

Xcorporeal, Inc.  
Form 10-Q  
November 19, 2008

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

**FORM 10-Q**

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED **SEPTEMBER 30, 2008**

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

Commission file number **001-33874**

**XCORPOREAL, INC.**

(Exact name of small business issuer as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**75-2242792**

(IRS Employer Identification Number)

**12121 Wilshire Blvd., Suite 350, Los Angeles, California 90025**

(Address of principal executive offices)

**(310) 923-9990**

(Issuer's telephone number)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

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

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date.

**Class**

**Outstanding as of November 17, 2008**

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Common Stock, \$0.0001 par value

14,704,687 shares

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**INDEX**

<b>PART I — FINANCIAL INFORMATION</b>	<b>2</b>
<b>Item 1. Interim Financial Statements</b>	<b>2</b>
Balance Sheets at September 30, 2008 (unaudited) and December 31, 2007	2
Statements of Operations (unaudited) for the three and nine months ended September 30, 2008 and September 30, 2007 and the period from inception (May 4, 2001) to September 30, 2008	3
Statements of Cash Flows (unaudited) for the nine months ended September 30, 2008 and September 30, 2007 and the period from inception (May 4, 2001) to September 30, 2008	4
Statement of Stockholders Equity (Deficit) for the nine months ended September 30, 2008 and the period from inception (May 4, 2001) to September 30, 2008 (unaudited)	5
Notes to the Interim Financial Statements	6
<b>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</b>	<b>15</b>
<b>Item 3. Quantitative and Qualitative Disclosures about Market Risk</b>	<b>19</b>
<b>Item 4. Controls and Procedures</b>	<b>19</b>
<b>PART II — OTHER INFORMATION</b>	<b>21</b>
<b>Item 1. Legal Proceedings</b>	<b>21</b>
<b>Item 1A. Risk Factors</b>	<b>22</b>
<b>Item 2. Unregistered Sales of Equity Securities ; Use of Proceeds from Registered Securities</b>	<b>23</b>
<b>Item 6. Exhibits</b>	<b>24</b>
<b>Signatures</b>	<b>25</b>

**PART I — FINANCIAL INFORMATION****ITEM 1. Financial Statements**

**XCORPOREAL, INC.**  
**(a Development Stage Company)**  
**BALANCE SHEETS**  
**(Unaudited)**

	September 30, 2008	December 31, 2007
<b>ASSETS</b>		
Current		
Cash and cash equivalents	\$ 253,042	\$ 106,495
Marketable securities, at fair value	5,756,685	16,401,898
Restricted cash	67,788	68,016
Prepaid Expenses & Other Current Assets	300,473	408,303
Total current assets	6,377,988	16,984,712
Property and equipment, net	304,749	266,912
Other assets	877	922
Total Assets	\$ 6,683,614	\$ 17,252,546
<b>LIABILITIES</b>		
Current		
Accounts payable	\$ 1,180,138	\$ 1,125,239
Accrued professional fees	3,049,015	425,228
Accrued royalties	270,833	83,333
Accrued compensation	139,564	196,541
Accrued other liabilities	120,330	68,946
Payroll liabilities	10,955	11,926
Deferred rent	40,929	-
Other current liabilities	115,400	115,400
Total Current Liabilities	4,927,164	2,026,613
Shares issuable	4,615,000	-
<b>COMMITMENTS &amp; CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred Stock, \$0.0001 par value, 10,000,000 shares authorized, none outstanding	-	-
Common Stock, \$0.0001 par value, 40,000,000 shares authorized, 14,704,687 and 14,372,472 outstanding on September 30, 2008 and December 31, 2007, respectively	1,470	1,437
Additional paid-in capital	41,526,283	36,822,316
Deficit accumulated during the development stage	(44,386,303)	(21,597,820)

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Total Stockholders' (Deficit) Equity	(2,858,550)	15,225,933
Total Liabilities & Stockholders' (Deficit) Equity	\$ 6,683,614	\$ 17,252,546

See accompanying notes to interim financial statements.

**XCORPOREAL, INC.**  
**(a Development Stage Company)**  
**STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>May 4, 2001 (Date</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>of Inception) to</b>
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>	<b>September 30,</b>
					<b>2008</b>
<b>Operating Expenses:</b>					
Selling, general and administrative	\$ 2,111,578	\$ 2,664,405	\$ 7,756,230	\$ 8,254,693	\$ 22,158,922
Research and development	12,694,055	2,087,753	18,900,027	4,775,887	27,328,519
Other expenses	1,871,430	-	1,871,430	-	1,871,430
Depreciation and amortization	27,253	9,243	75,837	14,626	108,103
Loss before other income, income taxes, and other expenses	(16,704,316)	(4,761,401)	(28,603,524)	(13,045,206)	(51,466,974)
Interest and other income	44,871	290,677	278,941	910,603	1,546,171
Change in fair value of shares issuable	5,538,000	-	5,538,000	-	5,538,000
Loss before income taxes and other expenses	(11,121,445)	(4,470,724)	(22,786,583)	(12,134,603)	(44,382,803)
Income taxes	300	-	1,900	-	3,500
Net Loss	\$ (11,121,745)	\$ (4,470,724)	\$ (22,788,483)	\$ (12,134,603)	\$ (44,386,303)
Basic and diluted loss per share	\$ (0.76)	\$ (0.32)	\$ (1.57)	\$ (0.86)	
Weighted average number of shares outstanding	14,704,687	14,089,180	14,561,070	14,162,687	

See accompanying notes to interim financial statements.

