for such services.

On October 7, 2008, the Company appointed Dr. Mel Sorensen to its Board of Directors. Dr. Sorenson is a medical oncologist with extensive experience in cancer drug development, first at the National Cancer Institute, then at Bayer and Glaxo Smith Kline, before becoming President and CEO of a new cancer therapeutics company, Ascenta Therapeutics, in 2004. Dr. Sorenson will be paid an annual consulting fee of \$40,000, payable in quarterly installments over a one year period commencing October 7, 2008, to assist the Company in identifying a strategic partner. Dr. Sorenson was also granted a stock option to purchase 200,000 shares of the Company's common stock, exercisable at \$0.50 per share for a period of five years from each tranche's vesting date. The option vests as to 25,000 shares on January 1, 2009, and a further 25,000 shares on the first day of each subsequent calendar quarter until all of the shares are vested.

## **Off-Balance Sheet Arrangements**

At September 30, 2008, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

#### ITEM 4T. CONTROLS AND PROCEDURES

#### (a) Evaluation of Disclosure Controls and Procedures

Disclosure Controls and procedures are designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports filed under the Exchange Act is accumulated and communicated to management.

As of September 30, 2008, the Company's Chief Executive Officer and Chief Financial Officer (who is the same individual) evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based upon and as of the date of that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that the information required to be disclosed in the reports the Company files and submits under the Exchange Act is recorded, processed, summarized, and reported as and when required.

#### (b) Changes in Internal Controls Over Financial Reporting

There were no changes in the Company's internal control over financial reporting or in other factors that materially affect, or are reasonably likely to materially affect, those controls subsequent to the date of the Company's most recent evaluation.

## PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The Company is currently not a party to any pending or threatened legal proceedings.
Item 1A. Risk Factors
Not applicable.
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
Not applicable.
Item 3. Defaults Upon Senior Securities
Not applicable.
Item 4. Submission of Matters to a Vote of Security Holders
Not applicable.
Item 5. Other Information
Not applicable.
Item 6. Exhibits
A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which immediately precedes such exhibits, and is incorporated herein by reference.

## **SIGNATURES**

By:

In accordance with the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Registrant)

Date: November 12, 2008

/s/ JOHN S. KOVACH

John S. Kovach

Chief Executive Officer and Chief Financial Officer (Principal financial and accounting officer)

#### INDEX TO EXHIBITS

Exhibit Number	Description of Document
10.1	Services Agreement between Lixte Biotechnology, Inc. and Freestate of Bavaria represented by University of Regensburg dated January 5, 2007, previously filed as an exhibit to the Company's Current Report on Form 8-K filed on January 11, 2007, and incorporated herein by reference.
10.2	Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated February 5, 2007, previously filed as an exhibit to the Company's Current Report on Form 8-K filed on February 9, 2007, and incorporated herein by reference.
10.3	2007 Stock Compensation Plan adopted by the Company's Board of Directors on June 20, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended June 30, 2007, and incorporated herein by reference.
10.4	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Stephen K. Carter dated September 12, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.5	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.6	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.7	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated September 12, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.8	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Mirador Consulting, Inc. dated September 20, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.9	Consulting Agreement between Lixte Biotechnology Holdings, Inc. and Francis Johnson dated September 12, 2007, previously filed as an exhibit to the Company's Quarterly Report on Form 10-QSB for the Quarterly Period Ended September 30, 2007, and incorporated herein by reference.
10.10	Amendment to Agreement between Lixte Biotechnology Holdings, Inc. and Chem-Master International, Inc. dated January 29, 2008, previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2008, and incorporated herein by reference.
10.11	Amendment No. 5 to Cooperative Research and Development Agreement between The National Institute of Neurological Disorders and Stroke and Lixte Biotechnology, Inc. dated June 17, 2008, previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the Quarterly Period Ended June 30, 2008, and incorporated herein by reference.
	Period Ended June 30, 2008, and incorporated herein by reference.

10.12	Unsecured Demand Promissory Note with interest at 5% per annum between Lixte Biotechnology Holdings, Inc. and Gil Schwartzberg dated October 3, 2008. (1)
10.13	Stock Option Agreement between Lixte Biotechnology Holdings, Inc. and Mel Sorensen dated October 7, 2008. (1)
10.14	Director Stipend Agreement between Lixte Biotechnology Holdings, Inc. and Mel Sorensen dated October 7, 2008. (1)
31.1	Certifications under Section 302 of the Sarbanes-Oxley Act of 2002. (1)
32.1	Certifications under Section 906 of the Sarbanes-Oxley Act of 2002. (1)

(1) Filed herewith.

