CLEVELAND BIOLABS INC
Form 10-Q
November 15, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

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

For the transition period from ____ to ____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, New York	14203
(Address of principal executive offices)	(Zip Code)

(Registrant's telephone number, including area code) (716) 849-6810

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company þ

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

As of November 10, 2010, there were 27,451,840 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARY
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In this report, except as otherwise stated or the context otherwise requires, the terms “Cleveland BioLabs” and “CBLI” refer to Cleveland BioLabs, Inc., but not its consolidated subsidiary and ‘the Company,” “we,” “us” and “our” refer to Cleveland BioLabs, Inc. together with its consolidated subsidiary. Our common stock, par value $0.005 per share is referred to as “common stock.”

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

September 30, 2010 (unaudited) and December 31, 2009

	September 30 2010 (unaudited)	December 31 2009
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 6,411,805	$ 963,100
Accounts receivable:	2,955,238	3,391,347
Interest receivable	33,062	-
Other current assets	473,574	381,030
Total current assets	9,873,679	4,735,477
EQUIPMENT		
Computer equipment	368,013	323,961
Lab equipment	1,488,827	1,159,478
Furniture	387,905	376,882
	2,244,745	1,860,321
Less accumulated depreciation	1,285,834	995,408
	958,911	864,913
OTHER ASSETS		
Intellectual property	1,045,495	929,976
Deposits	32,129	23,482
	1,077,624	953,458
TOTAL ASSETS	$ 11,910,214	$ 6,553,848

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

September 30, 2010 (unaudited) and December 31, 2009

	September 30 2010 (unaudited)	December 31 2009
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 325,492	$ 1,208,632
Deferred revenue	16,852	2,329,616
Accrued expenses	400,318	1,405,715
Accrued warrant liability	18,837,766	8,410,379
Total current liabilities	19,580,428	13,354,342
LONG TERM LIABILITIES		
Deferred revenue	2,300,194	-
Total long term liabilities	2,300,194	-
STOCKHOLDERS' EQUITY		
Preferred stock, $.005 par value		
Authorized - 10,000,000 shares at September 30, 2010 and December 31, 2009		
Series D convertible preferred stock,		
Issued and outstanding 0 and 466.85		
shares at September 30, 2010 and December 31, 2009, respectively	-	2
Common stock, $.005 par value		
Authorized - 80,000,000 shares at September 30, 2010 and December 31, 2009, respectively		
Issued and outstanding 27,101,386 and 20,203,508		
shares at September 30, 2010 and December 31, 2009, respectively	135,507	101,018
Additional paid-in capital	69,274,716	62,786,418
Accumulated other comprehensive loss	(19,827)	-
Accumulated deficit	(82,694,896)	(69,687,932)
Total Cleveland BioLabs, Inc. stockholders' equity	(13,304,500)	(6,800,494)
Noncontrolling Interest in stockholders' equity	3,334,092	-
Total stockholders' equity	(9,970,408)	(6,800,494)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,910,214	$ 6,553,848

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF OPERATIONS

Three and Nine Months Ending September 30, 2010 and 2009 (unaudited)

	Three Months Ended		Nine Months Ended	
	September 30 2010 (unaudited)	September 30 2009 (unaudited)	September 30 2010 (unaudited)	September 30 2009 (unaudited)
REVENUES				
Grant and contract	$ 3,189,488	$ 3,223,094	$ 11,570,599	$ 9,717,803
	3,189,488	3,223,094	11,570,599	9,717,803
OPERATING EXPENSES				
Research and development	3,083,665	3,327,609	10,951,560	10,602,591
Selling, general and administrative	1,073,528	986,569	5,664,229	3,945,595
Total operating expenses	4,157,193	4,314,178	16,615,789	14,548,186
LOSS FROM OPERATIONS	(967,705)	(1,091,084)	(5,045,190)	(4,830,383)
OTHER INCOME				
Interest income	49,448	2,046	62,860	19,303
Sublease revenue	42,305	11,337	142,735	20,348
Total other income	91,753	13,383	205,595	39,651
OTHER EXPENSE				
Warrant issuance costs	-	-	231,980	266,970
Interest expense	-	-	-	1,960
Foreign exchange loss	1,339	-	1,339	-
Change in value of warrant liability	6,408,248	4,111,578	8,105,544	9,565,276
Total other expense	6,409,587	4,111,578	8,338,863	9,834,206
NET LOSS	$ (7,285,539)	$ (5,189,279)	$ (13,178,458)	$ (14,624,938)
LESS: (INCOME)/LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	82,246	-	171,494	-
NET LOSS ATTRIBUTABLE TO CLEVELAND BIOLABS, INC.	$ (7,203,293)	$ (5,189,279)	$ (13,006,964)	$ (14,624,938)
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	-	(123,900)	-	(615,352)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	(7,203,293)	(5,313,179)	(13,006,964)	(15,240,290)
	$ (0.27)	$ (0.33)	$ (0.51)	$ (1.00)

NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED				
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	26,984,059	15,878,331	25,756,300	15,184,785

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Period From January 1, 2009 to December 31, 2009 and to
September 30, 2010 (unaudited)

	Stockholders' Equity	
	Common Stock	
	Shares	Amount
Balance at January 1, 2009	13,775,805	$ 68,879
Issuance of options	-	-
Issuance of restricted shares	291,532	1,458
Recapture of expense for nonvested options forfeited	-	-
Restricted stock awards		-
Exercise of options	194,675	973
Conversion of Series B Preferred Shares to Common	4,693,530	23,468
Dividends on Series B Preferred Shares	-	-
Issuance of shares - Series D financing	-	-
Allocation of financing proceeds to fair value of Series D warrants	-	-
Fees associated with Series D Preferred offering	-	-
Conversion of Series D Preferred Shares to Common	572,353	2,862
Exercise of warrants	675,613	3,378
Net Loss	-	-
Balance at December 31, 2009	20,203,508	$ 101,018
Issuance of options	-	-
Issuance of shares	415,919	2,080
Recapture of expense for nonvested options forfeited	-	-
Restricted stock awards	-	-
Exercise of options	143,648	718
Issuance of shares - 2010 common stock equity offering	1,538,462	7,692
Allocation of financing proceeds to fair value of warrants	-	-
Fees associated with 2010 common stock equity offering	-	-
Conversion of Series D Preferred Shares to Common	4,576,979	22,885
Exercise of warrants	222,870	1,114
Noncontrolling interest capital contribution to Incuron, LLC	-	-
Net Loss	-	-
Other comprehensive income		
Foreign currency translation adjustment	-	-
Balance at September 30, 2010	27,101,386	$ 135,507

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Period From January 1, 2009 to December 31, 2009 and to
September 30, 2010 (unaudited)

	Stockholders' Equity			
	Preferred Stock			
	Series B	Amount	Series D	Amount
Balance at January 1, 2009	3,160,974	$ 15,805	-	$ -
Issuance of options	-	-	-	-
Issuance of restricted shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Conversion of Series B Preferred Shares to Common	(3,160,974)	(15,805)	-	-
Dividends on Series B Preferred Shares	-	-	-	-
Issuance of shares - Series D financing	-	-	543	3
Allocation of financing proceeds to fair value of Series D warrants	-	-	-	-
Fees associated with Series D Preferred offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	-	-	(76)	(1)
Exercise of warrants	-	-	-	-
Net Loss	-	-	-	-
Balance at December 31, 2009	-	$ -	467	$ 2
Issuance of options	-	-	-	-
Issuance of shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Issuance of shares - 2010 common stock equity offering	-	-	-	-
Allocation of financing proceeds to fair value of warrants	-	-	-	-
Fees associated with 2010 common stock equity offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	-	-	(467)	(2)
Exercise of warrants	-	-	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	-
Net Loss	-	-	-	-
Other comprehensive income				
Foreign currency translation adjustment	-	-	-	-
Balance at September 30, 2010	-	$ -	-	$ -

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Period From January 1, 2009 to December 31, 2009 and to
September 30, 2010 (unaudited)

	Stockholders' Equity				
	Additional Paid-in Capital	Other Comprehensive Income/(Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at January 1, 2009	$ 56,699,750	$ -	$ (56,246,172)	$ -	$ 538,261
Issuance of options	1,784,240	-	-	-	1,784,240
Issuance of restricted shares	991,612	-	-	-	993,070
Recapture of expense for nonvested options forfeited	(50,197)	-	-	-	(50,197)
Restricted stock awards	33,333	-	-	-	33,333
Exercise of options	361,884	-	-	-	362,857
Conversion of Series B Preferred Shares to Common	(7,663)	-	-	-	-
Dividends on Series B Preferred Shares	-	-	(615,351)	-	(615,351)
Issuance of shares - Series D financing	5,428,304	-	-	-	5,428,307
Allocation of financing proceeds to fair value of Series D warrants	(3,016,834)		-	-	(3,016,834)
Fees associated with Series D Preferred offering	(720,175)	-	-	-	(720,175)
Conversion of Series D Preferred Shares to Common	(2,861)	-	-	-	-
Exercise of warrants	1,285,026	-	-	-	1,288,404
Net Loss	-	-	(12,826,409)	-	(12,826,409)
Balance at December 31, 2009	$ 62,786,418	$ -	$ (69,687,932)	$ -	$ (6,800,494)
Issuance of options	2,340,457	-	-	-	2,340,457
Issuance of shares	1,440,135	-	-	-	1,442,215
Recapture of expense for nonvested options forfeited	(39,483)	-	-	-	(39,483)
Restricted stock awards	9,963	-	-	-	9,963
Exercise of options	263,361	-	-	-	264,079
Issuance of shares - 2010 common stock equity offering	4,992,310	-	-	-	5,000,002
Allocation of financing proceeds to fair value of warrants	(2,629,847)	-	-	-	(2,629,847)
Fees associated with 2010 common stock equity offering	(578,118)	-	-	-	(578,118)
Conversion of Series D Preferred Shares to Common	(22,883)	-	-	-	-

Exercise of warrants	712,403	-	-	-	713,517
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	3,509,402	3,509,402
Net Loss	-	-	(13,006,964)	(171,494)	(13,178,458)
Other comprehensive income					
Foreign currency translation adjustment	-	(19,827)	-	(3,816)	(23,643)
Balance at September 30, 2010	$ 69,274,716	$ (19,827)	$ (82,694,896)	$ 3,334,092	$ (9,970,408)

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Three and Nine Months Ended September 30, 2010 and 2009 (unaudited)

	Three Months Ended		Nine Months Ended	
	September 30 2010 (unaudited)	September 30 2009 (unaudited)	September 30 2010 (unaudited)	September 30 2009 (unaudited)
Net loss including noncontrolling interests	$ (7,285,539)	$ (5,189,279)	$ (13,178,458)	$ (14,624,938)
Other comprehensive income (loss) (net of income taxes)				
Foreign currency translation adjustment	95,947	-	(23,643)	-
Comprehensive income including noncontrolling interests	(7,189,592)	(5,189,279)	(13,202,101)	(14,624,938)
Comprehensive (income)/loss attributable to noncontrolling interests	66,759	-	175,310	-
Comprehensive Income (Loss) attributable to Cleveland BioLabs, Inc.	$ (7,122,833)	$ (5,189,279)	$ (13,026,791)	$ (14,624,938)

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2010 and 2009 (unaudited)

	September 30 2010 (unaudited)	September 30 2009 (unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (13,178,458)	$ (14,624,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	290,426	268,074
Amortization	10,801	-
Noncash salaries and consulting expense	3,753,152	2,113,965
Warrant issuance costs	231,980	266,970
Change in value of warrant liability	8,105,544	9,565,276
Loss on abandoned patents	-	23,984
Changes in operating assets and liabilities:		
Accounts receivable - trade	436,109	(1,679,406)
Interest receivable	(33,225)	9,488
Other current assets	(93,147)	90,423
Deposits	(8,689)	-
Accounts payable	(882,961)	176,326
Deferred revenue	(12,570)	967,983
Accrued expenses	(1,005,220)	(270,717)
Total adjustments	10,792,200	11,532,366
Net cash used in operating activities	(2,386,259)	(3,092,572)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of short-term investments	-	1,000,000
Purchase of equipment	(384,424)	(48,393)
Costs of patents pending	(127,074)	(151,555)
Net cash (used in) provided by investing activities	(511,499)	800,052
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of preferred stock	-	5,428,307
Financing costs on preferred stock	-	(720,175)
Issuance of common stock	5,000,002	-
Noncontrolling interest capital contribution to Incuron, LLC	3,509,402	-
Financing costs on common stock offering	(350,632)	-
Warrant issuance costs	(140,697)	(266,970)
Dividends	-	(936,644)
Exercise of options	264,079	285,747
Exercise of warrants	86,743	299,998
Net cash provided by financing activities	8,368,897	4,090,263

Effect of exchange rate change on cash and equivalents	(22,435)	-
INCREASE IN CASH AND EQUIVALENTS	5,448,705	1,797,743
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	963,100	299,849
CASH AND EQUIVALENTS AT END OF PERIOD	$ 6,411,805	$ 2,097,592

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2010 and 2009 (unaudited)

	September 30 2010 (unaudited)	September 30 2009 (unaudited)
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ -	$ 1,960
Cash paid during the period for income taxes	$ -	$ -
Supplemental schedule of noncash financing activities:		
Issuance of stock options to employees, consultants, and independent board members	$ 2,340,457	$ 1,527,719
Recapture of expense for nonvested options forfeited	$ (39,483)	$ (37,878)
Issuance of shares to consultants and employees	$ 1,442,214	$ 599,217
Amortization of restricted shares to be issued to employees and consultants	$ 9,963	$ 24,907
Conversion of warrant liability to equity due to exercise of warrants	$ 626,775	$ -
Noncash financing costs on common stock offering	$ 227,486	$ -
Noncash warrant issuance costs	$ 91,283	$ -
Conversion of preferred stock to common stock	$ 1,454,540	$ 19,114,136
Accrual of Series B preferred stock dividends	$ -	$ 615,351

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization

Cleveland BioLabs, Inc. ("CBLI") and its subsidiary (collectively, the "Company") is a biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on the concept of modulation of cell death for therapeutic benefit. CBLI was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York.

The consolidated financial statements include the accounts of CBLI's majority-owned, Russian subsidiary, Incuron, LLC ("Incuron") a limited liability company formed on January 31, 2010, in the Russian Federation. All intercompany balances and transactions have been eliminated in consolidation.

In May, 2010, CBLI contributed certain intellectual property rights to Incuron in exchange for an 83.9% membership interest. The minority partner, Bioprocess Capital Ventures ("BCV") contributed a total of 105,840,000 Russian rubles (approximately $3.4 million based on the current exchange rate) during April and June of 2010 in exchange for the remaining 16.1% membership interest. Incuron was formed to develop CBLI's curaxin technology for certain medical applications including oncology. The participation agreement between CBLI and BCV entered in December 2009 and amended in April 2010, requires (i) additional capital contributions in the amount of 69,730,000 Russian rubles (approximately $2.3 million based on the current exchange rate) by BCV and (ii) further contributions up to 373,927,000 Russian rubles (approximately $12.1 million based on the current exchange rate) by BCV contingent on the achievement of pre-determined scientific milestones and contingent contributions by CBLI to preserve CBLI's intended ultimate membership interest in Incuron of 50.1%. Incuron commenced operations in May 2010 and the results of its research and development efforts have been included in the Company's results of operations since that date.

The Company's financial statements have been prepared on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America, or GAAP, and on a going concern basis which contemplates the realization of assets and the liquidation of liabilities in the ordinary course of business. The Company has incurred substantial losses from operations which raises a question about its ability to continue as a going concern. The Company sustained a net loss of $13,006,964, for the nine months ended September 30, 2010 and $12,826,409 for the fiscal year ended December 31, 2009.

The Company continues to explore investment and licensing arrangements and plans to submit proposals for government contracts and grants over the next two years totaling over $10 million. The Company has two applications pending totaling nearly $52 million. Many of the proposals will be submitted to government agencies that have awarded contracts and grants to the Company in the recent past. Finally, the Company has implemented cost containment efforts that permit the incurrence of those costs that are properly funded, either through a government contract or grant or other capital sources. It is expected that the successful implementation of the financing and cost containment efforts identified above will allow the Company to continue to realize its assets and liquidate its liabilities in the ordinary course of business.