**XCORPOREAL, INC.**  
**(a Development Stage Company)**  
**STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	Nine Months Ended September 30,		May 4, 2001 (Date of Inception) to September 30, 2008
	2008	2007	
<b>Cash flows used in operating activities</b>			
Net Loss for the Period	\$ (22,788,483)	\$ (12,134,603)	\$ (44,386,303)
<b>Adjustments to reconcile net loss to net cash (used in) operating activities:</b>			
Stock Based Compensation	3,813,158	2,233,238	7,798,894
Non-employee Stock Based Compensation	92,842	2,923,344	5,172,762
Common Stock Issuance for consulting services rendered	798,000	-	896,000
Increase in shares issuable	10,153,000	-	10,153,000
Mark to market of shares issuable	(5,538,000)	-	(5,538,000)
Depreciation	75,792	14,562	107,980
<b>Net Change in assets and liabilities:</b>			
Decrease (increase) in Prepaid Expenses & Other Current Assets	107,830	(223,935)	(300,473)
Decrease (increase) in Other Assets	45	64	(877)
Increase in Accounts Payable and Accrued Liabilities	2,859,622	323,248	4,733,464
Increase in Deferred Rent	40,929	-	40,929
Increase in Other Current Liabilities	-	-	115,400
Net Cash Used in Operating Activities	(10,385,265)	(6,864,082)	(21,207,224)
<b>Cash Flows from Investing Activities</b>			
Capital Expenditures	(113,629)	(207,321)	(412,729)
Restricted Cash	228	(87,996)	(67,788)
Purchase of marketable securities	(8,598,102)	(21,932,739)	(33,598,102)
Sale of marketable securities	19,243,315	2,323,422	27,841,417
Net Cash Provided by (Used in) Investing Activities	10,531,812	(19,904,634)	(6,237,202)
<b>Cash Flows from Financing Activities</b>			
Capital Stock issued	-	-	27,434,348
Advances from related party	-	-	64,620
Additional Proceeds from the Sale of Common Stock in 2006	-	-	198,500
Net Cash Provided by Financing Activities	-	-	27,697,468
Increase/(decrease) in cash during the period	146,547	(26,768,716)	253,042
Cash, beginning of the period	106,495	27,440,987	-
Cash, end of the period	\$ 253,042	\$ 672,271	\$ 253,042

Supplemental disclosure of cash flow information; cash  
paid for:

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Interest	\$	-	\$	-	\$	-
Income taxes	\$	1,900	\$	-	\$	3,500

See accompanying notes to interim financial statements.



**XCORPOREAL, INC.**  
**(a Development Stage Company)**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**For the Period May 4, 2001 (Inception) to September 30, 2008**  
**(Unaudited)**

	Common Stock		Additional	Deficit	
	Shares	Amount	Paid-in	Accumulated	Total
			Capital	During	
				Development	
				Stage	
Common stock issued for cash at \$0.01 per share	2,500,000	\$ 250	\$ 24,750		\$ 25,000
Net Loss for the year ended December 31, 2001				\$ (40,255)	(40,255)
Balance as of December 31, 2001	2,500,000	250	24,750	(40,255)	(15,255)
Common stock issued for cash at \$0.05 per share	1,320,000	132	65,868		66,000
Net Loss for the year ended December 31, 2002				(31,249)	(31,249)
Balance as of December 31, 2002	3,820,000	382	90,618	(71,504)	19,496
Net Loss for the year ended December 31, 2003				(12,962)	(12,962)
Balance as of December 31, 2003	3,820,000	382	90,618	(84,466)	6,534
Net Loss for the year ended December 31, 2004				(23,338)	(23,338)
Balance as of December 31, 2004	3,820,000	382	90,618	(107,804)	(16,804)
Net Loss for the year ended December 31, 2005				(35,753)	(35,753)
Balance as of December 31, 2005	3,820,000	382	90,618	(143,557)	(52,557)
Common stock issued for a license rights at \$0.0001 per share	9,600,000	960	40		1,000
Capital stock cancelled	(3,420,000)	(342)	342		-
Warrants granted for consulting fees			2,162,611		2,162,611
Forgiveness of related party debt			64,620		64,620
Common stock issued for cash at \$7.00, net of placement fees of \$2,058,024	4,200,050	420	27,341,928		27,342,348
Stock-based compensation expense			264,251		264,251
Net loss for the period				(4,380,212)	(4,380,212)
Balance as of December 31, 2006	14,200,050	1,420	29,924,410	(4,523,769)	25,402,061
Capital stock cancelled	(200,000)	(20)	20		-
Common stock issued pursuant to consulting agreement at \$4.90 per share	20,000	2	97,998		98,000
	352,422	35	(37,406)		(37,371)

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Recapitalization pursuant to merger					
Warrants granted for consulting services			2,917,309		2,917,309
Stock-based compensation expense			3,721,485		3,721,485
Additional Proceeds from the Sale of Common Stock in 2006			198,500		198,500
Net loss for the period				(17,074,051)	(17,074,051)
Balance as of December 31, 2007	14,372,472	1,437	36,822,316	(21,597,820)	15,225,933
Common stock issued as compensation for consulting services at \$3.61 per share					
	200,000	20	721,980		722,000
Warrants granted for consulting services			75,489		75,489
Stock-based compensation expense			1,121,118		1,121,118
Net loss for the period				(6,350,365)	(6,350,365)
Balance as of March 31, 2008	14,572,472	1,457	38,740,903	(27,948,185)	10,794,175
Common stock issued as compensation for consulting services at \$3.80 per share					
	20,000	2	75,998		76,000
Cashless exercise of warrants	112,215	11	(11)		0
Warrants granted for consulting services			9,256		9,256
Stock-based compensation expense			960,840		960,840
Net loss for the period				(5,316,373)	(5,316,373)
Balance as of June 30, 2008	14,704,687	1,470	39,786,986	(33,264,558)	6,523,898
Stock-based compensation expense			1,739,297		1,739,297
Net loss for the period				(11,121,745)	(11,121,745)
Balance as of September 30, 2008	14,704,687	\$ 1,470	\$ 41,526,283	\$ (44,386,303)	\$ (2,858,550)

See accompanying notes to interim financial statements.