#### PROMISSORY NOTE

\$100,000

East Setauket, New York October 2, 2008

FOR VALUE RECEIVED, the undersigned, Lixte Biotechnology Holdings, Inc., a Delaware corporation (the "Company"), hereby promises to pay to Gil Schwartzberg, or order, the principal sum of \$100,000 on demand, with interest on the unpaid balance of such principal sum from the date hereof at the rate of 5% per annum.

Payments of principal and interest shall be made in lawful money of the United States of America at the principal office of the payee named above or at such other place as the holder hereof shall have designated to the Company in writing.

This Note is subject to prepayment, without penalty, at any time.

If legal action is instituted by the holder hereof to enforce this Note, the Company promises to pay holder's reasonable attorneys' fees.

Lixte Biotechnology Holdings, Inc.

By: John Kovach, President

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#### STOCK OPTION AGREEMENT

THIS STOCK OPTION AGREEMENT ("Agreement") is made by and between LIXTE BIOTECHNOLOGY HOLDINGS, INC, a Delaware corporation (the "Company"), and MEL SORENSEN (the "Optionee").

WHEREAS, Optionee has been elected a director of the Company.

NOW, THEREFORE, in consideration of the mutual benefit to be derived herefrom, the Company and Optionee agree as follows:

- 1. Grant of Option. The Company hereby grants to Optionee, subject to all the terms and provisions of the Stock Compensation Plan, as such Plan may be hereinafter amended, a copy of which is attached hereto and incorporated herein by this reference (the "Plan"), the right, privilege and option ("Option") to purchase 200,000 shares of its common stock ("Stock") at \$0.50 per share, in the manner and subject to the conditions provided hereinafter and in the Plan and any amendments thereto and any rules and regulations thereunder.
- 2. Vesting and Exercise of Option. The Optionee shall be vested in 12.5% of the total number of shares subject to the Option on January 1, 2009 and in the same proportion on the first date of each quarter until 100% of the shares are vested. Any exercise may be with respect to any part or all of the shares then vested and exercisable pursuant to such Option.
- 3. <u>Termination of Option</u>. Except as otherwise provided in this Agreement or the Plan, to the extent not previously exercised, the Option shall terminate upon the first to occur of any of the following events:
  - Five years from the date of the vesting of a particular tranche hereunder;
- b. the date the Optionee is no longer a member of the Board of Directors of the Company. Any vested Option granted hereunder to such Optionee to expire one year after the date of such termination. Any Option that has not vested in the Optionee as of the date of termination of service with the Company shall immediately expire and shall be null and void.
- c. 12 months after the date of the Optionee's death. The Option may be exercised (subject to the condition that no Option shall be exercisable after its expiration and only to the extent that the Optionee's right to exercise such Option was vested at the time of the Optionee's death) at any time within 12 months after the Optionee's death by the executors or administrators of the Optionee or by any person or persons who shall have acquired the Option directly from the Optionee by bequest or inheritance. Any Option that has not vested in the Optionee as of the date of death, shall immediately expire and shall be null and void.
  - d. the dissolution or liquidation of the Company; or
  - e. the breach by Optionee of any provision of the Plan or this Agreement.
- Method of Exercise. An Option shall be exercised by written notice to the Company by the Optionee (or successor in the event of death). Such written notice shall state the

The same

number of shares with respect to which the Option is being exercised and designate a time, during normal business hours of the Company, for the delivery thereof ("Exercise Date"), which time shall be at least ten days after the giving of such notice unless an earlier date shall have been mutually agreed upon. At the time specified in the written notice, the Company shall deliver to the Optionee at the principal office of the Company, or such other appropriate place as may be determined by the Board, a certificate or certificates for such shares. Notwithstanding the foregoing, the Company may postpone delivery of any certificate or certificates after notice of exercise for such reasonable period as may be required to comply with any applicable listing requirements of any securities exchange. In the event an Option shall be exercisable by any person other than the Optionee, the required notice under this Section shall be accompanied by appropriate proof of the right of such person to exercise the option. The option exercise price shall be payable in full on or before the option Exercise Date in any one of the following alternative forms:

- Full payment in cash or certified bank or cashier's check:
- b. A full recourse promissory note executed by the Optionee, made payable to the Company bearing interest at such rate as the Board shall determine, but in no case less than the "Applicable Federal Rate" at the time the note is executed applicable under the Code to obligations of the same duration. The note shall contain such terms and conditions as may be determined by the Board; provided, however, that the full principal amount of the note and all unpaid interest accrued thereon shall be due not later than five years from the date of exercise. The Company may obtain from the Optionee a security interest in all shares of Stock issued to the Optionee under the Plan for the purpose of securing payment under the note and shall retain possession of the stock certificates representing such shares in order to perfect its security interest;
- c. Full payment in shares of Stock or other securities of the Company having a fair market value on the Exercise Date in the amount equal to the option exercise price;
- d. A combination of the consideration set forth in Sections (a), (b) and (c) hereof equal to the option exercise price; or
- e. Any other method of payment including, but not limited to, the delivery by Optionee of an irrevocable direction to a securities broker approved by the Company to sell the Stock and to deliver all or part of the sales proceeds to the Company in payment of all or part of the exercise price and any withholding taxes.
- Restrictions on Exercise and Delivery. The exercise of each Option shall be subject to the condition that, if at any time the Board shall determine, in its sole and absolute discretion.
- a. the satisfaction of any withholding tax or other withholding liabilities, is necessary or desirable as a condition of, or in connection with, such exercise or the delivery or purchase of Stock pursuant thereto,