Note 2. Summary of Significant Accounting Policies

A. Basis of Presentation - The information at September 30, 2010 and for the three months and nine months ended September 30, 2010 and September 30, 2009, is unaudited. In the opinion of management, these financial statements have been prepared on a basis consistent with the Company's annual audited financial statements and

include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2009, which were contained in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC").

B. Cash and Equivalents - The Company considers highly liquid investments with a maturity date of three months or less to be cash equivalents. In addition, the Company maintains cash and equivalents at financial institutions, which may exceed federally insured amounts at times and which may, at times, significantly exceed balance sheet amounts due to outstanding checks. Included in cash equivalents are cash balances and certificates of deposits held by Incuron totaling $2,420,765 and $0 as of September 30, 2010 and December 31, 2009, respectively.

C. Marketable Securities and Short Term Investments - The Company considers investments with a maturity date of more than three months to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders' equity. The cost of available-for-sale securities sold is determined based on the specific identification method.

D. Accounts Receivable - The Company extends unsecured credit to customers under normal trade agreements and according to terms of government contracts and grants, which generally require payment within 30 days. Management estimates an allowance for doubtful accounts which is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There is no allowance for doubtful accounts as of September 30, 2010 and December 31, 2009.

E. Equipment - Equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Leasehold improvements are depreciated on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. Expenditures for maintenance and repairs are charged to expense as incurred. Major expenditures for renewals and betterments are capitalized and depreciated. Depreciation expense was $97,429 and $87,531 for the three months ended September 30, 2010 and 2009, respectively. Depreciation expense was $290,426 and $268,074 for the nine months ended September 30, 2010 and 2009, respectively.

F. Impairment of Long-Lived Assets - Long-lived assets to be held and used, including equipment and intangible assets subject to depreciation and amortization, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

G. Intellectual Property - The Company capitalizes the costs associated with the preparation, filing, and maintenance of patent applications relating to intellectual property. If the patent applications are approved, costs paid by the Company associated with the preparation, filing, and maintenance of the patents will be amortized on a straight-line basis over the shorter of 20 years from the initial application date or the anticipated useful life of the patent. If the patent application is not approved, the costs associated the patent application will be expensed as part of selling, general and administrative expenses at that time. Capitalized intellectual property is reviewed annually for impairment.

A portion of this intellectual property is owned by the Cleveland Clinic Foundation (“CCF”) and granted to the Company through an exclusive licensing agreement. As part of the licensing agreement, the Company agrees to bear the costs associated with the preparation, filing and maintenance of patent applications relating to this intellectual property. Gross capitalized patents and patents pending costs were $784,468 and $688,355 for eleven patent applications as of September 30, 2010 and December 31, 2009, respectively. Two of the CCF patent applications were approved by several nations and are amortized on a straight-line basis over the weighted average estimated remaining life of approximately fourteen years. The remainder of the CCF patent applications are still pending approval. The Company recognized $4,120, and $0 in amortization expense for the three months ended September 30, 2010 and 2009, respectively. The Company recognized $11,255, and $0 in amortization expense for the nine months ended September 30, 2010 and 2009, respectively.

The Company also has submitted patent applications as a result of intellectual property exclusively developed and owned by the Company. Gross capitalized patents pending costs were $222,715 and $199,371 for four patent applications as of September 30, 2010 and December 31, 2009, respectively. The patent applications are still pending approval.

The Company has also submitted two patent applications as a result of the collaborative research agreement with the Roswell Park Cancer Institute (“RPCI”). As part of this collaborative agreement, the Company agrees to bear the costs associated with the preparation, filing and maintenance of patent applications related to the intellectual property being

developed. Gross capitalized patents pending costs were $13,716 and $8,340 for two patent applications as of September 30, 2010 and December 31, 2009, respectively.

The Company has also submitted one patent application as a result of the collaborative research agreement with the ChemBridge Corporation ("ChemBridge"). As part of this collaborative agreement, the Company agrees to bear the costs associated with the preparation, filing and maintenance of patent applications related to the intellectual property being developed. Gross capitalized patents pending costs were $39,971 and $38,484 for this patent application as of September 30, 2010 and December 31, 2009, respectively.

Below is a summary of the major identifiable intangible assets and weighted average amortization periods for each identifiable asset:

	As of September 30, 2010			
Intangible Assets	Cost	Accumulated Amortization	Net Intangible Asset	Weighted Average Amortization Period (Years)
Patents	$ 239,015	$ 15,375	$ 223,640	14.2
Patent applications	821,855	-	821,855	n.a.
	$ 1,060,870	$ 15,375	$ 1,045,495	

The estimated amortization expense for the next five years for approved patents is as follows:

2010	$ 14,418
2011	$ 15,330
2012	$ 15,330
2013	$ 15,330
2014	$ 15,330

H. Line of Credit - The Company has a working capital line of credit that is fully secured by cash equivalents and short-term investments. This fully-secured, working capital line of credit carries an interest rate of prime minus 1%, a borrowing limit of $600,000, and will expire on May 31, 2011. At September 30, 2010 and December 31, 2009, there were no outstanding borrowings under this credit facility.

I. Accrued Warrant Liability – The Company issued warrants as part of the Series D Private Placement (as defined in Note 3) and as part of the 2010 Common Stock Equity Offering (as defined in Note 3). The warrants are accounted for as derivative instruments in accordance with the FASB Accounting Standards Codification on derivatives and hedging as the warrants are not indexed to the Company's stock and as the warrants contain a cashless exercise provision. The warrants are initially recorded as accrued warrant liabilities based on their fair values on the date of issuance. Subsequent changes in the value of the warrants are shown in the statement of operations as "Change in value of warrant liability."

The Series D Private Placement warrants carry a seven-year term and are exercisable for common shares of the Company at $1.60 per share. The Company has a balance in accrued warrant liability of $15,752,534 and $8,410,379 at September 30, 2010 and December 31, 2009 for these warrants, respectively.

The 2010 Common Stock Equity Offering warrants carry a five-year term and are exercisable six months after the grant date for common shares of the Company at $4.50 per share. The Company has a balance in accrued warrant liability of $3,085,232 and $0 at September 30, 2010 and December 31, 2009 for these warrants, respectively.

The remaining outstanding warrants that were not part of the Series D Private Placement or the 2010 Common Stock Equity Offering were treated as equity upon issuance and continue to be treated as equity since these remaining warrants do not contain any mandatory redemption features or other provisions that would require classifications of these warrant instruments outside of permanent equity. Furthermore, these warrants do not contain any contingent exercise provisions or anti-dilution provisions that impact the fixed-for-fixed option.

J. Foreign Currency Translation - The Company translates all assets and liabilities of its foreign subsidiary, where the U.S. dollar is not the functional currency, at the period-end exchange rate and translates income and expenses at the average exchange rates in effect during the period. The net effect of this translation is recorded in the consolidated financial statements as accumulated other comprehensive income (loss).

K. Fair Value of Financial Instruments - Financial instruments, including cash and equivalents, accounts receivable, accounts payable and accrued liabilities, are carried at net realizable value.

The Company values its financial instruments in accordance with the FASB Accounting Standards Codification on fair value measurements and disclosures which establishes a hierarchy for the inputs used to measure fair value. The fair value hierarchy prioritizes the valuation inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs in which little or no market data exists, therefore requiring a company to develop its own assumptions. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of September 30, 2010 and December 31, 2009.

The Company carries its Series D Private Placement warrants at fair value totaling $15,752,534 and $8,410,379 as of September 30, 2010 and December 31, 2009, respectively. The Company carries its 2010 Common Stock Equity Offering warrants at fair value totaling $3,085,232 and $0 as of September 30, 2010 and December 31, 2009, respectively. The Company used Level 3 inputs for valuation of the warrants, and their fair values were determined using the Black-Scholes option pricing model based on the following assumptions:

	Preferred D Warrant Value at September 30, 2010	2010 Offering Warrant Value at September 30, 2010
Stock price	$ 5.16	$ 5.16
Exercise price	$ 1.60	$ 4.50
Term in years	2.74	2.21
Volatility	104.20%	88.01%
Annual rate of quarterly dividends	-	-
Discount rate- bond equivalent yield	0.58%	0.47%

	Fair Value As of September 30, 2010	Fair Value Measurements at September 30, 2010 Using Fair Value Hierarchy		
Liabilities		Level 1	Level 2	Level 3
Series D Preferred Warrant liability	$ 15,752,534			$ 15,752,534
2010 Offering Warrant liability	$ 3,085,232			$ 3,085,232
Total	$ 18,837,766			$ 18,837,766

The following tables set forth a summary of changes in the fair value of the Company's Level 3 warrant liabilities using significant unobservable inputs for the three and nine months ended September 30, 2010 and 2009.

	For the Three Months Ended September 30, 2010		
	Series D Private Placement	2010 Common Stock Equity Offering	Total
Beginning balance	$ 10,741,246	$ 1,935,386	$ 12,676,632
Total gains or losses (realized/unrealized)			
Included in earnings as change in value of warrant liability	5,258,402	1,149,846	6,408,248
Purchases, issuances, sales and settlements, net	(247,114)	-	(247,114)
Ending balance	$ 15,752,534	$ 3,085,232	$ 18,837,766
The amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to	$ 5,175,293	$ 1,149,846	$ 6,325,139

assets still held at the reporting date			

	For the Three Months Ended September 30, 2009		
	Series D Private Placement	2010 Common Stock Equity Offering	Total
Beginning balance	$ 8,470,532	$ -	$ 8,470,532
Total gains or losses (realized/unrealized)			
Included in earnings as change in value of warrant liability	4,111,578	-	4,111,578
Purchases, issuances, sales and settlements, net	-	-	-
Ending balance	$ 12,582,110	$ -	$ 12,582,110
The amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	$ 4,111,578	$ -	$ 4,111,578

	For the Nine Months Ended September 30, 2010		
	Series D Private Placement	2010 Common Stock Equity Offering	Total
Beginning balance	$ 8,410,379	$ -	$ 8,410,379
Total gains or losses (realized/unrealized)			
Included in earnings as change in value of warrant liability	7,968,929	136,615	8,105,544
Purchases, issuances, sales and settlements, net	(626,774)	2,948,617	2,321,843
Ending balance	$ 15,752,534	$ 3,085,232	$ 18,837,766
The amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	$ 7,744,051	$ 136,615	$ 7,880,666

	For the Nine Months Ended September 30, 20009		
	Series D Private Placement	2010 Common Stock Equity Offering	Total
Beginning balance	$ -	$ -	$ -
Total gains or losses (realized/unrealized)			
Included in earnings as change in value of warrant liability	9,565,276	-	9,565,276
Purchases, issuances, sales and settlements, net	3,016,834	-	3,016,834
Ending balance	$ 12,582,110	$ -	$ 12,582,110
The amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	$ 9,565,276	$ -	$ 9,565,276

At March 31, 2010, the assumption for the expected term in years used to value the Series D Private Placement warrants was changed based on an analysis of warrant exercise activity for the twelve months since issuance. At the time the warrants were issued, an expected term of two years was established based on the expectation that the warrants would be exercised earlier in their term as the warrants were immediately exercisable at a price below the market price of the stock. At March 31, 2010, the Company determined that the safe harbor method for determining of the assumption relating to the expected term was more appropriate based on the limited exercise experienced to date. The safe harbor method calculates the expected term as one half of the remaining term of the warrants.

The Company recognized a fair value measurement loss of $5,258,402 and $4,111,578 on the Series D Private Placement warrants for the three months ended September 30, 2010 and 2009, respectively. The Company recognized a fair value measurement loss of $1,149,846 and $0 on the 2010 Common Stock Equity Offering warrants for the three months ended September 30, 2010 and 2009, respectively. In total, the Company recognized a fair value measurement loss of $6,408,248 and $4,111,578 for the three months ended September 30, 2010 and 2009, respectively.

The Company recognized a fair value measurement loss of $7,968,929 and $9,565,276 on the Series D Private Placement warrants for the nine months ended September 30, 2010 and 2009, respectively. The Company recognized a fair value measurement loss of $136,615 and $0 on the 2010 Common Stock Equity Offering warrants for the nine months ended September 30, 2010 and 2009, respectively. In total, the Company recognized a fair value measurement loss of $8,105,544 and $9,565,276 for the nine months ended September 30, 2010 and 2009 respectively.

The Company does not have any other non-recurring assets and liabilities that are required to be presented on the balance sheets at fair value.

L. Use of Estimates - The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under these circumstances. Actual results could differ from those estimates.

M. Revenue Recognition - Revenue sources consist of government grants, government contracts and commercial development contracts.

Revenues from government grants and contracts are for research and development purposes and are recognized in accordance with the terms of the award and the government agency. Grant revenue is recognized in one of two different ways depending on the grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized during the period that the costs were incurred according to the terms of the government grant. Fixed cost grants require no proof of costs at the time of invoicing, but proof is required for audit purposes and grant revenue is recognized during the period that the costs were incurred according to the terms of the government grant. The grant revenue under these fixed costs grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the government fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

Government contract revenue is recognized as allowable research and development expenses are incurred during the period and according to the terms of the government contract.

The Company recognizes revenue related to the funds received from the State of New York under the sponsored research agreement with the RPCI. This results in the recognition of revenue as allowable costs are incurred. The Company recognizes revenue on research laboratory services and the subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset and the prepaid asset is recognized as expense.

Commercial revenue is recognized when the service or development is delivered or upon complying with the relevant terms of the commercial agreement.

N. Deferred Revenue – Deferred revenue results when payment is received in advance of revenue being earned. The Company makes a determination as to whether the revenue has been earned by applying a percentage-of-completion analysis to compute the need to recognize deferred revenue. The percentage of completion method is based upon (1) the total income projected for the project at the time of completion and (2) the expenses incurred to date. The percentage-of-completion can be measured using the proportion of costs incurred versus the total estimated cost to complete the contract.

The Company received $2,000,000 in funds from the State of New York through RPCI during the second quarter of 2007. The Company received an additional $1,000,000 in funds from the State of New York through RPCI during the second quarter of 2008. The Company is recognizing this revenue over the terms and conditions of the sponsored research agreement. The Company recognizes revenue on research laboratory services and the purchase and subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset.

For the nine months ended September 30, 2010, the Company recognized $12,570 as revenue resulting in a balance of deferred revenue of $2,317,046 at September 30, 2010. At December 31, 2009, the balance in deferred revenue was $2,329,616. $2,300,194 is classified as long-term as of September 30, 2010, due to the schedule of collaborations planned over the life of the agreement.

O. Research and Development – Research and development expenses consist primarily of costs associated with salaries and related expenses for personnel, costs of materials used in research and development, costs of facilities and costs

incurred in connection with third-party collaboration efforts. Expenditures relating to research and development are expensed as incurred.

P. Equity Incentive Plan - On May 26, 2006, the Company's Board of Directors adopted the 2006 Equity Incentive Plan (“Plan”) to attract and retain persons eligible to participate in the Plan, motivate participants to achieve long-term Company goals and further align participants' interests with those of the Company's other stockholders. The Plan was to expire on May 26, 2016 and the aggregate number of shares of stock which could be delivered under the Plan may not exceed 2,000,000 shares. On February 14, 2007, these 2,000,000 shares were registered with the SEC by filing a Form S-8 registration statement. On April 29, 2008, the stockholders of the Company approved an amendment and restatement of the Plan (the “Amended Plan”) that clarified certain aspects of the Plan, contained updates that reflect changes and developments in federal tax laws and set the expiration date at April 29, 2018. On June 8, 2010, the stockholders of the Company approved an additional amendment to the Plan increasing the total shares that could be awarded under the Amended Plan to 7,000,000. As of September 30, 2010, there were 3,512,585 stock options and 753,451 shares granted under the Amended Plan and 122,332 shares forfeited leaving 2,856,296 shares of stock available to be awarded under the Amended Plan.