**XCORPOREAL, INC.**  
**(a Development Stage Company)**  
**NOTES TO INTERIM FINANCIAL STATEMENTS**  
**September 30, 2008**  
**(Unaudited)**

**Note 1 — Interim Reporting**

While information presented in the accompanying interim financial statements is unaudited, it includes all adjustments, which are, in the opinion of management, necessary to present fairly the financial position, results of operations, and cash flows for the interim period presented.

The results of operations for the period ended September 30, 2008 are not necessarily indicative of the results that can be expected for the year ended December 31, 2008.

**Note 2 — Nature of Operations and Going Concern Uncertainty**

On October 12, 2007, pursuant to a merger agreement with Xcorporeal, Inc. (referred to hereinafter as Operations), our newly-formed wholly-owned merger subsidiary, merged with and into Operations, which became our wholly-owned subsidiary and changed its name to "Xcorporeal Operations, Inc." We changed our name from CT Holdings Enterprises, Inc. (CTHE) to "Xcorporeal, Inc." and amended our certificate of incorporation and bylaws to read substantially as Operations. As a result, our authorized common stock changed from 60,000,000 shares to 40,000,000 common shares, and our authorized preferred stock changed from 1,000,000 shares to 10,000,000 shares, resulting in total authorized capital stock of 50,000,000 shares.

Immediately prior to the merger, we caused a one-for-8.27 reverse split of our common stock. Each share of Operations common stock was then converted into one share of our common stock. In addition, we assumed all outstanding Operations options and warrants to purchase Operations common stock.

In this merger, CTHE is considered to be the legal acquirer and Xcorporeal to be the accounting acquirer. As the former shareholders of Operations owned over 97% of the outstanding voting common stock of CTHE immediately after the merger and CTHE was a public shell company, Operations is considered the accounting acquirer and the transaction is considered to be a recapitalization of Operations.

Historical financial statements prior to the merger were restated to be those of Operations. The merger is accounted for as if it were an issuance of the common stock of Operations to acquire our net assets, accompanied by a recapitalization. Historical stockholders' equity of Operations is retroactively restated for the equivalent number of shares received in the merger, after giving effect to the difference in par value with an offset to paid-in capital. The assets and liabilities of Operations are carried forward at their predecessor carrying amounts. Retained deficiency of Operations is carried forward after the merger. Operations prior to the merger are those of Operations. Earnings per share for periods prior to the merger are restated to reflect the number of equivalent shares received by Operations' stockholders. The costs of the transaction will be expensed to the extent they exceed cash received from CTHE. References to "we," "us," "our" and the "company" after consummation of the merger include CTHE and Operations.

As a result of the merger, we transitioned to a development stage company focused on researching, developing, and commercializing technology and products related to the treatment of kidney failure.

We expect to incur negative cash flows and net losses for the foreseeable future. Based upon our current plans, we believe that our existing cash reserves will not be sufficient to meet our operating expenses and capital requirements before we achieve profitability. Accordingly, we may seek to raise additional funds through public or private

placement of shares of preferred or common stock or through public or private financing. Our ability to meet our cash obligations as they become due and payable will depend on our ability to sell securities, borrow funds, reduce operating costs, or some combination thereof. We may not be successful in raising necessary funds on acceptable terms, or at all. As a result of these conditions, there is substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Upon receipt of the approximate \$27.3 million raised through a private placement which closed in the fourth quarter of 2006, we strategically began our operating activities and research and development efforts which resulted in a net loss of \$17.1 million in 2007, and \$22.8 million in the nine months ended September 30, 2008 including a net \$4.6 million fair value accrual of a potential 9.23 million shares issuance discussed in Note 4-Legal Proceedings below. In addition, we invested \$25.0 million in high grade money market funds and marketable securities of which we sold \$19.2 million of the investments, leaving a balance of \$5.8 million as of September 30, 2008.

We are a medical device company developing an innovative *extra-corporeal* platform technology to be used in devices to replace the function of various human organs. The platform leads to three initial products: (i) a Portable Artificial Kidney (PAK) for hospital Renal Replacement Therapy, (ii) a PAK for home hemodialysis and (iii) a Wearable Artificial Kidney (WAK) for continuous ambulatory hemodialysis. Our rights to the WAK derive in part from a License Agreement dated September 1, 2006, between Operations and National Quality Care, Inc. ("NQCI") pursuant to which we obtained the exclusive rights to the technology designated therein (the "License Agreement"). See Note 4-Legal Proceedings below.

We have focused much of our efforts on development of the PAK, which has not been derived from the technology covered by the License Agreement. Through the productive research and development efforts of the PAK, we have completed functional prototypes of our hospital and home PAKs that we plan to commercialize after 510(k) notification clearance from the Food and Drug Administration (FDA) which we plan to seek by next year. Prior to the 510(k) submission to the FDA for clinical use under direct medical supervision, the units will undergo final verification and validation. It generally takes 4 to 12 months from the date of a 510(k) submission to obtain clearance from the FDA, although it may take longer. As we begin to shift out of the phase of development and build of the prototype equipment, reducing the related spending on research and development costs as well as consulting and material costs, see Note 16-Product Development Agreement, we expect that our monthly expenditures will remain somewhat constant. With this transition, there will be a shift of resources towards verification and validation of our devices along with developing a marketing plan for the PAK.

In addition, we have used some of our resources for the development of the WAK which we have demonstrated a feasibility prototype. Commercialization of the WAK will require development of a functional prototype and likely a full pre-market approval by the FDA, which could take several years. Once the Technology Transaction has closed and the results of the arbitration proceeding described in Note 4-Legal Proceedings are final, we will determine whether to devote additional resources to development of the WAK.

Because neither the PAK nor the WAK is yet at a stage where it can be marketed commercially, we are not able to predict the portion of our future business which will be derived from each.

### **Note 3 — Development Stage Company**

We are a development stage company, devoting substantially all of our efforts to the research, development, and commercialization of kidney failure treatment technologies.