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- the listing, registration, or qualification of any shares deliverable upon such exercise is desirable or necessary, under any state or federal law, as a condition of, or in connection with, such exercise or the delivery or purchase of shares pursuant thereto, or
- the consent or approval of any regulatory body is necessary or desirable as a condition of, or in connection with, such exercise or the delivery or purchase of shares pursuant thereto,

then in any such event, such exercise shall not be effective unless such withholding, listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. Optionee shall execute such documents and take such other actions as are required by the Board to enable it to effect or obtain such withholding, listing, registration, qualification, consent or approval. Neither the Company nor any officer or member of the Board or the Committee, shall have any liability with respect to the non-issuance or failure to sell shares as the result of any suspensions of exercisability imposed pursuant to this Section.

- 6. Nonassignability. Options may not be sold, pledged, assigned or transferred in any manner other than by will or by the laws of intestate succession, and may be exercised during the lifetime of Optionee only by Optionee. Any transfer by Optionee of any Option granted under the Plan or this Agreement shall void such Option and the Company shall have no further obligation with respect to such Option. No Option shall be pledged or hypothecated in any way, nor shall any Option be subject to execution, attachment or similar process.
- Restrictive Legends. Each certificate evidencing the shares acquired upon exercise of an Option hereunder, including any certificate issued to any transferred thereof, shall be imprinted with legends substantially in the form set forth in the Plan.
- 8. <u>Rights as Shareholder</u>. Neither Optionee nor his executor, administrator, heirs or legatees, shall be, or have any rights or privileges of a shareholder of the Company in respect of the Stock unless and until certificates representing such Stock shall have been issued in Optionee's name.
- 9. No Right of Employment. Neither the grant nor exercise of any Option nor anything in the Plan or this Agreement shall impose upon the Company or any other corporation any obligation to employ or continue to employ any Optionee. The right of the Company and any other corporation to terminate any employee shall not be diminished or affected because an Option has been granted to such employee.
- Definitions. Capitalized terms shall have the meaning set forth in the Plan unless otherwise defined herein.
- 11. Notices. Any notice to be given under the terms of this Agreement shall be addressed to the Company in care of its Secretary at its principal office, and any notice to be given to Optionee shall be addressed to such Optionee at the address maintained by the Company for such person or at such other address as the Optionee may specify in writing to the Company.



- 12. <u>Binding Effect</u>. This Agreement shall be binding upon and inure to the benefit of Optionee, his heirs and successors, and of the Company, its successors and assigns.
- 13. <u>Governing Law.</u> This Agreement shall be governed by the laws of the State of Delaware.
- 14. Application of Plan. The Company has delivered and the Optionec hereby acknowledges receipt of a copy of the Plan. The parties agree and acknowledge that the Option granted hereunder is granted pursuant to the Plan and subject to the terms and provisions thereof, and the rights of the Optionee are subject to modifications and termination in certain events as provided in the Plan.

IN WITNESS WHEREOF, this Agreement is effective as of, and the date of grant shall be October 7, 2008.

LIXTE BIOTECHNOLOGY HOLDINGS, INC

Name John S. Kovach

Title: President

OPTIONEE

Mel Sorensen

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## LIXTE BIOTECHNOLOGY HOLDINGS, INC.

## OPTION CERTIFICATE

(Non-Incentive Stock Option)

THIS IS TO CERTIFY that Lixte Biotechnology Holdings, Inc., a Delaware corporation (the "Company"), has granted to Director named below ("Optionee") a non-incentive stock option (the "Option") to purchase shares of the Company's Common Stock (the "Shares") under its 2006 Stock Option Plan (the "Plan") and upon the terms and conditions set forth below and in the attached Stock Option Agreement:

Name of Optionee:	Mel Sorensen		
Address of Optionee:	7 Rapps Run Drive		
	Malvern, Pennsylvania 19355		
Number of Shares:	200,000		
Option Exercise Price:	\$.50	per share	
Date of Grant:	October 7, 2008		
Option Expiration Date:	Five years from date of vesting subject to		
	earlier termination as set forth in the Option		
	Agreement		