During the three months ended September 30, 2010, the Company issued 175,499 stock options and 40,054 shares of common stock for the following:

- 90,499 stock options issued to employees and consultants under the Company's incentive bonus plan.
- 80,000 stock options to two new employees as part of their compensation.
- 5,000 stock options to a consultant for payment of accounting services rendered.
- 36,635 shares of common stock to four consultants for payment of corporate strategy consulting services rendered. The shares were valued at $156,711.
- 3,419 shares of common stock to one consultant for payment of financial consulting services rendered. The shares were valued at $12,514

During the nine months ended September 30, 2010, the Company issued 1,021,932 stock options and 306,919 shares of common stock for the following:

- 230,932 stock options issued to employees and consultants under the Company's incentive bonus plan.
- 175,000 stock options to six new employees as part of their compensation.
- 46,000 stock options to two consultants for payment of corporate strategy consulting services rendered.
- 10,000 stock options to two consultants for payment of accounting services rendered.
- 140,000 stock options to outside board members as part of their compensation.
- 420,000 stock options to the executive management team for the 2009 executive compensation bonus plan.
- 59,717 shares of common stock to outside board members as part of their compensation. The shares were valued at $196,076.
- 181,379 shares of common stock to seven consultants for payment of corporate strategy consulting services rendered. The shares were valued at $663,595.
- 65,823 shares of common stock to four consultants for payment of financial consulting services rendered. The shares were valued at $238,137.

During the year ended December 31, 2009, the Company issued 787,932 stock options and 211,532 shares of common stock for the following:

- 452,932 stock options issued to employees and consultants under the Company's incentive bonus plan.
- 140,000 stock options to independent directors as part of their compensation as directors.
- 135,000 stock options to employees and consultants for a performance bonus.
- 60,000 stock options to a consultant for payment of investor relations services rendered.
- 103,484 shares of common stock to three consultants for payment of corporate strategy consulting services rendered. The shares were valued at $399,323.
- 78,048 shares of common stock to five consultants for payment of financial consulting services rendered. The shares were valued at $291,763.
- 30,000 shares of common stock to an employee for a performance bonus. The shares were valued at $99,900.

Q. Stock-Based Compensation - The Company recognizes and values employee stock-based compensation under the provisions of the FASB Accounting Standards Codification on stock compensation.

The fair value of each stock option granted is estimated on the grant date. The Black Scholes model is used for standard stock options, but if market conditions are present within the stock options, the Company utilizes Monte Carlo simulation to value the stock options. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. The Company uses a risk-free rate published by the St. Louis Federal Reserve at the time of the option grant, assumes a forfeiture rate of zero, assumes an expected dividend yield rate of zero based on the Company's intent not to issue a dividend in the foreseeable future, uses an

expected life based on the safe harbor method, and computes an expected volatility based on the volatility of similar high-growth, publicly-traded, biotechnology companies' common stock. In 2008, the Company began to include the use of its own stock in the volatility calculation and is layering in the volatility of the stock of the Company with that of comparable companies since there is not adequate trading history to rely solely on the volatility of the Company. The Company recognizes the fair value of share-based compensation in net income on a straight-line basis over the requisite service period.

During the three months ended September 30, 2010 and September 30, 2009, the Company granted 175,499 and 65,221 stock options, respectively. The Company recognized a total of $388,186 and $306,694 in expense related to stock options for the three months ended September 30, 2010 and September 30, 2009, respectively. The Company also recaptured $696 and $0 of previously recognized expense due to the forfeiture of non-vested stock options during the three months ended September 30, 2010 and September 30, 2009, respectively. The net expense for options for the three months ended September 30, 2010 and September 30, 2009 was $387,490 and $306,694, respectively.

During the nine months ended September 30, 2010 and September 30, 2009, the Company granted 1,021,932 and 723,276 stock options, respectively. The Company recognized a total of $1,332,457 and $1,527,719 in expense related to stock options for the nine months ended September 30, 2010 and September 30, 2009, respectively. The Company also recaptured $39,483 and $37,878 of previously recognized expense due to the forfeiture of non-vested stock options during the nine months ended September 30, 2010 and September 30, 2009, respectively. The Company also incurred an additional $37,800 of expense for stock options awarded under the 2009 Executive Compensation Plan. These options were originally expensed in 2009 based on the December 31, 2009 variables, but were not issued until May 18, 2010. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing an increase in the grant date fair value. This increase in the grant date fair value from $2.31 to $2.40 per share resulted in the incurrence of $37,800 in expense. The net expense for options for the nine months ended September 30, 2010 and September 30, 2009 was $1,330,774 and $1,489,841, respectively.

The assumptions used to value these option and grants using the Black-Scholes option valuation model are as follows:

	2010 YTD	2009
Risk-free interest rate	1.46-2.75%	1.87-2.74%
Expected dividend yield	0%	0%
Expected life	5-6 years	5-6 years
Expected volatility	84.23-89.55%	84.13-90.06%

The weighted average, estimated grant date fair values of stock options granted during the three months ended September 30, 2010 and September 30, 2009 were $2.59 and $1.76, respectively.

The following tables summarize the stock option activity for the nine months ended September 30, 2010 and September 30, 2009, respectively.

	Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2009	2,517,007	$ 5.46	
Granted	1,021,932	$ 3.45	
Exercised	143,648	$ 1.84	
Forfeited, Canceled	91,155	$ 7.10	
Outstanding, September 30, 2010	3,304,136	$ 4.95	8.01
Exercisable, September 30, 2010	2,962,511	$ 4.76	7.98

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2008	1,948,874	$ 6.17	
Granted	723,276	$ 2.72	
Exercised	149,534	$ 1.91	
Forfeited, Canceled	3,313	$ 4.00	
Outstanding, September 30, 2009	2,519,303	$ 5.43	8.22
Exercisable, September 30, 2009	2,161,153	$ 5.05	8.18

The Company recognized $169,224 and $95,375 in expense for shares issued under the Amended Plan during the three months ended September 30, 2010 and September 30, 2009, respectively. The Company issued a total of 40,054 shares and 25,772 shares during the three months ended September 30, 2010 and September 30, 2009, respectively. In addition, the Company recognized $3,333 and $8,333 in compensation expense related to the amortization of restricted shares during the three months ended September 30, 2010 and September 30, 2009, respectively.

The Company also recognized $1,442,215 and $599,217 in expense for shares issued under the Amended Plan during the nine months ended September 30, 2010 and September 30, 2009, respectively. The Company issued a total of 415,919 shares and 193,312 shares during the nine months ended September 30, 2010 and September 30, 2009, respectively. In addition, the Company recognized $9,963 and $24,907 in compensation expense related to the amortization of restricted shares during the nine months ended September 30, 2010 and September 30, 2009, respectively.

R. Income Taxes - No income tax expense was recorded for the nine months ended September 30, 2010, as the Company does not expect to have taxable income in 2010 and does not expect any current federal or state tax expense. A full valuation allowance has been recorded against the Company's deferred tax asset, which is primarily related to operating loss and tax credit carryforwards and accrued expenses.

S. Net Loss Per Share - Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period.

The following table presents the calculation of basic and diluted net loss per share for the three months and nine months ended September 30, 2010 and September 30, 2009:

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Net loss available to common stockholders	$ (7,203,293)	$ (5,313,179)	$ (13,006,964)	$ (15,240,289)
Net loss per share, basic and diluted	$ (0.27)	$ (0.33)	$ (0.51)	$ (1.00)
Weighted-average shares used in computing net	26,984,059	15,878,331	25,756,300	15,184,785

loss per share, basic and diluted	

The Company has excluded all outstanding preferred shares, warrants and options from the calculation of diluted net loss per share because all such securities are antidilutive for all periods presented.

The total number of shares excluded from the calculations of diluted net loss per share, prior to application of the treasury stock method is as follows:

Common Equivalent Securities	September 30, 2010	September 30, 2009
Preferred Shares	-	3,723,695
Warrants	9,745,046	8,939,528
Options	3,304,136	2,519,303
Total	13,049,182	15,182,526

T. Concentrations of Risk - Grant and contract revenue was comprised wholly from grants and contracts issued by federal and state governments and accounted for 100.0% total revenue for the nine months ended September 30, 2010 and September 30, 2009. Although the Company anticipates ongoing federal grant and contract revenue, there is no guarantee that this revenue stream will continue in the future.

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents and securities available-for-sale. The Company maintains deposits in federally insured institutions in excess of federally insured limits. The Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investment portfolio and maturities of investments, which are designed to meet safety and liquidity.

U. Foreign Currency Exchange Rate Risk - The Company has entered into a manufacturing agreement to produce one of its drug compounds with a foreign third party and is required to make payments in the foreign currency. As a result, the Company's financial results could be affected by changes in foreign currency exchange rates. Currently, the Company's exposure primarily exists with the Euro. As of September 30, 2010, the Company is obligated to make payments under the agreements of 1,470,709 Euros. As of September 30, 2010, the Company has purchased forward contracts for 751,344 Euros and, therefore, at September 30, 2010, had foreign currency commitments of $987,040 for Euros given prevailing currency exchange spot rates.

V. Comprehensive Income/(Loss) - The Company applies the FASB Accounting Standards Codification on comprehensive income that requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

W. Recently Issued Accounting Pronouncements – In January 2010, the Financial Accounting Standards Board ("FASB") issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures for each class of assets and liabilities rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update became effective for the Company with the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the Company with the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update did not have a material effect on the Company's financial statements.

In September 2009, the FASB provided updated guidance (1) on whether, in a revenue arrangement, multiple deliverables exist, how the deliverables should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis or by retrospective application. The adoption of this guidance did not materially impact the

Company's financial statements.

Note 3. Stock Transactions

See Note 2P – Equity Incentive Plan for stock transactions made under the Company's Equity Incentive Plan.

Series D Preferred Stock and Warrants and Related Adjustments

On February 2, 2009, the Company issued 75,000 restricted shares of common stock to designees of the placement agents in the Series D Preferred Stock offering.

On February 13, 2009, March 20, 2009, and March 27, 2009, the Company entered into Securities Purchase Agreements ("Purchase Agreements") with various accredited investors ("Purchasers"), pursuant to which the Company agreed to sell to the Purchasers an aggregate of 542.84 shares of Series D Convertible Preferred Stock, with a par value of $0.005 per share and a stated value of $10,000 per share ("Series D Preferred"), and Common Stock Purchase Warrants ("Series D Warrants") to purchase an aggregate of 3,877,386 shares of the Company's common stock, par value $0.005 per share ("Series D Private Placement"). The Series D Warrants have a seven-year term and an exercise price of $1.60. Each share of Series D Preferred was initially convertible into approximately 7,143 shares of common stock, subject to adjustment as described below.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the Series D Warrants was approximately $5,428,307 (representing $10,000 for each Series D Preferred together with a Series D Warrant). After related fees and expenses, the Company received net proceeds of approximately $4,460,000.

In consideration for its services as exclusive placement agent, Garden State Securities, Inc. received cash compensation and Series D Warrants to purchase an aggregate of approximately 387,736 shares of common stock. In the aggregate, Series D Preferred and Series D Warrants issued in the transaction were initially convertible into, and exercisable for, approximately 8,142,508 shares of common stock subject to adjustment as described below. Each share of Series D Preferred was initially convertible into a number of shares of common stock equal to the stated value of the share ($10,000), divided by $1.40 ("Conversion Price"), subject to adjustment as discussed below. As of February 9, 2010, all shares of Series D Preferred were converted into an aggregate of 4,576,979 shares of the Company's common stock, and no shares of Series D Preferred remained outstanding.

At the time of its issuance, the Series D Preferred ranked junior to the Company's Series B Convertible Preferred Stock and senior to all shares of common stock and other capital stock of the Company. The terms of the Series D Preferred provide that if the Company fails to meet certain milestones, the Conversion Price would, unless the closing price of the common stock was greater than $3.69 on the date the relevant milestone is missed, be reduced to 80% of the Conversion Price in effect on that date ("Milestone Adjustment"). As described further below, the first Milestone Adjustment became effective on December 31, 2009. In addition to the Milestone Adjustment, the conversion provision of the Series D Preferred provide for periodic adjustments to the Conversion Price beginning on August 13, 2009 (the "Initial Adjustment Date"), whereby the Conversion Price was reduced to 95% of the Conversion Price on the Initial Adjustment Date, and on each three month anniversary of the Initial Adjustment Date, the then Conversion Price is to be reduced by $0.05 (subject to adjustment) until maturity or converted as described below. The Conversion Price is also subject to proportional adjustment in the event of any stock split, stock dividend, reclassification or similar event with respect to the common stock and to anti-dilution adjustment in the event of any Dilutive Issuance as defined in the Certificate of Designation.

Immediately after the completion of the transactions contemplated by the Purchase Agreements, the conversion price of the Company's Series B Preferred was adjusted, pursuant to weighted-average anti-dilution provisions, to $4.67, causing the conversion rate of Series B Preferred into common stock to change to approximately 1-to-1.49893. In addition, the exercise prices of the Company's Series B Warrants and Series C Warrants were adjusted, pursuant to weighted-average anti-dilution provisions, to $6.79 and $7.20, from the original exercise prices of $10.36 and $11.00, respectively. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from $2.00 to $1.48. In addition to the adjustment to the exercise prices of the Series B Warrants and Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,609,261 and 408,032, from 2,365,528 and 267,074, respectively. For certain warrants issued prior to the Company's initial public offering, the aggregate number of shares of common stock issuable increased from 281,042 to 379,792.

The fair value of the 4,265,122 Series D Warrants issued with the Series D Private Placement was $3,016,834 and was computed using the Black-Scholes option pricing model using the following assumptions:

	Warrants Issued on February 13, 2009	Warrants Issued on March 20, 2009	Warrants Issued on March 27, 2009
Stock price (prior day close)	$ 2.95	$ 1.41	$ 2.44
Exercise price	$ 2.60	$ 1.60	$ 1.60
Term in years	2.00	2.00	2.00
Volatility	110.14%	108.87%	111.57%
Annual rate of quarterly dividends	-	-	-
Discount rate- bond equivalent yield	0.89%	0.87%	0.90%
Discount due to lack of marketability	40%	40%	40%

The Company recorded a 40% reduction in the calculated value as shown above as the shares of common stock into which the Series D Warrants were convertible were not registered on the date such warrants were issued. This 40% reduction was determined based on research that indicated that historical median and mean discounts for lack of marketability were approximately 25% and further research that indicated that impact of the 2008-2009 economic downturn warranted an increase in historical discounts for lack of marketability by an additional 11 to 27 basis points.

The value assigned to the warrants could not exceed the value of the gross proceeds at the issuance date of each tranche of the offering. As such, the value assigned to the warrants on the March 27, 2009 tranche of the Series D Private Placement was reduced to $789,000 which represents the gross proceeds from that tranche of the offering. In addition, since the Series D Preferred was convertible into shares of common stock, an embedded beneficial conversion feature existed. However, the beneficial conversion feature was considered a deemed dividend, and since the Company had an accumulated deficit, there was no effect on the statement of stockholders' equity.

On August 13, 2009, pursuant to the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, the Conversion Price of the Series D Preferred was automatically reduced from $1.40 to $1.33 ("Adjustment"). The Adjustment caused the number of shares of common stock into which the 542.84 outstanding shares of Series D Preferred could be converted to increase from 3,877,386 to 4,081,445. In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the Adjustment caused the exercise price of the Series B Warrants to decrease from $6.79 to $6.73, the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants to increase from 3,609,300 to 3,641,479, the exercise price of the Series C Warrants to decrease from $7.20 to $7.13 and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants to increase from 408,036 to 412,042. Certain other warrants issued prior to the Company's initial public offering were also affected by the Adjustment causing their exercise price to decrease from $1.48 to $1.47 and the aggregate number of shares of common stock issuable to increase from 343,537 to 345,855.

On October 26, 2009, the SEC declared effective a registration statement of the Company registering up to 4,366,381 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. This number represented 4,366,381 shares of common stock issuable upon the conversion or exercise of the securities issued in the Company's February and March 2009 private placement. Of these 4,366,381 shares of common stock, up to 3,863,848 shares were issuable upon conversion of Series D Preferred and up to 502,533 shares were issuable upon exercise of the Series D Warrants. The Company will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercised warrants for the underlying shares of common stock, the Company will receive the exercise price of those warrants unless the warrant holder exercises the warrants using the cashless provision. The registration statement was filed to satisfy registration rights that the Company had granted as part of the private placement. Since the securities are convertible into common shares and the underlying shares of common stock are freely tradable after conversion, the 40% reduction described above was eliminated when calculating fair market values of the Series D Warrants. Subsequent to the effectiveness of the registration statement and as of December 31, 2009, 13.4 Series D Preferred shares were converted into common stock and 71,429 Series D Warrants were exercised for common stock.