*Risks and Uncertainties*— We operate in an industry that is subject to intense competition, government regulation, and rapid technological change. Our operations are subject to significant risk and uncertainties including financial, operational, technological, legal, regulatory, and other risks associated with a development stage company, including the potential risk of business failure.

### **Note 4 – Legal Proceedings**

On December 1, 2006, Operations initiated arbitration against National Quality Care, Inc. (NQCI) for NQCI's failure to fully perform its obligations under the License Agreement dated September 1, 2006. On September 1, 2006, Operations also entered into a Merger Agreement with NQCI which contemplated that Operations would acquire NQCI as a wholly owned subsidiary pursuant to a triangular merger, or would issue to NQCI shares of common stock in consideration of the assignment of the technology relating to the WAK and other medical devices which, as listed under "Technology" on the License Agreement, are "all existing and hereafter developed Intellectual Property, Know-How, Licensor Patents, Licensor Patent Applications, Derivative Works and any other technology, invented, improved or developed by Licensor, or as to which Licensor owns or holds any rights, arising out of or relating to the research, development, design, manufacture or use of (a) any medical device, treatment or method as of the date of

this Agreement, (b) any portable or continuous dialysis methods or devices , specifically including any wearable artificial kidney, or Wearable Artificial Kidney, and related devices, (c) any device, methods or treatments for congestive heart failure, and (d) any artificial heart or coronary device” (the “Technology Transaction”). The merger was not consummated.

On January 3, 2008, the arbitrator issued an order denying NQCI’s motion to amend its counterclaim to add us as a successor company following the merger. However, in the Second Interim Award, the arbitrator found that we are the successor to Operations as a result of the merger, even though we are not a party to any of the agreements or the arbitration, and ordered that our shares should be issued to NQCI rather than shares of Operations.

On June 9, 2008, the arbitrator issued an Interim Award granting specific performance of the Technology Transaction. The Interim Award stated that the total aggregate shares of stock to be received by NQCI at the Closing should equal 48% of all Operations shares outstanding as of the date of the Merger Agreement. On September 1, 2006, there were 10,000,000 shares of Operations common stock outstanding. Copies of the License Agreement and Merger Agreement are attached as exhibits to our amended current report on Form 8-K/A filed with the Securities and Exchange Commission on June 11, 2008.

On August 4, 2008, the arbitrator issued a Second Interim Award, stating that 9,230,000 shares of our common stock should be issued to NQCI to effectuate the Technology Transaction. As of November 17, 2008, there were 14,704,687 shares of our common stock issued and outstanding. Accordingly, following Closing of the Technology Transaction, NQCI would be our largest stockholder and would own approximately 39% of our total outstanding shares.

The arbitrator has not ordered us to close the Technology Transaction. However, the arbitrator found that, with the exception of shareholder approval, virtually all conditions to Closing the Technology Transaction have been waived. The award further states that, if we or our stockholders do not approve the issuance of our stock to effectuate the Technology Transaction, all of the Technology covered by the License will be declared the sole and exclusive property of NQCI, and the arbitrator will schedule additional hearings to address whether the PAK technology is included within that Technology, and whether NQCI is entitled to compensatory damages and the amount of damages, if any, under these circumstances. Upon closing of the Technology Transaction, the License Agreement will terminate, and we will own all of the Technology.

The Second Interim Award also states that the License Agreement will remain in full force and effect until the Technology Transaction closes or the arbitrator determines that it will never close. NQCI has made a claim for reimbursement of approximately \$690,000 in alleged expenses, Licensor Expenses, under the License Agreement which were accrued under "Accrued professional fees" as of September 30, 2008. The Licensor Expenses was accrued in the three months ended June 30, 2008 with the expenditure recorded as Licensing Expense within research and development operating expenses. To date, we have not received any supporting backup of these alleged Licensor Expenses.

On August 15, 2008, the arbitrator awarded NQCI \$1.87 million to settle over \$4 million NQCI claimed in attorneys' fees and costs, stating that NQCI's lack of success and other factors warranted a substantial reduction in the sums claimed. The arbitrator stated in pertinent part: "National's success in the arbitration has been only partial and this is directly relevant to the question of the quantum of attorneys' fees which should be awarded. ... National sought eight or nine figure damages, but was awarded none. ... Further, National asserted claims for fraud, interference with contract, and other torts, all of which were rejected. This lack of success warrants a substantial reduction in the sums claimed." NQCI asked for a total of \$4.04 million in attorneys' fees and costs. The arbitrator awarded NQCI a total of \$1.87 million which have been accrued under "Accrued professional fees" as of September 30, 2008. The interim settlement of legal fees was accrued in the three and nine months ended September 30, 2008 with the expenditure recognized as "Other expenses" and payment pending to date.

In an August 29, 2008 Order Re Issuance of Xcorporeal Shares, the arbitrator stated that the shares should be issued directly to NQCI's stockholders. However, on September 4, 2008, the arbitrator issued an order that we should issue and deliver the 9,230,000 shares directly to NQCI, rather than directly to NQCI stockholders, if we obtain stockholder approval and elect to proceed with the Technology Transaction.

The Second Interim Award requires that we file a registration statement under the Securities Act to register for resale the shares to be issued to NQCI within 30 days after the closing of the Technology Transaction. The arbitrator acknowledged that our obligation is to file the registration statement and to use reasonable efforts to have the shares registered and not to guarantee registration and resultant actual public tradability. However, the arbitrator nevertheless ordered that the registration statement must be declared effective within 90 days. We have no control over whether the registration statement will be declared effective by the Securities and Exchange Commission (SEC), and no way to predict what further action, if any, the arbitrator may order if it is not declared effective.