Exercise Schedule: The Option shall become exercisable ("vest") as follows:

Date	Number of Shares
January 1, 2009	25,000
April 1, 2009	25,000
July 1, 2009	25,000
October 1, 2009	25,000
January 1, 2010	25,000
April 1, 2010	25,000
July 1, 2010	25,000
October 1, 2010	25,000

In Witness Whereof, the Company has granted to Optionee the Option as of the Date of Grant set forth above.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

OPTIONEE

Mel Sorensen

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### Lixte Biotechnology Holdings, Inc. 248 Route 25A No. 2 East Setauket, New York 11733

Phone (631) 751-2882

File No. 2392-1

October 7, 2008

Dr. McI Sorensen 7 Rapps Run Drive Malvern, Pennsylvania 19355

Re: Director Stipend

Dear Mel:

We are delighted that you have agreed to join the Board of Directors of Lixte Biotechnology Holdings, Inc. This will confirm that, in addition to performing your customary duties as an outside member of the Company's Board of Directors, you have agreed to act in an advisory role in connection with strategic development of the Company's intellectual properties. In this connection, we have agreed to pay you the sum of \$40,000 payable in quarterly installments of \$10,000 commencing on October 7, 2008. At the sole discretion of the Company's Board of Directors, you may receive a bonus based on performance. The term of your engagement will be for a period of one year from the date hereof.

In addition you will be subject to the following provisions:

# Proprietary Rights and Nondisclosure and Nonuse of Confidential Information. Proprietary Rights and Nondisclosure and Nonuse of Confidential Output Description:

- 1.1 It is understood that during the term of this engagement, you may be exposed to information that is confidential and proprietary to the Company. All such information (hereinafter "Lixte Confidential Information"), whether written or oral, tangible or intangible, that is made available, disclosed, or otherwise made known to you by the Company or its employees under this letter shall be considered confidential and shall be considered the sole property of the Company. Lixte Confidential Information shall be (a) marked as confidential, or (b) otherwise represented by the disclosing party as confidential either before or within a reasonable time after its disclosure to the receiving party. This obligation of confidentiality shall remain in effect for a period of five (5) years after the expiration or termination of this letter.
- 1.2 The obligations of confidentiality set forth in Paragraph 1.1 shall not apply to any information that:



- is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation under this letter; or
- b. was already known to you as evidenced by prior written documents in your possession; or
- is disclosed to you by a third party who is not in default of any confidentiality obligation to the disclosing party hereunder; or
- d. is developed by or on behalf of you, without reliance on confidential information received hereunder as evidenced by written documents in your possession; or
- e. has been approved in writing by one party for publication by the other party; or
- f: is required to be disclosed in compliance with applicable laws or regulations.
- 2. Nonsolicitation; Nondisparagement. You acknowledge that during the course of your engagement by the Company, you have and will continue to have the opportunity to develop relationships with existing employees, clients, distributors, and prospective clients, and other business associates of the Company, which relationships constitute goodwill of the Company and that the Company would be irreparably damaged if you were to take actions that would damage or misappropriate such goodwill. You accordingly agree that during the period commencing on the date hereof and ending on the first anniversary of the conclusion of the term, you shall not, directly or indirectly, either for the benefit of yourself or any other person, do any of the following:
- Solicit any employee of the Company to terminate his employment with the Company, or employ any such individual during his employment with the Company and for a period of six months after such individual terminates his employment with the Company;
- Solicit any distributor or customer, or prospective distributor or customer, of the Company to terminate his relationship with the Company, or accept any business from any such distributor or customer, or prospective distributor or customer, of the Company; or
- c. Make any public statement, comment or remark that disparages the integrity or competence of a Company officer, director, employee, or shareholder, that disparages any product or service of the Company, or that is reasonably likely to cause injury to the relationships between the Company and any existing or prospective distributor, client, contractual counterparty, supplier, customer, employee, consultant or



Dr. Mel Sorensen October 7, 2008 Page 3

other business associate of the Company. Likewise, the Company agrees that it shall not make any public statement, comment or remark that disparages your integrity or competence.

If the forgoing is acceptable to you, please sign and return a copy of this agreement.

Very truly yours,

Lixte Biotechnology Holdings, Inc.

y: / pus

Agreed to:

Mel Sorensen

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## CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, John S. Kovach, certify that:
- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008 of Lixte Biotechnology Holdings, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and I have:
- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2008 By: /s/ JOHN S. KOVACH

John. S. Kovach

Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)

# CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008 (the "Quarterly Report") with the Securities and Exchange Commission, I, John S. Kovach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 12, 2008

By: /s/ JOHN S. KOVACH

John S. Kovach

Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)