On November 13, 2009, the Conversion Price of the Series D Preferred automatically reduced from $1.33 to $1.28 ("Second Adjustment"). The Second Adjustment caused the number of shares of common stock into which the 470.25 outstanding shares of Series D Preferred could be converted to increase from 3,627,041 to 3,673,844. In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the Second Adjustment caused the exercise price of the Series B Warrants to decrease from $6.73 to $6.68, the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants to increase from 3,641,479 to 3,668,727, the exercise price of the Series C Warrants to decrease from $7.13 to $7.08 and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants to increase from 412,042 to 414,952. Certain

other warrants issued prior to the Company's initial public offering were also affected by the Second Adjustment causing their exercise price to decrease from $1.47 to $1.46 and the aggregate number of shares of common stock issuable to increase from 111,447 to 112,210.

On December 31, 2009, the conversion price of the Company's Series D Convertible Preferred Stock was reduced from $1.28 to $1.02. This reduction was the result of the Milestone Adjustment provided in the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred. This reduction caused the number of shares of common stock issuable upon conversion of the Series D Preferred to increase from 3,647,281 to 4,576,979 as of December 31, 2009. In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, this adjustment caused the exercise price of the Series B Warrants to decrease from $6.68 to $6.37, the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants to increase from 3,668,727 to 3,847,276, the exercise price of the Series C Warrants to decrease from $7.08 to $6.76 and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants to increase from 414,952 to 434,596. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from $1.46 to $1.39. For these warrants issued prior to the Company's initial public offering, the aggregate number of shares of common stock issuable increased from 112,210 to 117,861.

As a result of the satisfaction of certain conditions contained in Section 8(a) of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, filed with the Secretary of State of Delaware on February 13, 2009, including that the closing sale price of the Company's common stock on the NASDAQ Capital Market has exceeded 300% of the conversion price of the Series D Preferred ($1.02) for 20 consecutive trading days, on February 9, 2010, 466.85 shares of Series D Preferred, which represented all outstanding Series D Preferred, converted into 4,576,979 shares of common stock.

2010 Common Stock Equity Offering and Related Adjustments

On March 2, 2010, the Company issued 1,538,462 shares of common stock and Common Stock Purchase Warrants to purchase an aggregate of 1,015,385 shares of common stock, for an aggregate purchase price of $5,000,000. The Warrants are exercisable commencing six months following issuance and expire on March 2, 2015. The placement agent also received additional warrants to purchase 123,077 shares of common stock.

The fair value of the 1,138,462 Warrants issued with the 2010 Common Stock Equity Offering was $2,948,617 and was computed using the Black-Scholes option pricing model using the following assumptions:

	Warrants Issued on February 25, 2010
Stock price (prior day close)	$ 4.26
Exercise price	$ 4.50
Term in years	2.75
Volatility	104.01%
Annual rate of quarterly dividends	-
Discount rate- bond equivalent yield	1.28%

Immediately after the completion of the 2010 Common Stock Equity Offering, pursuant to weighted-average anti-dilution provisions of the Series B Warrants and Series C Warrants, the exercise price of the Company's Series B Warrants reduced from $6.37 to approximately $5.99, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants increased from 3,847,276 to approximately 4,091,345; and the exercise price of the Company's Series C Warrants reduced from $6.76 to approximately $6.35, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 434,596 to approximately 462,654.

Other Issuances

On January 1, 2010, the Company issued 34,000 shares of common stock to several consultants of the Company.

On January 4, 2010, the Company issued 70,000 shares of common stock to several consultants of the Company.

Note 4. Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the FDA and the first commercial sale of the Company's products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties.

The Company is also party to three agreements that require it to make milestone payments, royalties on net sales of the Company's products and payments on sublicense income received by the Company. As of September 30, 2010,

$350,000 in milestone payments have been made under one of these agreements. There are no milestone payments or royalties on net sales accrued for any of the three agreements as of September 30, 2010 and December 31, 2009.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending litigation or other material legal proceedings. From time to time in the ordinary course of business, the Company may be subject to claims brought against it. It is not possible to state the ultimate liability, if any, that could result to the Company as a result of these matters.

The Company currently has operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. The operating lease expenses recognized were $81,139 and $95,120 for the three months ended September 30, 2010 and September 30, 2009, respectively. The operating lease expenses recognized were $264,286 and $268,557 for the nine months ended September 30, 2010 and September 30, 2009, respectively.

Annual future minimum lease payments under present lease commitments are as follows:

	Operating Leases
2010 remaining quarter	$ 81,139
2011	315,342
2012	147,915
2013	3,540
	$ 547,937

The Company has entered into stock option agreements with key employees, board members and consultants with exercise prices ranging from $0.66 to $17.00. These awards were approved by the Company's Board of Directors. The options expire ten years from the date of grant except for 18,000 options that expire on December 31, 2012, subject to the terms applicable in the agreement.

The following tables summarize the stock option activity for the nine months ended September 30, 2010 and September 30, 2009:

	Options	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2009	2,517,007	$ 5.46
Granted	1,021,932	$ 3.45
Exercised	143,648	$ 1.84
Forfeited, Canceled	91,155	$ 7.10
Outstanding, September 30, 2010	3,304,136	$ 4.95

	Options	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2008	1,948,874	$ 6.17
Granted	723,276	$ 2.72
Exercised	149,534	$ 1.91
Forfeited, Canceled	3,313	$ 4.00
Outstanding, September 30, 2009	2,519,303	$ 5.43

The Company has entered into warrant agreements with strategic partners, consultants and investors with exercise prices ranging from $1.60 to $10.00. These awards were approved by the Company's Board of Directors. The warrants expire between five and seven years from the date of grant, subject to the terms applicable in the agreement. A list of the total warrants awarded and exercised appears below:

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	Warrants		Weighted Average Exercise Price Per Share	Number of Common Shares Exerciseable Into
Outstanding, December 31, 2009	6,956,673	$	3.71	8,641,893
Granted	1,138,461	$	4.50	1,138,461
Exercise Price Adjustment		$	(0.14)	272,127
Exercised	267,512	$	1.54	301,717
Forfeited, Canceled	3,973	$	1.39	5,718
Outstanding, September 30, 2010	7,823,649	$	3.90	9,745,046

	Warrants		Weighted Average Exercise Price Per Share	Number of Common Shares Exerciseable Into
Outstanding, December 31, 2008	3,453,268	$	8.86	3,453,268
Granted	4,265,122	$	1.20	4,265,122
Exercise Price Adjustment		$	(3.35)	1,522,007
Exercised	291,444	$	1.17	300,869
Forfeited, Canceled	-		n/a	-
Outstanding, September 30, 2009	7,426,946	$	3.59	8,939,528

The Company has entered into employment agreements with three key executives who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

The Company was awarded a $440,000 grant from the New York Empire State Certified Development Corporation. The award provides minimum employee levels required to receive the remainder of the award and contains provisions of recapture of monies paid if required employment levels are not maintained.

The Company is not currently a party to any pending material legal actions. From time to time in the ordinary course of business, the Company may be subject to claims brought against it.

Note 5. Subsequent Events

No material subsequent events have occurred since the balance sheet date of September 30, 2010.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our research and development, efforts and clinical trials, product demand, market acceptance and other factors discussed below and in our other SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2009. See also the Risk Factors discussed under Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2009. This management's discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this filing and in our Annual Report on Form 10-K for the year ended December 31, 2009.

OVERVIEW

Cleveland BioLabs, Inc. is a biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on the concept of modulation of cell death for therapeutic benefit. CBLI was incorporated in Delaware and commenced business operations in June 2003. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. Our pipeline includes products from two primary families of compounds: protectans and curaxins. We are developing protectans as drug candidates that protect healthy tissues from acute stresses such as radiation, chemotherapy and ischemia (pathologies that develop as a result of blocking blood flow to a part of the body). Curaxins are being developed by Incuron, our majority-owned, newly formed Russian subsidiary, as anticancer agents that could act as mono-therapy drugs or in combination with other existing anticancer therapies.

On July 20, 2006, we sold 1,700,000 shares of common stock, par value $0.005 per share, in our initial public offering at a per share price of $6.00. Our common stock is listed on the NASDAQ Capital Market under the symbol “CBLI.”

Technology

Our development efforts are based on discoveries made in connection with the investigation of the cell-level process known as apoptosis. Apoptosis is a highly specific and tightly regulated form of cell death that can occur in response to external events such as exposure to radiation, toxic chemicals or internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack and acute renal failure. Conversely, apoptosis is also an important protective mechanism that allows the body to shed itself of defective cells, which otherwise can cause cancerous growth.

Research has demonstrated that apoptosis is sometimes suppressed naturally. For example, most cancer cells develop resistance to apoptotic death caused by drugs or natural defenses of the human body. Our research is geared towards identifying the means by which apoptosis can be affected and manipulated depending on the need.

If the need is to protect healthy tissues against an external event such as exposure to radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the toxicities of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe toxicities of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

On the other hand, if the need is to destroy cancerous cells, we focus our research efforts on restoring apoptotic mechanisms that are suppressed in tumors, so that those cancerous cells will once again become vulnerable to apoptotic death. In this regard, we believe that our drug candidates could have significant potential for improving, and becoming vital to, the treatment of cancer patients.

Through our research and development ("R&D"), and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation.

We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans - modified factors of microbes that protect cells from apoptosis, and which therefore have a broad spectrum of potential applications. The potential applications include both non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment toxicities.

- Curaxins - small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including hormone-refractory prostate cancer, renal cell carcinoma ("RCC") (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

In the area of radiation protection, we have achieved high levels of protection in animal models. With respect to cancer treatment, the biology of cancer is such that there is no single drug that can be successfully used to treat a significant proportion of the large number of different cancers and there is wide variability in individual responses to most therapeutic agents. This means there is a continuing need for additional anticancer drugs for most cancers.

These drug candidates demonstrate the value of our scientific foundation. Based on the accelerated review and approval status currently available for drugs qualifying for Fast Track status, our most advanced drug candidate, Protectan CBLB502 may be approved for treatment of acute radiation syndrome within 18 - 24 months. Another drug candidate, Curaxin CBLC102, demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008. In November 2010, the first patient was dosed in a multi-center trial of Curaxin CBLC102 in patients with liver tumors in The Russian Federation.

STRATEGIES AND OBJECTIVES

Our primary objective is to become a leading developer of drugs for the protection of human tissues against radiation and other stresses and for cancer treatment. Key elements of our strategy include:

- Aggressively working towards the commercialization of Protectan CBLB502. Our most advanced drug candidate, Protectan CBLB502, offers the potential to protect normal tissues against exposure to radiation. Because CBLB502 demonstrates the potential to address an unmet medical need and is intended to treat a serious or life-threatening condition, CBLB502 has been granted Fast Track status by the U.S. Food and Drug Administration ("FDA"). The Fast Track designation will allow us to file a Biologic License Application ("BLA"), on a rolling basis and will allow the FDA to review the filing as it is received rather than waiting for the complete submission prior to commencing the review process. In addition, our BLA filing will be eligible for priority review, which could result in an abbreviated review time of six months. We expect to complete development of Protectan CBLB502 for treatment of acute radiation syndrome and initiate submission of the BLA with the FDA in 2011.

- Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic ("CCF"), one of the top research medical facilities in the world, is one of our co-founders. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute ("RPCI"), in Buffalo, New York. We have continued our research and development program that we initiated at CCF at RPCI and RPCI shares valuable expertise with us as developmental efforts are performed on our drug candidates. These partnerships will enhance the speed and efficiency of our clinical research and provide us with access to the state-of-the-art clinical development facilities of a globally recognized cancer research center.

- Utilizing governmental initiatives to target our markets. Our focus on drug candidates such as Protectan CBLB502, which has applications that have been deemed useful for military and defense purposes, provides us with a built-in market for our drug candidates. This enables us to invest less in costly retail and marketing resources. In an effort to improve our responsiveness to military and defense needs, we have established a collaborative relationship with the Department of Defense ("DoD"), and the Biomedical Advanced Research and Development Authority ("BARDA"), of the

Department of Health and Human Services ("HHS").

- Utilizing and developing other strategic relationships. We have collaborative relationships with other leading organizations that enhance our drug development and marketing efforts. For example, one of our founders, with whom we maintain a strategic partnership, is ChemBridge Corporation. Known for its medicinal chemistry expertise and synthetic capabilities, ChemBridge provides valuable resources to our drug development research including access to a chemical library of almost 2,000,000 compounds.

RESEARCH AND DEVELOPMENT

We are highly dependent on the success of our R&D efforts and, ultimately, upon regulatory approval and market acceptance of our products under development.

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with our R&D projects. As a result, the costs to complete such projects, as well as the period in which net cash outflows from such programs are expected to be incurred, may not be reasonably estimated. From our inception to September 30, 2010, we spent $68,539,954 on R&D.

Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. In addition, we have sustained losses from operations in each fiscal year since our inception in June 2003, and we may exhaust our financial resources and be unable to complete the development of our products due to the substantial investment in R&D that will be required for the next several years. We expect to spend substantial additional sums on the continued R&D of proprietary products and technologies with no certainty that losses will not increase or that we will ever become profitable as a result of these expenditures.

The testing, marketing and manufacturing of any product for use in the U.S. will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on the product’s potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

PRODUCTS IN DEVELOPMENT

Protectans

We are exploring a new natural source of factors that temporarily suppress the programmed cell death (apoptosis) response in human cells, which can be rapidly developed into therapeutic products. These inhibitors, known as protectans, are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian hosts. We have established a technological process for screening of these factors and their rapid preclinical evaluation. These inhibitors may be used as protection from cancer treatment toxicities and antidotes against injuries induced by radiation and other stresses associated with severe pathologies (i.e., heart attack or stroke).

We currently have issued patents and pending patent applications relating to nine sets of patent applications that were filed over the past seven years around various aspects and qualities of the protectan family of compounds. The first patent covering the method of protecting a mammal from radiation using flagellin or its derivatives was granted by the U.S. Patent and Trademark Office (US Patent No. 7,638,485 titled "Modulating Apoptosis") and the European Patent Office (European Publication Number FP 1706133, titled "Methods of Protecting Against Radiation Using Flagellin."). This patent was also granted by the nine member countries of the Eurasian Patent Organization and the

Ukraine and we have received a notice of allowance for this patent from the State Intellectual Property Office of the People's Republic of China. A second patent titled "Method of Protecting Against Apoptosis using Lipopeptides was granted by South Africa (Patent Number 2008/00126) and we have received an notice of intent to grant from the Eurasian Patent Organization. A second patent titled "Small Molecule Inhibitors of MRP1 and Other Multidrug Responders" was approved by several nations, not including the U.S and we have received a notice of intent to grant from the Eurasian Patent Organization. We believe that with the patent applications filed to date in the U.S. and internationally around various properties of protectan compounds, we have protected the potentially broad uses of our protectan technology. The patents belonging to the first patent family referenced above have a legal expiration date of December 1, 2024 and the patents belonging to the second patent family referenced above have a legal expiration date of June 12, 2026.

We spent approximately $13,738,983 and $8,995,500 on R&D for protectans for all applications in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $2,694,882 and $3,268,615, respectively. For the nine months ended September 30, 2010 and 2009, we spent $10,021,195 and $10,028,839, respectively. From our inception to September 30, 2010, we spent $50,268,677 on R&D for protectans.

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans family. Protectan CBLB502 represents a rationally designed derivative of the microbial protein, flagellin. Flagellin is secreted by Salmonella typhimurium and many other Gram-negative bacteria, and in nature, arranges itself in a hollow cylinder to form the filament in bacterial flagellum and acts as a natural activator of NF-kB (nuclear factor-kappa B), a protein complex widely used by cells as a regulator of genes that control cell proliferation and cell survival. Thus, Protectan CBLB502 reduces injury from acute stresses by mobilizing several natural cell protective mechanisms, including inhibition of apoptosis, reduction of oxidative damage and induction of factors (cytokines) that induce protection and regeneration of stem cells in bone marrow and the intestines.