The Technology Transaction will be accounted for as a purchase of the Technology in exchange for shares of our common stock. In accordance with FASB Concepts Statement No. 7, *Using Cash Flow Information and Present Value in Accounting Measurements*, the Technology Transaction will be measured based on the fair value of the shares surrendered on the date of issuance, which is clearly more evident than the fair value of the intellectual property. Through the evaluation of the components of the intellectual property and information pursuant to the arbitration suggesting it may not be proprietary, we have determined the intellectual property is not economically viable. However, continuing research on the technology will be useful in developing the prototype of our Wearable Artificial Kidney. In accordance with FASB 2, *Accounting for Research and Development Costs*, and its related interpretations, we will expense the value of the intellectual property, determined in process research and

development, at the date of acquisition.

Pursuant to the Second Interim Award, stating that, if the Technology Transaction is submitted to and approved by our stockholders, 9,230,000 shares of our common stock should be issued to NQCI to effectuate the transaction, we accrued for the 9.23 million shares of our common stock. As the Second Interim Award states that a registration statement for any issued shares must be declared effective within 90 days, and such contingency is not within our control, we have recorded the issuance as a liability, rather than as equity. The fair value of the 9.23 million shares was measured using the closing price of our common stock on August 4, 2008, the date of the Second Interim Award, and revalued, marked to market, as of the end of this interim reporting period, September 30, 2008. The fair value of the accrued shares on August 4, 2008, was \$10,153,000 which was revalued at \$4,615,000 as of September 30, 2008, resulting in a \$5,538,000 non-operating gain to the statement of operations for the three and nine months ended September 30, 2008. The net fair value of \$4,615,000 was accrued under "Shares issuable" as of September 30, 2008. Stockholders' approval and issuance of the shares are pending to date.

Although we may seek stockholder approval for the issuance of the 9.23 million shares of our common stock to effectuate the Technology Transaction, we are uncertain whether the SEC will approve a form of proxy to solicit stockholder approval of the transaction, our stockholders will vote to approve the transaction, shares will be issued to NQCI, or the SEC will declare effective a registration statement to register the shares for resale. If the Technology Transaction does not close, the arbitrator may issue alternative relief. In the event of an alternate award, the above accrual may be adjusted and the accrual or the actual settlement will be recorded to coincide with the alternate award.



If the 9.23 million shares contemplated by the Second Interim Award are issuable pursuant to a shareholder vote and the shares are issued pursuant to either a registration of such shares or the waiver of the registration proposal by the arbitrator, then the \$4.6 million contingent liability record on our balance sheet becomes an addition of 9.23 million shares to our outstanding common shares and increases stockholders' equity by the 9.23 million shares multiplied by the trading price of our shares on that day.

The arbitrator has stated that he has not yet issued a final award that may be confirmed or challenged in a court of competent jurisdiction. A party to the arbitration could challenge the interim award in court, even after stockholders approve the transaction. In addition, the arbitrator could again change the award by granting different or additional remedies, even after stockholders approve the transaction. We cannot guarantee that the arbitrator would order that stockholders be given another opportunity to vote on the transaction, even if such changes are material. Arbitrators have broad equitable powers, and arbitration awards are difficult to challenge in court, even if the arbitrator makes rulings that are inconsistent or not in accordance with the law or the evidence.

The above legal proceedings are discussed in further detail below in Part II-Other Information, Item 1. Legal Proceedings.

#### **Note 5 — Cash Equivalents and Marketable Securities**

We invest available cash in short-term commercial paper, certificates of deposit, money market funds, and high grade marketable securities. We consider any liquid investment with an original maturity of three months or less when purchased to be cash equivalents. Investments, including certificates of deposit with maturity dates greater than three months when purchased and which have readily determined fair values, are classified as available-for-sale investments and reflected in current assets as marketable securities at fair market value. Our investment policy requires that all investments be investment grade quality and no more than ten percent of our portfolio may be invested in any one security or with one institution. At September 30, 2008, all of our cash was held in high grade money market funds and marketable securities.

Restricted cash represents deposits secured as collateral for a bank credit card program.

#### **Note 6 — Fair Value Measurements**

Effective January 1, 2008, we adopted SFAS No. 157, "Fair Value Measurements," ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. This statement does not require any new fair value measurements; rather, it applies to other accounting pronouncements that require or permit fair value measurements. In February 2008, FSP FAS 157-2, "Effective Date of FASB Statement No. 157", was issued, which delays the effective date of SFAS 157 to fiscal years and interim periods within those fiscal years beginning after November 15, 2008 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). We elected to defer the adoption of the standard for these non-financial assets and liabilities.

Fair value is defined under SFAS 157 as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. SFAS 157 also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Beginning January 1, 2008, assets and liabilities recorded at fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Level inputs, as defined by SFAS 157, are as follows:

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- Level I - inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
- Level II - inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
- Level III - unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The following tables summarize fair value measurements by level at September 30, 2008 for assets and liabilities measured at fair value on a recurring basis:

	Level I	Level II	Level III	Total
Cash and cash equivalents	\$ 253,042	\$ -	\$ -	\$ 253,042
Marketable securities:				
Commercial paper	3,708,821	-	-	3,708,821
Corporate securities				
fixed rate	651,811	-	-	651,811
Money market fund	1,396,053	-	-	1,396,053
Restricted cash	67,788	-	-	67,788
Total assets	\$ 6,077,515	\$ -	\$ -	\$ 6,077,515

Short-term investments classified as available-for-sale were as follows:

	Aggregate Fair Value	September 30, 2008 Gross Unrealized Gains / (Losses)	Estimated Fair Value
Commercial paper	\$ 3,708,821	\$ -	\$ 3,708,821
Corporate securities			
fixed rate	651,811	-	651,811
Total	\$ 4,360,632	\$ -	\$ 4,360,632

Xcorporeal reviews impairments associated with the above in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and FASB Staff Position FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," to determine the classification of the impairment as temporary or other-than-temporary. Xcorporeal considers these investments not to be temporarily impaired as of September 30, 2008.

There were no gross unrealized gains or losses as of September 30, 2008.

#### Note 7 - Property and Equipment

Property and equipment consist of the following at September 30, 2008:

Property and equipment	\$ 412,729
Accumulated depreciation	(107,980)
Property and equipment, net	\$ 304,749

Depreciation expense for the three and nine months ended September 30, 2008 and 2007 was \$27,238 and \$75,792, and \$9,229 and \$14,562, respectively.

#### Note 8 – Shares Issuable

Pursuant to the August 4, 2008, Second Interim Award, stating that, if the Technology Transaction is submitted to and approved by our stockholders, 9,230,000 shares of our common stock should be issued to NQCI to effectuate the transaction, , we accrued for the 9,230,000 shares of our common stock. As the Second Interim Award states that a

registration statement for any issued shares must be declared effective within 90 days, and such contingency is not within our control, we have recorded the issuance as a liability, rather than as equity. Until issuance, the shares issuable will be recorded at fair value in accordance with EITF 00-19, with subsequent changes in fair value recorded as non-operating gain or loss to our statement of operations. The fair value of the shares will be measured using the closing price of our common stock on the reporting date. The measured fair value of \$10,153,000 for the accrued 9.23 million shares on August 4, 2008, the date of the Second Interim Award, was accrued under "Shares issuable" and expensed to "Research and development". From marking to market, the fair value of the shares issuable was revalued at \$4,615,000 as of September 30, 2008. The resulting non-operating gain of \$5,538,000 to the statement of operations for the three and nine months ended September 30, 2008 was recognized as "Change in fair value of shares issuable". Stockholder approval and issuance of the shares are pending to date.

Although we may seek stockholders' approval for the issuance of 9.23 million shares of our common stock to effectuate the Technology Transaction, we are uncertain whether the SEC will approve the form of proxy to solicit stockholder approval of the transaction, our stockholders will vote to approve the transaction, shares will be issued to NQCI, or the SEC will declare effective the registration statement to register the shares for resale. If the Technology Transaction does not close, the arbitrator may issue alternative relief. In the event of an alternate award, the above accrual may be adjusted and the accrual or the actual settlement will be recorded to coincide with the alternate award.

**Note 9 - Leases**

As of February 22, 2008, we entered into a 5 year lease agreement and relocated our corporate office to a location in Los Angeles, CA. The total lease payments will be \$1,096,878 over a 5 year period. As of September 30, 2008, our remaining total lease payments are \$1,009,838.

The following is a schedule by years of future minimum lease payments required under the 5-year corporate office lease as of September 30, 2008:

Year ending December 31:	
	(
2008	\$ 52,2241 )
2009	215,859
2010	224,650
2011	233,528
2012	242,842
	(
2013	40,7352 )
Total minimum payments required	
	\$ 1,009,838

( 1 ) excludes lease payments made through September 30, 2008  
 ( 2 ) initial term of the lease agreement ends February 2013

On May 15, 2008, we executed the second amendment to the sublease agreement for office and warehouse space from Aubrey Group, Inc. (Aubrey). Pursuant to the amendment, we acquired additional office and warehouse space. In addition, our monthly sublease rent increased to \$8,715 through December 31, 2008. As of September 30, 2008, our remaining total sublease payments are \$17,429 for the remaining time we will occupy the subleased space from Aubrey which we have given notice to vacate by the end of November 2008.

**Note 10 — Interest Income**

Interest income of \$44,871 and \$278,941, and \$290,677 and \$910,603 was reported for the three and nine months ended September 30, 2008 and 2007, respectively.

**Note 11 – Other Expenses**

On August 15, 2008, the arbitrator in the NQCI arbitration issued another interim award, awarding NQCI a total of \$1,871,430 in attorney's fees and costs. Pursuant to the award, we accrued the liability under "Accrued professional fees" and captured the expenditure in "Other expenses" in the three and nine months ended September 30, 2008.

**Note 12 — Related Party Transactions**

In connection with the contribution of the assets to our company, on August 31, 2006 we issued to Consolidated National, LLC (CNL), of which Terren Peizer, who beneficially owns 42.4% of our outstanding common stock, is the sole managing member and beneficial owner, an aggregate of 9,600,000 shares of common stock of which 6,232,596 shares are still held by CNL.

The Chief Medical and Scientific Officer of our Company, Dr. Victor Gura, owns 15,497,250 shares of common stock of NQCI (or approximately 20.9% of NQCI's common stock outstanding as of October 17, 2008 with whom we entered into the License Agreement. Such shares include 800,000 shares owned by Medipace Medical Group, Inc., an affiliate of Dr. Gura, and 250,000 shares subject to warrants held by Dr. Gura which are currently exercisable.

Pursuant to a consulting agreement effective December 1, 2007, Daniel S. Goldberger, then a director, provided consulting services as interim Chief Executive Officer. In consideration of the services, we paid Mr. Goldberger \$15,000 per month during the first two months and \$12,500 per month thereafter during the term of the consulting agreement. From execution through September 30, 2008, Mr. Goldberger was compensated \$130,000 for his services. Mr. Goldberger resigned as interim Chief Executive Officer on October 6, 2008, and as a director on October 7, 2008, and remains a strategic consultant to the Company thru the end of 2008. Mr. Goldberger will receive an additional \$22,500 in compensation for such services.

Dr. Gura maintains an office located in Beverly Hills, California. Pursuant to a reimbursement agreement effective January 29, 2008, we reimburse 50% of the rental and 50% of his monthly parking. The term of the agreement commenced on April 23, 2007, the date of the office lease agreement, and continue until the date on which he ceases to use the remote office to perform his duties as our Chief Medical and Scientific Officer. From commencement through September 30, 2008, we reimbursed our Chief Medical and Scientific Officer \$1,507 and \$31,187 for 50% of the monthly parking and rental, respectively.