Protectan CBLB502 is a single agent, anti-radiation therapy with demonstrated significant survival benefits at a single dose in animal models. Animal studies indicate that Protectan CBLB502 protects mice without increasing the risk of radiation-induced cancer development. The remarkably strong radioprotective abilities of Protectan CBLB502 are the result of a combination of several mechanisms of action. Potential applications for Protectan CBLB502 include reduction of radiation therapy or chemotherapy toxicities in cancer patients, protection from Acute Radiation Syndrome ("ARS"), in defense scenarios and protection from acute organ failure. Protectan CBLB502 is administered through intramuscular injection.

Six sets of patent applications have been filed for Protectan CBLB502, including two U.S. patent applications related to various aspects and properties for CBLB502 and related protectan compounds, including new methods of the use of flagellin derivatives and screening for new compounds with similar properties.

We spent approximately $13,732,416 and $8,021,040 on R&D for Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $2,869,779 and $3,267,201, respectively, on R&D for Protectan CBLB502. For the nine months ended September 30, 2010 and 2009, we spent $10,016,092 and $10,022,272, respectively, on R&D for Protectan CBLB502. From our inception to September 30, 2010, we spent $47,126,633 on R&D for Protectan CBLB502.

Non-medical Applications

Our scientists have demonstrated that injecting Protectan CBLB502 into mice, rats and non-human primates protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502, above any other radioprotectant known to us, is the ability to effectively protect not only the hematopoietic system, but also the gastrointestinal ("GI"), tract which is among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding or poor wound healing. GI damage often occurs at higher doses of radiation and may result in death through sepsis as a result of perforation of the GI tract. Protectan CBLB502's ability to effectively protect the hematopoietic system and GI tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. Protectan CBLB502 was shown to be safe at its therapeutic doses in rodents and non-human primates. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing, room temperature or extreme heat. Manufacturing of Protectan CBLB502 is cost efficient due to its high yield bacterial producing strain and simple purification process.

Protectan CBLB502 is being developed under the FDA's animal efficacy rule (21 C.F.R. § 314.610, drugs; § 601.91, biologics) to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accident. The animal efficacy rule creates a new regulatory paradigm for measuring efficacy by permitting the FDA to approve drugs and biologics for counterterrorism uses based on animal data when it is unethical or unfeasible to conduct human efficacy studies. Thus, this approval pathway requires demonstration of efficacy in at least one well-characterized animal model and safety and pharmacodynamics studies in animals and representative samples of healthy human volunteers to allow selection of an effective dose in humans. Protectan CBLB502 has demonstrated activity as a radioprotectant in several animal species, including non-human primates. Human safety, pharmacokinetic, pharmacodynamic and biomarker studies are the only stage of human testing required for approval in this indication.

We have successfully established current Good Manufacturing Practices ("cGMP"), quality manufacturing for Protectan CBLB502 and have completed two Phase I human safety studies for Protectan CBLB502 in ARS. The initial human Phase I safety and tolerability study involved single injections of Protectan CBLB502 in ascending-dose cohorts. The 50 participants in the study were assessed for adverse side effects over a 28-day time period and blood samples were obtained to assess the effects of Protectan CBLB502 on various biomarkers. Data from these subjects

indicates that Protectan CBLB502 was well tolerated and that normalized biomarker results corresponded to previously demonstrated activity in animal models of ARS. A pattern of biomarker production was observed consistent with those patterns seen in animals during mitigation of radiation-induced injury by dosing with Protectan CBLB502.

In January 2010, we began dosing in the second human safety study, a Phase Ib study, for CBLB502 and completed dosing in May 2010. This safety study included a total of 100 healthy volunteers randomized among four dosing regimens of CBLB502. Our goal is to complete the data analysis and filing of the final study report with the FDA in November 2010. Participants in the 100-subject study were assessed for adverse side effects and blood samples were obtained to assess the effects of CBLB502 on various biomarkers. The primary objectives of this study were to gather additional data on safety, pharmacokinetics, and cytokine biomarkers in a larger and broader subject population. Administration of CBLB502 resulted in a rapid and potent cytokine response, similar to that seen in the prior clinical trial and in previously conducted non-human primate studies. Single and double doses of CBLB502 were well tolerated. The primary adverse event associated with CBLB502 administration was a transient flu-like syndrome consistent with what was observed in the previous trial and which generally resolved within 24 hours. There was no difference in the adverse event profile between the doses tested. After determining an appropriate dose to take forward and determine the size of a definitive human safety study, we would then anticipate moving forward with a definitive safety study in a larger group of healthy human volunteers.

The Defense Threat Reduction Agency of the DoD awarded us a $1.3 million grant in March 2007, to fund “development leading to the acquisition” of Protectan CBLB502 as a radiation countermeasure, in collaboration with Armed Forces Radiobiology Research Institute, which has also received significant independent funding for work on Protectan CBLB502.

In March 2008, the DoD, awarded us a contract valued at up to $8.9 million over eighteen months through the Chemical Biological Medical Systems Joint Project Management Office Broad Agency Announcement ("BAA"), for selected tasks in the advanced development of Protectan CBLB502 as a Medical Radiation Countermeasure ("MRC"), to treat radiation injury following exposure to radiation from nuclear or radiological weapons (the “2008 DoD Contract”). The specific tasks include the completion by us of non-Good Laboratory Practices ("non-GLP") efficacy animal studies, Chemistry, Manufacturing and Controls ("CMC") tasks, in vitro and in vivo studies supporting CBLB502’s Investigational New Drug ("IND") application, definitive GLP efficacy studies, and drug formulation from single-dose vials within the timeframe of the contract. In September 2009, the DoD increased the funding under this contract by $0.6 million to $9.5 million to support bridging studies between lyophilized and liquid drug formulations. We successfully completed all tasks related to the 2008 DoD Contract by the contract end date of August 31, 2010.

As a government contract subject to the Federal Acquisition Regulation (“FAR”), pursuant to FAR 52.227-11 (Patent Rights – Ownership by the Contractor) we were permitted to retain title to any patentable invention or discovery made while performing the contract. However, no inventions were made by us during the performance of the 2008 DoD Contract. Had any inventions been made, the U.S. government would have received a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, pursuant to FAR 52.227-14 (Rights in Data – General), which was incorporated into the base 2008 DoD Contract and removed by the first amendment to the contract in June 2008, the U.S. government retains unlimited rights in the technical data produced between March and June 2008 in the performance of the 2008 DoD Contract.

In September 2008, we were awarded a $774,183 grant from the National Institute of Allergy and Infectious Diseases ("NIAID"), of the National Institutes of Health ("NIH"), to further study certain mitigating properties of Protectan CBLB502 in the context of hematopoietic damage from radiation exposure. In September 2009, NIAID awarded us an additional $458,512 for the continuation of the same grant.

In September 2008, BARDA awarded us a contract under the BAA titled, "Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation," for selected tasks in the advanced development of Protectan CBLB502. BARDA seeks to acquire developed medical countermeasures that will be clinically useful in a civilian medical emergency situation that results from or involves exposure of a large population to the effects of a nuclear detonation, a radiologic dispersive device (such as a dirty bomb), or exposure to radioactive material with or without combined injury or trauma.

The selected tasks in the Statement of Work include the following:

- Performing certain non-clinical experiments, including non-human primate experiments.
- Facilitating bone marrow transplantation in the rescue of irradiated mice by CBLB502 treatment.
- Performing stability studies of Good Manufacturing Practices-grade CBLB502 and conducting Phase II clinical trials.
- Submitting necessary regulatory documents to the BARDA and the FDA for approval.
- Planning, initiating and overseeing Phase II trials on healthy volunteers and drafting and finalizing the Phase II clinical reports and submitting such reports to the BARDA and the FDA.

The total contract value including all milestone-based options started at $13.3 million over a three-year period, with the first year's award of $3.4 million. In September 2009, BARDA increased the total contract value $2.3 million to

$15.6 million and awarded the first milestone option of $6.3 million. BARDA has since awarded the second, third and fourth milestone options under the contract for $1.47 million, $0.46 million and $4.14 million, respectively.

Pursuant to FAR 52.227-11, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject invention throughout the world. The U.S. government will also have unlimited rights in the data produced in the performance of the HHS Contract.

In September 2010, we were awarded a contract (the "2010 DoD Contract") by the Chemical Biological and Medical Systems ("CBMS") Medical Identification and Treatment Systems ("MITS") of the DoD for the advanced development and procurement of CBLB502 as a medical radiation countermeasure. The 2010 DoD Contract is valued at up to $45 million, including all options provided thereunder. Under the terms of the contract, CBMS-MITS will initiate funding of $14.8 million, including all options, for the advanced development of CBLB502 through the receipt of approval from the FDA. Selected tasks related to the advanced development of CBLB502 under the DoD contract include primarily conducting pilot animal model studies to support approval under the FDA animal rule. In addition, the 2010 DoD Contract includes options for the purchase of an aggregate of up to 37,500 troop-equivalent doses, in pre-determined increments, for $30,000,000. The 2010 DoD Contract requires us to provide the DoD with periodic status reports and to maintain, to the maximum extent possible, the employment of certain key personnel during the duration of the program.

Pursuant to FAR 52.227-11, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, pursuant to FAR 52.227-14 (Rights in Data – General) the U.S. government will also have unlimited rights in the technical data produced in the performance of the 2010 DoD Contract. Furthermore, the DoD has the right to terminate the 2010 DoD Contract at any time. In certain instances, the 2010 DoD Contract also limits our ability to engage in certain activities, such as subcontracting a portion of the work, without prior approval from the DoD.

The Project BioShield Act of 2004, which further expedites the approval of drug candidates for certain uses, is intended to bolster our nation's ability to provide protections and countermeasures against biological, chemical, radiological or nuclear agents that may be used in a military, terrorist or nuclear attack. This law also allows for the use of expedited peer review when assessing the merit of grants and contracts of up to $1,500,000 for countermeasure research. We have been awarded and successfully completed a $1,500,000 research grant pursuant to this law.

We spent approximately $13,676,289 and $7,264,813 on R&D for the non-medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $2,689,779 and $3,267,201, respectively, on R&D for the biodefense applications of Protectan CBLB502. For the nine months ended September 30, 2010 and 2009, we spent $10,016,092 and $9,966,145, respectively, on R&D for the biodefense applications of Protectan CBLB502. From our inception to September 30, 2010, we spent $45,293,577 on R&D for the biodefense applications of Protectan CBLB502.

Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and other countries / territories facing imminent nuclear and radiation threats. The HHS opportunity is particularly positive for us as the agency's mandate is to protect the U.S. civilian population in the event of a radiological emergency, including stockpiling radiation countermeasures for mass distribution. Our contract awards from the DoD and BARDA evidence the government's focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, Protectan CBLB502 should be well positioned to fulfill both of these needs, with its demonstrated unprecedented efficacy and survival benefits, unique ability to address both hematopoietic and GI damage, broad window of efficacy relative to radiation exposure and suitability for both military and civilian delivery scenarios. We believe that Protectan CBLB502 is the only radiation countermeasure with these capabilities in advanced development that can be self or buddy-administered, without the need of additional supportive care in a battlefield or civilian community setting.

We intend to enter into contracts to sell Protectan CBLB502 to various U.S. government agencies. Future sales to U.S. government agencies will depend, in part, on our ability to meet federal contract requirements and the existence and development of competitive compounds.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and cost efficient production of Protectan CBLB502 to date make it a primary candidate for clinical studies. Initially, Protectan CBLB502 will be developed for non-medical purposes — as a radioprotectant antidote for the protection of people with possible exposure to high doses of ionizing radiation. Our drug development strategy complies with the recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the approval of marketing an investigational drug, under the FDA rules, Protectan CBLB502 would be considered for approval for this indication based on Phase I safety studies in humans and efficacy studies in two animal species. Based upon this expedited approval process, Protectan CBLB502 could be approved for non-medical applications within 18 - 24 months. Because Phase II and Phase III testing involves applying a drug candidate to a large numbers of participants who suffer from the targeted disease and condition and can last for a total of anywhere from three to six or additional years, bypassing these phases represents a significant time and cost savings in receiving FDA approval.

As part of this expedited approval process, the FDA has indicated that it intends to engage in a highly interactive review of IND applications, New Drug Applications ("NDA") and BLA and to provide for accelerated review and licensure of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” status. The Fast Track program is designed to expedite the review of investigational drugs for the treatment of patients with serious or life-threatening diseases where there is an unmet medical need. Fast Track designations allow a company to file a NDA or BLA on a rolling basis and permits the FDA to review the filing as it is received, rather than waiting for the complete submission prior to commencing the review process. Additionally, NDAs and BLAs for fast track development programs are eligible for priority review, which may result in an abbreviated review time of six months. In July 2010, the FDA granted our application for Fast Track status in respect of CBLB502. Fast Track status will allow us to have additional interactions with the FDA, including extra in-person meetings and faster review of our BLA filing, which will expedite implementation of the CBLB502 development plan and preparation and approval of the BLA.

As part of the process to receive final FDA licensure for Protectan CBLB502 for non-medical applications, we have established cGMP compliant manufacturing of Protectan CBLB502. We were able to develop a complicated, high-yield manufacturing process for CBLB502 and prototype the process and resolve multiple challenges during the industrial development. We currently have drug substance corresponding to several hundred thousand projected human doses. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and if necessary, scale-up could be implemented relatively easily.

Prior to our submission for FDA licensure for Protectan CBLB502 for biodefense or non-medical applications, we will need to complete several interim steps, including:

- Conducting pivotal animal efficacy studies with the cGMP manufactured drug candidate under GLP - Good Laboratory Practices conditions. We expect to complete these studies in 2011. The studies have an approximate cost of $2,500,000 and are covered by a government development contract.

- Completing the analysis and reporting of the second Phase I safety study in 100 healthy human volunteers, which we expect to complete in November 2010. This study has an approximate cost of $1,400,000 and is covered by a government development contract .

- Performing a Phase II human safety study in a larger number of volunteers using the dose of Protectan CBLB502 previously shown to be safe in humans and efficacious in animals. We estimate completion of this study in 2011 at an approximate cost of $7,000,000 based on 500 subjects tested in four locations. This study is covered by a government development contract pending approval.

- Filing a BLA which we expect to initiate in 2011. At the present time, the costs of the filing cannot be approximated with any level of certainty.

Medical Applications

While our current focus remains on its non-medical applications, Protectan CBLB502 has been observed to dramatically increase the efficacy of radiotherapy of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve the overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received a placebo drug.

Protectan CBLB502 has demonstrated the ability to reduce the toxicities of a chemotherapeutic drug, cisplatin (Platinol), broadly used for the treatment of ovarian, endometrial, head and neck, lung, stomach and other types of cancer in animal models. Cisplatin treatment was used in the study as an example of chemotherapy-associated toxicity. Cisplatin injected at toxic doses is known to induce myelosuppression (suppression of bone marrow) and nephrotoxicity (kidney damage). The prospect of increasing patients' tolerance to chemotherapeutic drugs and optimizing treatment regimens would be a significant improvement in cancer treatment. It is estimated that approximately 40% of the roughly $50 billion annually spent on cancer treatment represents supportive care addressing toxicities of various treatments, including chemotherapy.

Consistent with this strategy, we plan to initiate a Phase I/II study for Protectan CBLB502 in head and neck cancer patients who are undergoing radiotherapy and radio-sensitizing chemotherapy in late 2010 / early 2011 for the medical

indication of CBLB502. The primary goal of this trial will be to demonstrate safety and tolerability of CBLB502 in cancer patients with a secondary goal of demonstrating potential efficacy of CBLB502 in a clinical setting. The primary endpoint of the study will be the reduction of toxicities of radiation and chemotherapy, such as mucositis (a painful inflammation and ulceration of oral mucosa causing difficulties with speaking and eating). Mucositis weakens the patient by not allowing for the oral intake of nutrients and fluids and forces the temporary suspension of radiotherapy and chemotherapy until the tissues of the mouth and throat have healed. Due to the ability of head and neck cancer cells to regrow during periods of interrupted treatment, any interruption in radiotherapy should be avoided. Since the main cause of treatment interruptions in radiotherapy or combinations of chemotherapy and radiotherapy treatment regimens of head and neck cancer is acute mucositis, the ability to prevent mucositis, and therefore, interruptions in treatment, could potentially result in better outcomes for patients with cancers of the head and neck.