### **Note 13 — License Agreement**

On August 31, 2006, we entered into a Contribution Agreement with a company whose sole managing member, Terren Peizer, who beneficially owns 42.4% of our outstanding common stock. We issued 9,600,000 shares of common stock in exchange for (a) the right, title, and interest to the name “Xcorporeal” and related trademarks and domain names, and (b) the right to enter into a License Agreement with National Quality Care, Inc. (NQCI) dated September 1, 2006 pursuant to which we obtained the exclusive rights to the technology relating to our kidney failure treatment and other medical devices which, as listed under “Technology” on the License Agreement, are “all existing and hereafter developed Intellectual Property, Know-How, Licensor Patents, Licensor Patent Applications, Derivative Works and any other technology, invented, improved or developed by Licensor, or as to which Licensor owns or holds any rights, arising out of or relating to the research, development, design, manufacture or use of (a) any medical device, treatment or method as of the date of this Agreement, (b) any portable or continuous dialysis methods or devices, specifically including any wearable artificial kidney, or Wearable Artificial Kidney, and related devices, (c) any device, methods or treatments for congestive heart failure, and (d) any artificial heart or coronary device.” Operations was a shell corporation prior to the transaction. We valued the License Agreement at the carry-over basis of \$1,000. As consideration for being granted the License, we agreed to pay to NQCI a minimum annual royalty of \$250,000, or 7% of net sales. We recorded \$520,833 in royalty expenses covering the minimum royalties from commencement of the License Agreement through September 30, 2008. The License Agreement expires in 2105. As of September 30, 2008, we had made one payment of the minimum annual royalty of \$250,000 in November 2008.

The License Agreement also stipulates the reimbursement of reasonable and necessary expenses incurred in the ordinary course of business consistent with past practices (“Licensor Expenses”) until the Closing or the termination of the Merger Agreement. The Second Interim Award from the arbitration with NQCI states that the License Agreement will remain in full force and effect until the Technology Transaction closes or the arbitrator determines that it will never close. As such, NQCI has made a claim for reimbursement of approximately \$690,000 in alleged expenses under the License Agreement which were accrued under “Accrued professional fees” as of September 30, 2008. To date, we have not received any supporting backup of this alleged Licensor Expenses. See Note 4-Legal Proceedings for further additional information related to this License Agreement.

### **Note 14 — Stock Options and Warrants**

#### ***Incentive Compensation Plan***

On October 12, 2007, we adopted the Xcorporeal, Inc. 2007 Incentive Compensation Plan and the related form of option agreement that are substantially identical to the 2006 Incentive Compensation Plan in effect at Operations immediately prior to the merger.

The plan authorizes the grant of stock options, restricted stock, restricted stock units, and stock appreciation rights. Effective February 28, 2007, there are 3,900,000 shares of common stock reserved for issuance pursuant to the plan (subject to adjustment in accordance with the provisions of the plan). The plan will continue in effect for a term of up to ten years.

On October 12, 2007, we also assumed options to purchase up to 3,880,000 shares of common stock, net 980,000 of which have since been forfeited, canceled, or expired, that were granted by Operations under its 2006 Incentive Compensation Plan.

As of September 30, 2008, there were 129,500 optioned shares outstanding and 3,770,500 shares available under the 2007 Incentive Compensation Plan.

#### ***Stock Options to Employees, Officer and Directors***

The Compensation Committee of our Board of Directors determines the terms of the options granted, including the exercise price, the number of shares subject to option, and the vesting period. Options generally vest over five years and have a maximum life of ten years.

In the three months ended September 30, 2008, an aggregate of 338,000 options were forfeited as a result of employee terminations and resignations. In addition, 200,000 options were cancelled pursuant to a Director's voluntary forfeiture with no other concurrent replacement award or other valuable consideration as his services as a Director remained and continued on the date of his voluntary forfeiture.

We reported \$1,731,200 and \$3,813,158 in stock-based compensation expense for employees, officers, and directors for the three and nine months ended September 30, 2008, respectively. For the three and nine months ended September 30, 2007, we reported \$749,774 and \$2,233,238 in stock-based compensation expense for employees, officers, and directors, respectively.



All compensation expense for stock options granted has been determined under the fair value method using the Black-Scholes option-pricing model with the following assumptions:

	For the nine months ended September 30, 2008
Expected dividend yields	zero
Expected volatility	136%
Risk-free interest rate	3.53-3.81%
Expected terms in years	3.12-8.88 years

***Warrants and Stock Options to Non-Employees***

During the nine months ended September 30, 2008, there was no issuance of warrants. However, there were cashless exercises of warrants during the three months ended June 30, 2008.

We reported \$8,097 and \$92,842 in stock-based compensation expense for consultants for the three and nine months ended September 30, 2008, respectively. We reported \$128,220 and \$2,923,344 in stock-based compensation expense for consultants for the three and nine months ended September 30, 2007, respectively.

Compensation for options granted to non-employees has been determined in accordance with SFAS No. 123R, EITF 96-18, and EITF 00-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Accordingly, compensation is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

For options and warrants issued as compensation to non-employees for services that are fully vested and non-forfeitable at the time of issuance, the estimated value is recorded in equity and expensed when the services are performed and benefit is received as provided by Financial Accounting and Standards Board ("FASB") Emerging Issues Task Force No. 96-18 "Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring or In Conjunction With Selling Goods Or Services."

All charges for warrants granted have been determined under the fair value method using the Black-Scholes option-pricing model with the following assumptions:

	For the nine months ended September 30, 2008
Expected dividend yields	zero
Expected volatility	136%
Risk-free interest rate	2.36-4.69%
Expected terms in years	1.14-4.05 years

The following table shows the change in unamortized compensation expense for stock options and warrants issued to employees, officers, directors and non-employees during the nine months ended September 30, 2008:

	Stock Options and Warrants Outstanding	Unamortized Compensation Expense
January 1, 2008	4,674,221	\$ 18,228,742
Granted in the period	55,000	207,448

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Forfeited & Cancelled in the period	(823,000) (1)	(2,386,795)
Expensed in the period	-	(5,353,382)
Exercised in the period	(325,000) (2)	-
September 30, 2008	3,581,221 \$	10,696,013

(1) One of our Directors voluntarily forfeited his 200,000 options on September 8, 2008. Due to his continued services as a Director on the date of his voluntary forfeiture, this was treated as a cancellation and all unamortized expense of \$924,021 was fully recognized in the period.