In other studies, we have demonstrated the potential of Protectan CBLB502 to be applicable to ischemic conditions. Our researchers, in collaboration with investigators from CCF, have demonstrated that a single injection of Protectan CBLB502 effectively prevents acute renal failure and subsequent death in a mouse model of ischemia-reperfusion renal injury.

The DoD awarded a $1 million grant to CCF in 2008 to conduct pre-clinical studies on Protectan CBLB502 for use in tourniquet and other ligation-reperfusion battlefield injuries where blood flow is stopped and then restored after a prolonged period of time. These studies have demonstrated Protectan CBLB502's ability to accelerate limb recovery in an animal model of tourniquet-mediated injury simulating the situation occurring in human. It has been demonstrated that injection of Protectan CBLB502 within 30 minutes of tourniquet removal leads to a marked reduction in the severity of injury, including reductions in tissue edema, pro-inflammatory cytokine production and leukocyte infiltration leading to accelerated recovery of limb function.

In September 2009, we were awarded a $5.3 million Grand Opportunities research grant under the American Recovery and Reinvestment Act of 2009 from the Office of the Director of NIH and NIAID. The grant will fund studies of molecular mechanisms by which Protectan CBLB502 mitigates GI damage from radiation exposure.

In contrast to the non-medical applications of CBLB502, the use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

In order for us to receive final FDA licensure for Protectan CBLB502 for medical applications, we will need to complete various tasks, including:

- Submitting an amendment to our CBLB502 IND application and receiving allowance from the FDA. We expect to submit the amendment in 2010. We estimate that the approximate cost of filing will be less than $100,000 which is covered by a government grant.

- Performing a Phase I/II human efficacy study on a small number of head and neck cancer patients. We expect to complete this study two years from the receipt of allowance from the FDA of the IND amendment at an approximate cost of $1,500,000 which is covered by a government development grant.

- Performing an additional Phase II efficacy study on a larger number of cancer patients. At the present time, the costs and the scope of this study cannot be approximated with any level of certainty.

- Performing a Phase III human clinical study on a large number of cancer patients and filing a BLA with the FDA. At the present time, the costs and scope of these steps cannot be approximated with any level of certainty.

Four sets of patent applications have been filed for the medical applications for Protectan CBLB502.

We spent approximately $56,127 and $756,227 on R&D for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $0 on R&D for the medical applications of Protectan CBLB502. For the nine months ended September 30, 2010 and 2009, we spent $0 and $56,127, respectively, on R&D for the medical applications of Protectan CBLB502. From our inception to September 30, 2010, we spent $1,833,056 on R&D for the medical applications of Protectan CBLB502.

Protectan CBLB612

While the bulk of our R&D has focused on Protectan CBLB502, we have conducted some preliminary research into a compound derived from the same family and which we refer to as Protectan CBLB612. Protectan CBLB612 is a modified lipopeptide mycoplasma that acts as a powerful stimulator and mobilizer of hematopoietic (bone marrow/blood production) stem cells ("HSC"), to peripheral blood. Potential applications for Protectan CBLB612 include accelerated hematopoietic recovery during chemotherapy and during donor preparation for bone marrow transplantation.

Our research indicates that Protectan CBLB612 is not only a potent stimulator of bone marrow stem cells, but also causes their mobilization and proliferation throughout the blood. A single administration of Protectan CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. Furthermore, the number of these stem cells in peripheral blood was increased ten-fold within four days of administration.

Protectan CBLB612 was also found to be highly efficacious in stimulating proliferation and mobilization of hematopoietic stem cells into peripheral blood in a primate model (Rhesus macaques). A single injection of Protectan CBLB612 in Rhesus macaques resulted in a 20-fold increase of hematopoietic progenitor cells in blood. At the peak of the effect (48-72 hours post-injection) the proportion of free-floating CD34+ cells in the total white blood cell count reached 30% (compared with 1.5% in normal blood). CD34 is a molecule present on certain cells within the human body. Cells expressing CD34, otherwise known as CD34+ cells, are normally found in the umbilical cord and bone marrow as hematopoietic cells.

This discovery opens a new and innovative way for us to address a broad spectrum of human diseases, some of which currently lack effective treatment. Direct comparisons of Protectan CBLB612 and the market leading drug used for stimulation of blood regeneration, G-CSF (Neupogen® or Neulasta®, Amgen, Inc.), demonstrated a stronger efficacy of Protectan CBLB612 as a propagator and mobilizer of HSC in peripheral blood.

Protectan CBLB612's strength as a stem cell stimulator was further demonstrated by the outcome of its combined use with G-CSF and Mozibil (AMD3100) (an FDA approved stem cell mobilizer from Genzyme Corporation) where the addition of Protectan CBLB612 resulted in eight to ten times higher yields of HSC in peripheral blood in comparison with the standard protocol.

In addition to efficacy in stimulation and mobilization of stem cells in animal models, Protectan CBLB612 was found to be highly effective in an animal bone marrow stem cell transplantation model. Blood from healthy mice treated by Protectan CBLB612 was transplanted into mice that received a lethal dose of radiation that killed hematopoietic (bone marrow/blood production) stem cells. A small amount of blood from the Protectan CBLB612 treated mice successfully rescued the mice with radiation-induced bone marrow stem cell deficiency. 100% of the deficient mice transplanted with blood from CBLB612 treated mice survived past the 60-day mark, while 85% of the untreated deficient mice died within the first three weeks of the experiment. The 60-day mark is considered to be the critical point in defining the presence of long-term, adult bone marrow stem cells, which are capable of completely restoring lost or injured bone marrow function. The rescuing effect of the peripheral blood of the treated mice was equivalent to that of conventional bone marrow transplantation.

Adult hematological bone marrow stem cell transplantation is currently used for hematological disorders (malignant and non-malignant), as well as some non-hematological diseases, such as breast cancer, testicular cancer, neuroblastoma, ovarian cancer, Severe Combined Immune Deficiency, Wiskott-Aldrich syndrome and Chediak-Higashi syndrome.

With efficacy and non-GLP safety already studied in mice and monkeys, Protectan CBLB612 entered formal pre-clinical safety and manufacturing development in February 2008. Further development of CBLB612 will continue upon achieving sufficient funding for completing pre-clinical development and a Phase I study. Development of Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the DoD.

Two sets of patent applications have been filed for Protectan CBLB612. One patent application, entitled “Methods of Protecting Against Apoptosis Using Lipopeptides” received a notice of grant of patent by South Africa (Patent Number 2008/00126) and a notice of intent to grant patent from the Eurasian Patent Organization ("EAPO"), which includes the Russian Federation and eight other member countries.

In September 2009, we executed a license agreement granting Zhejiang Hisun Pharmaceutical Co. Ltd. ("Hisun"), a leading pharmaceutical manufacturer in the People's Republic of China exclusive rights to develop and commercialize Protectan CBLB612 in China, Taiwan, Hong Kong and Macau. Under the terms of the license agreement, we received product development payments of $1.65 million for protectan research (including Protectan CBLB502). Hisun will be responsible for all development and regulatory approval efforts for Protectan CBLB612 in China. In addition, Hisun will pay us a 10% royalty on net sales over the 20-year term of the agreement. This royalty may decrease to 5% of net sales only in the event that patents for CBLB612 are not granted. We retain all rights to CBLB612 in the rest of the world.

In order for us to receive final FDA approval for Protectan CBLB612, we need to complete several interim steps, including:

- Conducting pivotal animal safety studies with cGMP-manufactured CBLB612;
- Submitting an IND application and receiving approval from the FDA to conduct clinical trials;
- Performing a Phase I dose-escalation human study;

- Performing Phase II and Phase III human efficacy studies using the dose of CBLB612 selected from the previous studies previously shown to be safe in humans and efficacious in animals; and
- Filing a New Drug Application.

Because of the uncertainties of the scope of the remaining clinical studies, we cannot currently estimate when any development efforts may be completed or the cost of completion. Nor can we estimate when we may realize any cash flow from the development of Protectan CBLB612.

We spent approximately $6,567 and $974,459 on R&D for Protectan CBLB612 in the fiscal years ended December 31, 2009 and December 31, 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $5,103 and $1,414, respectively, on R&D for Protectan CBLB612. For the nine months ended September 30, 2010 and 2009, we spent $5,103 and $6,567, respectively, on R&D for Protectan CBLB612. From our inception to September 30, 2010, we spent $3,142,044 on R&D for Protectan CBLB612. Further development and extensive testing will be required to determine its technical feasibility and commercial viability.

Curaxins

Curaxins are small molecules that are intended to destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that curaxins may be effective against a number of malignancies, including RCC, soft-tissue sarcoma, and hormone-refractory prostate cancer.

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. The work of our founders has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

One of the most important outcomes of this drug discovery program was the identification of the mechanism by which curaxins deactivate NF-kB. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF-kB not only in its stimulated form, but also in its basal form. The level of active NF-kB is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF-kB-DNA complexes, the cells with the highest basal or induced NF-kB activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF-kB by curaxins more advantageous compared to conventional strategies targeting NF-kB activators.

The discovery of the mechanism of action of curaxins allowed us to predict and later experimentally verify that curaxins could be used for treatment of multiple forms of cancers, including hormone-refractory prostate cancer, hepatocellular carcinoma, multiple myeloma, acute lymphocytic leukemia, acute myeloid leukemia, soft-tissue sarcomas and several others.

A significant milestone in the curaxin program was achieved with a breakthrough in deciphering the finer details of the mechanism of action of these compounds. Successful identification of the exact cellular moiety that binds to curaxins has provided a mechanistic explanation for the unprecedented ability of these compounds to simultaneously target several signal transduction pathways.

This additional mechanistic knowledge enabled us to discover additional advantages of curaxins and to rationally design treatment regimens and drug combinations, which have since been validated in experimental models. In addition, this understanding further strengthens our intellectual property position for this exciting class of principally new anticancer drugs.

In July 2010, a discovery regarding potential antiviral applications for our curaxin family of molecules was pre-published online in the Journal of Virology, the world's leading peer-reviewed journal in the field of virology (Gasparian, Neznanov, et al., Journal of Virology, doi:10.1128/JVI.02569-09; July 14, 2010).

The published study, conducted by our scientists in cooperation with investigators from RPCI and Cleveland State University, examined the ability of the Company's prototype Curaxin CBLC102, or quinacrine, and other similar compounds to inhibit a mechanism used by picornaviruses to synthesize their proteins that is essential for their viability. This group of viruses includes important human pathogens such as poliovirus. In particular, the specific interaction of curaxins with double-stranded RNA effectively blocks synthesis of viral, but not cellular proteins. This study provides proof of principle for the prospective extension of curaxins from anticancer to antiviral applications.

Nine sets of patent applications have been filed around the curaxin family of compounds.

We spent approximately $592,690 and $3,233,872 on R&D for curaxins overall in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $324,427 and $58,994 respectively on R&D for curaxins. For the nine months ended September 30, 2010 and 2009, we spent $728,888 and $573,753 respectively on R&D for curaxins. From our inception to September 30, 2010, we spent $12,963,170 on R&D for curaxins.

In December 2009, we entered into our Incuron joint venture with Bioprocess Capital Ventures ("BCV"), a Russian Federation venture capital fund, to develop our curaxin compounds for cancer, liver, viral and age related disease applications. According to the terms of the agreement, we transferred the aforementioned rights of curaxin molecules to the new joint venture, and BCV will contribute an aggregate of 549,497,000 Russian rubles (approximately $17.8 million based on the current exchange rate) to support development of the compounds. BCV made the first payments of 105,840,000 Russian rubles (approximately $3.4 million based on the current exchange rate) during April and June of 2010. Pursuant to the participation agreement, as amended, BCV will make an additional payment of 69,730,000 Russian rubles (approximately $2.3 million based on the current exchange rate) as part of its initial contribution. BCV will make the balance of its contribution upon the achievement of predetermined development milestones. The first milestone payment of 192,737,000 Russian rubles (approximately $6.4 million based on the current exchange rate) will be made upon approval to begin clinical trials on oncology patients with a selected lead curaxin compound, or upon progression of a clinical program of CBLC102. The second milestone payment of 181,190,000 Russian rubles (approximately $6.0 million based on the current exchange rate) will be made upon completion of at least one Phase I/II trial in cancer patients. Although it is anticipated that we will ultimately own 50.1% of the membership interest in Incuron, depending on the U.S. dollar/Russian ruble exchange rate and the U.S. dollar-equivalent value of the aggregate contributions made by BCV, we may be required to either transfer a portion of its ownership interest to BCV or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to BCV, we may ultimately own less than 50.1% of the membership interest of Incuron, but will retain the right to appoint a majority of the members of the board of directors of Incuron. We serve as a subcontractor to Incuron to support certain mechanistic studies and oversee clinical development in the U.S.

Curaxin CBLC102

One of the curaxins from the 9-aminoacridine group is a long-known, anti-infective compound known as quinacrine, which we refer to as Curaxin CBLC102. It has been used for over 40 years to treat malaria, osteoarthritis and autoimmune disorders. However, we have discovered new mechanisms of action for quinacrine in the area of apoptosis. Through assay testing performed at Dr. Andrei Gudkov’s laboratories at CCF beginning in 2002, which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin (including RCC, sarcomas, prostate, breast and colon carcinomas), we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. As published in Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161), it has now been shown that treatment of cancer cells with CBLC102 results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target. Finally, CBLC102 has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates.

We launched a Phase II study with CBLC102 in January 2007 to provide proof of safety and of anti-neoplastic activity in cancer patients and establish a foundation for clinical trials of our new proprietary curaxin molecules, which have been designed and optimized for maximum anticancer effects, as well as for additional treatment regimens based on ongoing research into the precise molecular mechanisms of action of curaxins. Thirty-one patients were enrolled in the Phase II study of CBLC102 as a monotherapy in late stage, hormone-refractory taxane-resistant prostate cancer. All patients had previously received hormonal treatment for advanced prostate cancer and 28 of the 31 had

also previously received chemotherapy. One patient had a partial response, while 50% of the patients exhibited a decrease or stabilization in PSA velocity, a measure of the speed of prostate cancer progression. CBLC102 was well tolerated and there were no serious adverse events attributed to the drug. The trial demonstrated indications of activity and a remarkable safety profile in one of the most difficult groups of cancer patients.

The indications of activity and remarkable safety demonstrated in the CBLC102 Phase II trial, in conjunction with new mechanistic discoveries, point to additional potential treatment paradigms including combination therapies with existing drugs or prospective use as a cancer prevention agent. Additional potential uses for CBLC102 will be explored in conjunction with our strategic partners at RPCI and through the Incuron joint venture.

In November 2010, the first patient was dosed in a multi-center clinical trial of CBLC102 on patients with liver tumors in the Russian Federation. The study is an open-label, dose escalation, Phase 1b safety and tolerability study in patients with liver metastases of solid tumors of epithelial origin, or primary advanced hepatic carcinoma for which standard therapy has failed or does not exist. The primary objective of the study is to determine the maximum tolerated dose and dose limiting toxicity in patients receiving CBLC102. Secondary objectives of the study include describing the safety profile, pharmacokinetics, and response to CBLC102.

The study includes a dose escalation arm of up to 30 patients divided into five cohorts, with an additional six patients to be enrolled at the selected therapeutic dose. Patients will be treated with CBLC102 for eight weeks, with a loading dose administered in week 1 and maintenance doses administered in weeks 2-8. Dose escalation will be done gradually, starting with a loading dose of 300mg and a maintenance dose of 100mg. Recruitment is anticipated to take approximately six months, with overall duration of the study to last approximately 12 months.

The lead center for the study is the Russian Oncological Scientific Center ("ROSC") in Moscow, a leading oncology center in Russia. The national coordinator for the study is Professor S.A. Tyulyandin, MD, D.Sc., Deputy Director of Clinical Oncology and Director of Clinical Pharmacology and Chemotherapy at ROSC. Dr. Tyulyandin is one of the leading experts in drug therapy of malignant tumors in Russia and is considered a recognized expert on chemotherapy. Complex methods for the treatment of malignant neoplasms of the testes, and breast, ovarian and other tumors have been developed under his leadership.

New insights into the mechanism of action of Curaxin CBLC102 were published in one of the world's leading cancer journals, Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161). The published study uncovered additional molecular mechanisms underlying the anticancer activity of CBLC102, which was previously known to involve simultaneous targeting of two key regulators of the controlled cell death process (p53 and NF-kB). It has now been shown that treatment of cancer cells with CBLC102 results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target.

Another breakthrough discovery related to the mechanism of action of CBLC102 was published in an international health science journal, Cell Cycle (Neznanov et al., Cell Cycle 8:23, 1-11; December 1, 2009). This study examined the ability of CBLC102 to inhibit heat shock response, a major adaptive pro-survival pathway that rescues cells from stressful conditions involving accumulation of misfolded proteins (known as proteotoxic stress). Tumor cells typically become dependent on constitutive activity of this salvaging mechanism making them selectively susceptible to its inhibitors, especially if applied in combination with certain cancer therapies provoking proteotoxic stress.

The potential use of curaxins as adjuvants to cancer therapies inducing proteotoxic stress, such as bortezomib (Velcade(R)) or thermotherapy, opens a whole new avenue of potential treatment options that may broaden the spectrum of responding tumors by cutting off an escape mechanism.

Three sets of patent applications have been filed for Curaxin CBLC102.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for FDA licensure. Because of the uncertainties of the scope of the remaining clinical studies, we cannot currently estimate when any development efforts may be completed or the cost of completion. Nor can we estimate when we may realize any cash flow from the development of Curaxin CBLC102.

We spent approximately $262,637 and $1,741,194 on R&D for Curaxin CBLC102 in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $86,131 and $34,074, respectively, on R&D for Curaxin CBLC102. For the nine months ended September 30, 2010 and 2009, we spent $288,061 and $252,209, respectively, on R&D for Curaxin CBLC102. From our inception to September 30, 2010, we spent $7,017,180 on R&D for Curaxin CBLC102.

Other Curaxins

As mentioned above, screening of the chemical library for compounds capable of restoring normal function to wild type p53 in the context of RCC yielded three chemical classes of compounds. Generation of focused chemical libraries around the hits from one of these classes and their structure-activity optimization brought about a new

generation of curaxins. As the part of this program performed in the partnership with ChemBridge Corporation, more than 800 proprietary compounds were screened for p53 activation, efficacy in animal tumor models, selective toxicity and metabolic stability in the presence of rat and human microsomes. The most active compounds were efficacious in preventing tumor growth in models for colon carcinoma, melanoma, ovarian cancer, RCC, and breast cancer.

As a result of this comprehensive hit-to-lead optimization program, we have developed CBLC137, which is a drug candidate with proprietary composition of matter belonging to our next generation of highly improved curaxins. CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. CBLC137 has favorable pharmacological characteristics, is suitable for oral administration and demonstrates a complete lack of genotoxicity. It shares all of the positive aspects of CBLC102, but significantly exceeds the former compound's activity and efficacy in preclinical tumor models. Further development of CBLC137 will continue through the Incuron joint venture.

Six sets of patent applications have been filed for other curaxins.

We spent approximately $330,053 and $1,492,678 on R&D for other curaxins in the fiscal years ended December 31, 2009 and 2008, respectively. For the quarters ended September 30, 2010 and 2009, we spent $238,296 and $24,920, respectively, on R&D for other curaxins. For the nine months ended September 30, 2010 and 2009, we spent $440,827 and $321,544, respectively, on R&D for other curaxins. From our inception to September 30, 2010, we spent $5,945,990 on R&D for other curaxins.

CBLC137 is at a very early stage of its development and, as a result, it is premature to estimate when any development may be completed, the cost of development or when any cash flow could be realized from development.

FINANCIAL OVERVIEW

Including several non-cash charges, our net loss increased from $5,189,279 for the three months ended September 30, 2009 to $7,285,539 for the three months ended September 30, 2010, an increase of $2,096,260 or 40.4%. We incurred non-cash charges of depreciation and amortization of $101,549 and $87,531, non-cash salaries and consulting fees of $560,048 and $410,402 and a change in the value of warrants of $6,408,248 and $4,111,578 for the three months ended September 30, 2010 and 2009, respectively. Excluding these non-cash charges, our net loss decreased $364,074 or 62.8% from $579,768 for the three months ended September 30, 2009 to $215,694 for the three months ended September 30, 2010. This decrease was due to lower R&D costs.

Including several non-cash charges, our net loss decreased from $14,624,938 for the nine months ended September 30, 2009 to $13,178,458 for the nine months ended September 30, 2010, a decrease of $1,446,480 or 9.9%. We incurred non-cash charges of depreciation and amortization of $301,227 and $268,074, non-cash salaries and consulting fees of $2,782,951 and $2,113,965 and a change in the value of warrants of $8,105,544 and $9,565,276 for the nine months ended September 30, 2010 and 2009, respectively. Excluding these non-cash charges, our net loss decreased $688,887 or 25.7% from $2,677,623 for the nine months ended September 30, 2009 to $1,988,736 for the nine months ended September 30, 2010. This decrease was due to increased government funding and our cost containment efforts that include incurring R&D costs that are predominantly supported through government funding or direct investment and reducing general and administrative costs.

Equity Overview

On March 16, 2007, we consummated a transaction with various accredited investors pursuant to which we agreed to sell to the investors, in a private placement, an aggregate of approximately 4,288,712 shares of Series B Convertible Preferred Stock and Series B Warrants to purchase approximately 2,144,356 shares of our common stock pursuant to a securities purchase agreement of the same date. The Series B Warrants expire on March 15, 2012 and had an initial per share exercise price of $10.36. The aggregate purchase price paid by the investors for the Series B Preferred and Series B Warrants was approximately $30,000,000. Also issued in the transaction as partial compensation for services rendered by the placement agents were Series C Warrants, which had an initial per share exercise price of $11.00 and were originally exercisable for 267,074 shares of common stock. The Series C Warrants also expire on March 15, 2012. After related fees and expenses, we received net proceeds of approximately $29,000,000. On September 16, 2009, the outstanding Series B Preferred shares reached their termination date and, in accordance with their terms, were automatically converted into shares of common stock.

On February 13, 2009, March 20, 2009, and March 27, 2009, we entered into purchase agreements with various accredited investors, pursuant to which we agreed to sell to these investors an aggregate of 542.84 shares of Series D Convertible Preferred Stock and Series D Warrants to purchase an aggregate of 3,877,386 shares of the Company's common stock. The warrants have a seven-year term and a per share exercise price of $1.60. Each share of Series D

Preferred was convertible into the number of shares of common stock equal to (1) the stated value of the share ($10,000), divided by (2) the then-current conversion price (initially $1.40, but subject to adjustment as described below). At the initial conversion price of $1.40, each share of Series D Preferred was convertible into approximately 7,143 shares of common stock. The aggregate purchase price paid by the investors for the Series D Preferred and the warrants was approximately $5,428,307 (representing $10,000 for each share together with a warrant). After related fees and expenses, we received net proceeds of approximately $4,460,000. In consideration for its services as exclusive placement agent, Garden State Securities received cash compensation and warrants to purchase an aggregate of approximately 387,736 shares of common stock.

The conversion price of the Series D Preferred was subject to certain automatic adjustments, pursuant to which it reduced from $1.40 to $1.33 on August 13, 2009 and from $1.33 to $1.28 on November 13, 2009. On December 31, 2009, the conversion price of the Series D Preferred reduced from $1.28 to $1.02 because the Company failed to meet a particular development milestone by the end of 2009. At the conversion price of $1.02, each shares of Series D Preferred was convertible into approximately 9,804 shares of common stock. Upon completion of the Series D Preferred transaction and upon each adjustment to the conversion price of the Series D Preferred, the exercise prices of the Company's Series B Warrants and Series C Warrants, and the exercise price of certain other warrants issued prior to the Company's initial public offering, were reduced pursuant to weighted-average anti-dilution provisions. In addition to the adjustment to the exercise prices of these warrants, the aggregate number of shares issuable upon exercise of these warrants increased on each such occasion.

On February 9, 2010, all outstanding shares of Series D Preferred automatically converted into approximately 4,576,979 shares of common stock at the conversion price of $1.02, as a result of the Company's closing sales price being above a certain level for 20 consecutive trading days as well as the satisfaction of certain other conditions.

On February 25, 2010, we entered into a Securities Purchase Agreement with various accredited investors, pursuant to which we agreed to sell an aggregate of 1,538,462 shares of our common stock and warrants to purchase an aggregate of 1,015,384 shares of our common stock, for an aggregate purchase price of $5,000,000. The transaction closed on March 2, 2010. After related fees and expenses, the Company received net proceeds totaling approximately $4,500,000. The Company intends to use the proceeds of the private placement for working capital purposes. The common stock was sold at a price of $3.25 per share, and the warrants have an exercise price of $4.50 per share, subject to future adjustment for various events, such as stock splits or dilutive issuances. The warrants are exercisable commencing six months following issuance and expire on March 2, 2015. For its services as placement agent, Rodman & Renshaw, LLC received gross cash compensation in the amount of approximately $350,000, and it and its designees collectively received warrants to purchase 123,077 shares of common stock. The common stock and the shares of common stock underlying the warrants issued to the purchasers and Rodman & Renshaw have not been and will not be registered under the Securities Act of 1933.

Immediately after the completion of this transaction on March 2, 2010, pursuant to weighted-average anti-dilution provisions:

- the exercise price of the Series B Warrants reduced from $6.37 to $5.99, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants increased from 3,847,276 to 4,091,345; and

- the exercise price of the Series C Warrants reduced from $6.76 to $6.35, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 434,596 to 462,654.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues, expenses and other reported disclosures. We believe that we consistently apply these judgments and estimates and the financial statements and accompanying notes fairly represent all periods presented. However, any differences between these judgments and estimates and actual results could have a material impact on our statements of income and financial position. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances.

Note 2 to our financial statements includes disclosure of our significant accounting policies. Critical accounting estimates, as defined by the SEC, are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments and estimates of matters that are inherently uncertain. While all decisions regarding accounting policies are important, we believe that our policies regarding revenue recognition, R&D expenses, intellectual property related costs, stock-based compensation expense and fair value measurements could be considered critical, and are discussed in more detail below.

Revenue Recognition

Our revenue sources consist of government grants, government contracts and a commercial licensing and development contract.

Grant revenue is recognized using two different methods depending on the type of grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized during the period that the costs were incurred.

Fixed-cost grants require no proof of costs and are paid as a request for payment is submitted for expenses. The grant revenue under these fixed cost grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

We recognize revenue related to the funds received from the State of New York under the sponsored research agreement with RPCI as allowable costs are incurred. We recognize revenue on research laboratory services and the subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset.

Government contract revenue is recognized as allowable R&D expenses are incurred during the period and according to the terms of the contract.

Commercial revenue is recognized when the service or development is delivered or upon complying with the relevant terms of the commercial agreement including licensing agreements granting the rights to further develop technology leading to commercialization in certain territories.

Research and Development Expenses

R&D costs are expensed as incurred. These expenses consist primarily of our proprietary R&D efforts, including salaries and related expenses for personnel, costs of materials used in our R&D costs of facilities and costs incurred in connection with our third-party collaboration efforts. Pre-approved milestone payments made by us to third parties under contracted R&D arrangements are expensed when the specific milestone has been achieved. As of September 30, 2010, $50,000 has been paid to CCF for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102, $250,000 has been paid to CCF as a result of commencing Phase II clinical trials for Curaxin CBLC102 and $50,000 has been paid to CCF relating to the filing of an IND with the FDA for Protectan CBLB502. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

Intellectual Property Related Costs

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 20 years from the initial application date or the anticipated useful life of the patent. If the patent application is not approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be expensed as part of selling, general and administrative expenses at that time.

Through December 31, 2009, we capitalized $929,976 in expenditures less amortization associated with the preparation, filing and maintenance of certain of our patents. We capitalized an additional $121,272, amortized an additional $10,801 and recognized a deferred gain of $5,048 related to foreign currency translation for the nine months ended September 30, 2010, resulting in a balance of capitalized intellectual property totaling $1,045,495.

Stock-based Compensation

All stock-based compensation, including grants of employee stock options, is recognized in the statement of operations based on its fair value.

The fair value of each stock option granted is estimated on the grant date using accepted valuation techniques such as the Black Scholes Option Valuation model or Monte Carlo Simulation depending on the terms and conditions present within the specific option being valued. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from

the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on the safe harbor method; and presently compute an expected volatility based on a method layering in the volatility of our common stock with that of the volatility of similar high-growth, publicly-traded, biotechnology companies' common stock due to the limited trading history of our company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the nine months ended September 30, 2010 and September 30, 2009, we granted 1,021,932 and 723,276 stock options, respectively. We recognized a total of $1,332,457 and $1,527,719 in expense related to stock options for the nine months ended September 30, 2010 and September 30, 2009, respectively. We also recaptured $39,483 and $37,878 of previously recognized expense due to the forfeiture of non-vested stock options during the nine months ended September 30, 2010 and September 30, 2009, respectively. We also incurred an additional $37,800 of expense for stock options awarded under the 2009 Executive Compensation Plan. These options were originally expensed in 2009 based on December 31, 2009 variables, but were not issued until May 18, 2010. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing an increase in the grant date fair value. This increase in the grant date fair value from $2.31 to $2.40 per share resulted in the incurrence of $37,800 in expense. The net expense for options for the nine months ended September 30, 2010 and September 30, 2009 was $1,330,774 and $1,489,841, respectively.

We also recognized a total of $1,272,990 and $599,217 in expense for shares issued and a total of $9,963 and $24,907 in expense related to the amortization of restricted shares for the nine months ended September 30, 2010 and September 30, 2009, respectively

Fair Value Measurement

We value our financial instruments based on fair value measurements and disclosures which establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs in which little or no market data exists, therefore requiring a company to develop its own assumptions. We do not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of September 30, 2010.

We analyzed all financial instruments with features of both liabilities and equity.

We carry the warrants issued in the Series D Private Placement at fair value using Level 3 inputs for its valuation methodology totaling $15,752,534 and $8,410,379 as of September 30, 2010 and December 31, 2009, respectively. We recognized a fair value measurement loss of $5,258,402 and $4,111,578 for the three months ended September 30, 2010 and 2009, respectively. We recognized a fair value measurement loss of $7,968,929 and $9,565,276 for the nine months ended September 30, 2010 and 2009, respectively.

We carry the warrants issued in conjunction with the 2010 Common Stock Equity Offering at fair value using Level 3 inputs for its valuation methodology totaling $3,085,232 and $0 as of September 30, 2010 and December 31, 2009, respectively. We recognized a fair value measurement loss of $1,149,846 and $0 for the three months ended September 30, 2010 and 2009, respectively. We recognized a fair value measurement loss of $136,615 and $0 for the nine months ended September 30, 2010 and 2009, respectively.

We did not identify any other non-recurring assets and liabilities that are required to be presented on the balance sheets at fair value.

Recently Issued Accounting Pronouncements

See Note 2W to financial statements in Item 1.

Results of Operations

The following table sets forth our statement of operations data for the three and nine months ended September 30, 2010 and 2009 and the years ended December 31, 2009 and 2008 and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing and in our annual report on Form 10-K for the year ended December 31, 2009.

	Three Months Ended 30-Sep-10 (unaudited)	Three Months Ended 30-Sep-09 (unaudited)	Nine Months Ended 30-Sep-10 (unaudited)	Nine Months Ended 30-Sep-09 (unaudited)	Year Ended December 31, 2009	Year Ended December 31, 2008
Revenues	$ 3,189,488	$ 3,223,094	$ 11,570,599	$ 9,717,803	$ 14,345,908	$ 4,705,597
Operating expenses	4,157,193	4,314,178	16,615,789	14,548,186	20,728,837	19,050,965

Other expense (income)	6,367,282	4,100,241	8,196,128	9,811,898	6,463,208	(59,597)
Net interest expense (income)	(49,448)	(2,046)	(62,860)	(17,343)	(19,728)	(259,844)
Net income (loss)	$ (7,285,539)	$ (5,189,279)	$ (13,178,458)	$ (14,624,938)	$ (12,826,409)	$ (14,025,927)

The following table summarizes R&D expenses for the three months and nine months ended September 30, 2010 and 2009 and the years ended December 31, 2009 and 2008 and since inception:

	Three Months Ended 30-Sep-10 (unaudited)	Three Months Ended 30-Sep-09 (unaudited)	Nine Months Ended 30-Sep-10 (unaudited)	Nine Months Ended 30-Sep-09 (unaudited)	Year Ended December 31, 2009	Year Ended December 31, 2008	Total Since Inception (unaudited)
Research and development	$ 3,083,665	$ 3,327,609	$ 10,951,560	$ 10,602,591	$ 14,331,673	$ 13,160,812	$ 68,539,954
General	$ 64,356	$ -	$ 201,477	$ -	$ -	$ 931,441	$ 5,308,107
Protectan CBLB502 - non-medical applications	$ 2,689,779	$ 3,267,201	$ 10,016,092	$ 9,966,145	$ 13,676,289	$ 7,264,813	$ 45,293,577
Protectan CBLB502 - medical applications	$ -	$ -	$ -	$ 56,127	$ 56,127	$ 756,227	$ 1,833,056
Protectan CBLB612	$ 5,103	$ 1,414	$ 5,103	$ 6,567	$ 6,567	$ 974,459	$ 3,142,044
Curaxin CBLC102	$ 86,131	$ 34,074	$ 288,061	$ 252,209	$ 262,637	$ 1,741,194	$ 7,017,180
Other Curaxins	$ 238,296	$ 24,920	$ 440,827	$ 321,544	$ 330,053	$ 1,492,678	$ 5,945,990

Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009

Revenue

Revenue decreased from $3,223,094 for the three months ended September 30, 2009 to $3,189,488 for the three months ended September 30, 2010, representing a decrease of $33,606 or 1.0%.

See the table below for further details regarding the sources of our government grant and contract revenue:

Agency	Program	Amount	Period of Performance	Revenue 2010 (Julyl 1 thru Sept. 30) (unaudited)	Revenue 2009 (July 1 thru Sept. 30) (unaudited)	Revenue 2009
DoD	DTRA Contract	$ 1,263,836	03/2007-02/2009	$ -	$ 80,079	$ 183,613
NY State/RPCI	Sponsored Research Agreement	$ 3,000,000	03/2007-02/2012	$ 4,213	$ 3,679	$ 35,696
DoD	DOD Contract	$ 9,590,000	05/2008-09/2010	$ 68,777	$ 1,313,900	$ 4,843,303
HHS	BARDA Contract	$ 15,600,000	09/2008-09/2011	$ 2,348,526	$ 1,172,088	$ 5,374,535
NIH	NIAID Grant	$ 1,232,695	09/2008-08/2010	$ -	$ 392,369	$ 1,021,095
NIH	NIAID GO Grant	$ 5,300,000	09/2009-08/2011	$ 739,882	$ 260,979	$ 1,237,666
DOD	CBMS-MITS Contract	$ 14,800,000	09/2010-03/2013	$ 28,090	$ -	$ -

Totals	$ 3,189,488	$ 3,223,094	$ 12,695,908

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we may receive additional revenue from licensing fees.

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the RPCI and CCF, clinical trials and consulting fees. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. We anticipate these expenses to increase as a result of increased legal and accounting fees in connection with our compliance with ongoing reporting and accounting requirements of the SEC and the expansion of our business.

Operating expenses decreased from $4,314,178 for the three months ended September 30, 2009 to $4,157,193 for the three months ended September 30, 2010, a decrease of $156,985 or 3.6%. We recognized a total of $560,048 of non-cash, stock-based compensation for the three months ended September 30, 2010, compared to $410,402 for the three months ended September 30, 2009. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from $3,903,776 for the three months ended September 30, 2009 to $3,597,145 for the three months ended September 30, 2010. This represents a decrease in operating expenses of $306,631 or 7.9% as explained below.

R&D costs decreased from $3,327,609 for the three months ended September 30, 2009 to $3,083,665 for the three months ended September 30, 2010. This represents a decrease of $243,944 or 7.3%. We recognized a total of $291,878 of R&D non-cash, stock based compensation for the three months ended September 30, 2010, compared to $230,977 for the three months ended September 30, 2009. Without the non-cash, stock-based compensation, R&D expenses decreased from $3,096,632 for the three months ended September 30, 2009 to $2,791,787 for the three months ended September 30, 2010, a decrease of $304,845 or 9.8%. The lower R&D expenses were a result of decreased subcontract costs.

Selling, general and administrative costs increased from $986,569 for the three months ended September 30, 2009 to $1,073,528 for the three months ended September 30, 2010. This represents an increase of $86,959 or 8.8%. We recognized a total of $268,170 of non-cash, stock-based compensation under selling, general and administrative costs for the three months ended September 30, 2010, compared to $179,.425 for the three months ended September 30, 2009. Without the non-cash, stock-based compensation, the selling, general and administrative expenses decreased from $807,144 for the three months ended September 30, 2009 to $805,358 for the three months ended September 30, 2010, a decrease of $1,786 or 0.2%. The lower general and administrative expenses were incurred as a result of a tax refund received from the State of New York partially offset by general and administrative costs to support the continued growth and development of our infrastructure including for our consolidated subsidiary, Incuron.

Until we introduce a product to the market, we expect these expenses in the categories mentioned above will be the largest categories in our income statement.

Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

Revenue

Revenue increased from $9,717,803 for the nine months ended September 30, 2009 to $11,570,599 for the nine months ended September 30, 2010, representing an increase of $1,852,796 or 19.1% resulting primarily from an increase in revenue from various federal grants and contracts including the DoD and BARDA contracts.

See the table below for further details regarding the sources of our government grant and contract revenue:

Agency	Program	Amount	Period of Performance	Revenue 2010 (thru September 30) (unaudited)	Revenue 2009 (thru September 30) (unaudited)	Revenue 2009
DoD	DTRA Contract	$ 1,263,836	03/2007-02/2009	$ -	$ 183,613	$ 183,613
NY State/RPCI	Sponsored Research Agreement	$ 3,000,000	03/2007-02/2012	$ 12,570	$ 28,338	$ 35,696
DOD	DOD Contract	$ 9,590,000	05/2008-09/2010	$ 564,432	$ 4,636,335	$ 4,843,303
HHS	BARDA Contract	$ 15,600,000	09/2008-09/2011	$ 8,789,749	$ 3,649,347	$ 5,374,535
NIH	NIAID Grant	$ 1,232,695	09/2008-02/2010	$ 560	$ 955,512	$ 1,021,095
NIH	NIAID Grant	$ 5,300,000	09/2009-08/2011	$ 2,175,197	$ 264,658	$ 1,237,666
DOD	CBMS-MITS Contract	$ 14,800,000	09/2010-03/2013	$ 28,090	$ -	$ -
			Totals	$ 11,570,599	$ 9,717,803	$ 12,695,908

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we may receive additional revenue from licensing fees.

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the RPCI and CCF, clinical trials and consulting fees. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. We anticipate these expenses to increase as a result of increased legal and accounting fees in connection with our compliance with ongoing reporting and accounting requirements of the SEC and the expansion of our business.

Operating expenses increased from $14,548,186 for the nine months ended September 30, 2009 to $16,615,789 for the nine months ended September 30, 2010, an increase of $2,067,603 or 14.2%. We recognized a total of $2,782,951 of non-cash, stock-based compensation for the nine months ended September 30, 2010, compared to $2,113,965 for the nine months ended September 30, 2009. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from $12,434,221 for the nine months ended September 30, 2009 to $13,832,838 for the nine months ended September 30, 2010. This represents an increase in operating expenses of $1,398,617 or 11.2% as explained below.

R&D costs increased from $10,602,591 for the nine months ended September 30, 2009 to $10,951,960 for the nine months ended September 30, 2010. This represents an increase of $348,969 or 3.3%. We recognized a total of $648,735 of R&D non-cash, stock based compensation for the nine months ended September 30, 2010, compared to $895,397 for the nine months ended September 30, 2009. Without the non-cash, stock-based compensation, the R&D expenses increased from $9,707,194 for the nine months ended September 30, 2009 to $10,302,825 for the nine months ended September 30, 2010, an increase of $595,631 or 6.1%. The higher R&D expenses were a result of increased costs to support the increase in grant and contract revenue.

Selling, general and administrative costs increased from $3,945,595 for the nine months ended September 30, 2009 to $5,664,229 for the nine months ended September 30, 2010. This represents an increase of $1,718,634 or 43.6%. We recognized a total of $2,134,216 of non-cash, stock-based compensation under selling, general and administrative costs for the nine months ended September 30, 2010, compared to $1,218,568 for the nine months ended September 30, 2009. Without the non-cash, stock-based compensation, the selling, general and administrative expenses increased from $2,727,027 for the nine months ended September 30, 2009 to $3,530,013 for the nine months ended September 30, 2010, an increase of $802,986 or 29.4.%. The higher general and administrative expenses were incurred as a result of higher G&A costs to support the growth of the company and costs to develop the infrastructure for our consolidated subsidiary, Incuron.

Until we introduce a product to the market, we expect these expenses in the categories mentioned above will be the largest categories in our statement of operations.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of September 30, 2010, we had an accumulated deficit of $82,694,896. Our principal sources of liquidity have been cash provided by sales of our securities, government grants and contracts and licensing agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government contracts and grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties, which to date we have not.

Net cash used in operating activities totaled $2,368,259 for the nine months ended September 30, 2010, compared to $3,092,572 used in operating activities for the nine months ended September 30, 2009. This decrease in cash used in operating activities resulted from cost containment efforts combined with focusing our R&D efforts on projects where grant and contract funding was awarded.

Net cash used in investing activities was $511,499 for the nine months ended September 30, 2010, and net cash provided by investing activities was $800,052 for the nine months ended September 30, 2009. The decrease in cash provided by investing activities resulted primarily from the liquidation of a short-term investment in 2009 as compared to 2010.

Net cash provided by financing activities totaled $8,368,897 for the nine months ended September 30, 2010, compared to net cash provided by financing activities of $4,090,263 for the nine months ended September 30, 2009. The increase in cash provided by financial activities was attributed to the investment in Incuron, LLC by BCV and the 2010 Common Stock Equity Offering during the first nine months of 2010 as compared to the Series D Preferred and Series D Warrants offering during the same period in 2009.

Under our exclusive license agreement with CCF, we may be responsible for making milestone payments to CCF in amounts ranging from $50,000 to $4,000,000. The milestones and corresponding payments for Protectan CBLB502 and Curaxin CBLC102 are set forth above under “Item 1 – Description of Business – Collaborative Research Agreements – Cleveland Clinic Foundation.”

Our agreement with CCF also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors. Accrued milestone payments, royalty payments and sublicense royalty payments are payable upon achievement of the milestone.

We believe that although existing cash resources will be sufficient to finance our currently planned operations beyond the next twelve months, these amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

Impact of Inflation

We believe that our results of operations are not dependent upon moderate changes in inflation rates.

Impact of Exchange Rate Fluctuations

We believe that our results of operations are somewhat dependent upon changes in foreign currency exchange rates. We have entered into agreements with foreign third parties to produce one of our drug compounds and are required to make payments in the foreign currency. As a result, our financial results could be affected by changes in foreign currency exchange rates. As of September 30, 2010, we are obligated to make payments under these agreements of 1,470,709 Euros. We have purchased 751,344. Euros and therefore, at September 30, 2010, had foreign currency risk of $987,040 for Euros given prevailing currency exchange spot rates.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Item 3: Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks, including changes to interest rates, foreign currency exchange rates and equity investment prices. To reduce the volatility related to these exposures, we may enter into various derivative hedging transactions pursuant to our investment and risk management policies. There are inherent risks that may only be partially offset by our hedging programs should there be unfavorable movements in interest rates, foreign currency exchange rates, or equity investment prices.

Interest Rate Risk. Our interest income is sensitive to changes in the general level of domestic interest rates, particularly since our investments are classified as short-term held to maturity. Due to our intention to hold our investments to maturity, we have concluded that there is no material interest rate risk exposure.

Our revolving credit facility also would have been affected by fluctuations in interest rates as it is based on prime minus 1%. As of September 30, 2010, we had not drawn on this facility.

Foreign Currency Risk. As of September 30, 2010, we have agreements with third parties that require payment in the foreign currency. As a result, our financial results could be affected by changes in foreign currency exchange rates. Currently, our exposure primarily exists with the Euro. As a consequence, movements in exchange rates could cause our foreign currency denominated expenses to fluctuate as a percentage of net revenue, affecting our profitability and cash flows. At this time, our exposure to foreign currency fluctuations is not material.

In addition, our consolidated financial reports are presented in U.S. dollars, whereas the functional currency for Incuron is Russian rubles. As such, we are subject to translation risks relating to exchange rates between the U.S. dollar and the Russian ruble. Therefore, due to Incuron, our results may be affected by changes in the exchange rate between U.S. dollars and Russian rubles. Furthermore, although it is anticipated that we will ultimately own 50.1% of the membership interest in Incuron, depending on the U.S. dollar/Russian ruble exchange rate and the U.S. dollar-equivalent value of the aggregate contributions made by BCV, we may be required to either transfer a portion of its ownership interest to BCV or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to BCV, we may ultimately own less than 50.1% of the membership interest of Incuron, but will retain the right to appoint a majority of the members of the board of directors of Incuron.

Finally, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business financial condition and results of operations. For example, currency exchange rate fluctuations could affect international demand for our products in the future. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the U.S. and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations. As a result, we cannot give any assurance as to the effect that future changes in foreign currency rates will have on our financial position, results of operations or cash flows.

Item 4: Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act as of September 30, 2010. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as

of September 30, 2010, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be declared by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2010, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - Other Information

Item 1. Legal Proceedings

As of September 30, 2010, we were not a party to any litigation or other legal proceeding.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) None.

(b) Not applicable.

(c) None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Removed and Reserved

Item 5. Other Information

None.

Item 6. Exhibits

(a) The following exhibits are included as part of this report:

Exhibit Number	Description of Document
10.1	Contract (W9113M-10-C-0088), effective as of September 15, 2010, between Cleveland BioLabs, Inc. and the U.S. Army Space and Missile Defense Command/Army Forces Strategic Command (the "2010 DoD Contract").
10.2	Amendment of Solicitation/Modification of Contract No. 1, effective as of September 17, 2010, to the 2010 DoD Contract.
10.3	Contract (HHSO100200800059C), effective as of September 16, 2008, between Cleveland BioLabs, Inc. and the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (the "BARDA Contract")
10.4	Amendment of Solicitation/Modification of Contract No. 1, effective June 24, 2009, to the BARDA Contract
10.5	Amendment of Solicitation/Modification of Contract No. 2, effective September 15, 2009, to the BARDA Contract
10.6	

	Amendment of Solicitation/Modification of Contract No. 3, effective March 22, 2010, to the BARDA Contract
10.7	Amendment of Solicitation/Modification of Contract No. 4, effective April 14, 2010, to the BARDA Contract
10.8	Amendment of Solicitation/Modification of Contract No. 5, effective July 22, 2010, to the BARDA Contract
10.9	Cooperative Research and Development Agreement, effective August 1, 2004, among The Uniformed Services University of the Health Sciences, The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., The Cleveland Clinic Foundation and Cleveland BioLabs, Inc.
31.1	Certification of Michael Fonstein, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of John A. Marhofer, Jr., Chief Financial Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification Pursuant To 18 U.S.C. Section 1350

Signatures

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

CLEVELAND BIOLABS, INC.

Dated: November 15, 2010	By:	/s/ MICHAEL FONSTEIN Michael Fonstein Chief Executive Officer (Principal Executive Officer)
Dated: November 15, 2010	By:	/s/ JOHN A. MARHOFER, JR. John A. Marhofer, Jr. Chief Financial Officer (Principal Financial Officer)