(2) The cashless exercises of the granted 325,000 warrant shares resulted in the issuance of an aggregate of 112,215 shares of our common stock.

	Number of Options and Warrants	Weighted Average Exercise Price
<b>Stock Options and Warrants</b>		
Balance at January 1, 2008	4,674,221	\$ 6.01
Granted	55,000	7.00
Exercised	(325,000)	1.00
Forfeited & Cancelled	(823,000)	6.51
Balance at September 30, 2008	3,581,221	\$ 6.37

### Note 15 — Stockholders' (Deficit) Equity

In response to the NQCI arbitration interim award associated to the Technology Transaction, we are planning to seek stockholders approval to issue 9,230,000 shares of our common stock directly to NQCI to effectuate the transaction. Upon issuance and delivery of the proposed shares, NQCI will be our largest stockholder, owning approximately 39% of our total outstanding shares.

As a result of the accrual for 9.23 million shares, discussed further in Note 4-Legal Proceedings and Note 8-Shares Issuable above, "Total Stockholders' (Deficit) Equity" has a negative balance with our deficit accumulated during the development stage being greater than our additional paid in capital as of September 30, 2008.

### Note 16 — Product Development Agreement

In July 2007, we entered into an agreement with Aubrey Group, Inc., an FDA-registered third-party contract developer and manufacturer of medical devices for the design and development of a Portable Artificial Kidney ("PAK"). The PAK will be designed for use as an Intermittent as well as a Continuous Renal Replacement Therapy (CRRT) in the hospital with medical supervision. The development is expected to be completed by the end of 2008 and projected labor and material costs were estimated at approximately \$5.1 million at the inception of the agreement and over the term. The agreement can be terminated at any time with 30 business days notice. From commencement through September 30, 2008, we incurred \$3,063,798 in expense for the services rendered under this agreement and anticipate incurring approximately \$200,000 for the remainder of 2008.

### Note 17 — Subsequent Events

On October 2, 2008, Kelly J. McCrann was unanimously appointed Chairman of the Board of Directors and Chief Executive Officer. With his new role, Mr. McCrann resigned from the Audit Committee and Compensation Committee with Dr. Hans Polaschegg taking his place on the Compensation Committee. On October 6, 2008, effective October 2, 2008, we entered into an employment agreement with Mr. McCrann for a term of two years at an initial annual base salary of \$325,000. He is eligible to receive discretionary bonuses based on achieving designated goals and milestones, and overall performance and profitability. Additionally, Mr. McCrann was granted 700,000 stock options at an exercise price of \$1.50 per share under our 2007 Incentive Compensation Plan, which vest 25% on each of the first, second, third, and fourth anniversaries of the grant date, with anti-dilution protections. Further, if we issue shares to NQCI pursuant to the arbitration with NQCI, Mr. McCrann, shall, upon the date of such issuance to NQCI, be granted an additional option, number of shares to be determined, under the 2007 Incentive Compensation Plan to purchase such shares of our common stock, at an exercise price equal to the greater of (a) \$1.50 per share or

(b) the fair market value of a share of our common stock on the grant date, necessary to preserve Mr. McCrann's ownership percentage of the company on a fully diluted basis, based upon the ownership percentage determined as of the date of initial grant. If Mr. McCrann is terminated without good cause or resigns for good reason, as defined in the employment agreement, we will be obligated to pay Mr. McCrann twelve months' base salary. A copy of Mr. McCrann's employment agreement is attached as an exhibit to our current report on Form 8-K filed with the Securities and Exchange Commission on October 8, 2008.

To comply with the American Stock Exchange rule requiring that a majority of our directors be independent, Daniel Goldberger and Dr. Victor Gura resigned as members of our board of directors on October 7, 2008.

In lieu of Mr. Goldberger's resignation as our interim CEO on October 6, 2008, we amended his consulting agreement. Pursuant to the amendment, Mr. Goldberger will provide the company with his services through year end. As consideration for his services, he will be paid \$12,500 for October 2008 and \$5,000 per month for each of November and December.

On October 6, 2008, with modification to the lease agreement on October 23, 2008, we entered into a 5 year lease agreement, commencing November 27, 2008 through November 26, 2013 with early possession on October 27, 2008, for our new operating facility in Lake Forest, CA. The monthly base rent will start at \$23,540 per month and increase annually by approximately 3%. The total minimum lease, base rent, payments will be \$1,515,120 over a 5 year period. As required by the agreement, we issued an 18 month, \$300,000, letter of credit secured by a new CD account as collateral. Upon execution of the lease agreement, we notified Aubrey of our intent to vacate our current subleased space by the end of November 2008. A copy of the lease agreement is attached as Exhibit 10.1 to this quarterly report on Form 10-Q.

On August 10, 2007, Terren S. Peizer entered into an Executive Chairman Agreement with Operations for an initial term of three years with automatic one-year renewals, which Executive Chairman Agreement was assumed by us. His base compensation is \$450,000 per annum as of July 1, 2007, with a signing bonus of \$225,000. Mr. Peizer will be entitled to receive an annual bonus at the discretion of the board based on performance goals and targeted at 100% of his base compensation. He is also eligible to participate in any equity incentive plans adopted by us. In the event Mr. Peizer's position is terminated without good cause or he resigns for good reason, we will be obligated to pay Mr. Peizer in a lump sum an amount equal to three years' base compensation bonus plus 100% of the targeted bonus. At the request of Mr. Peizer, we stopped making payments to him under the agreement in August 2008 and Mr. Peizer voluntarily relinquished his role as Executive Chairman in October 2008.

## **ITEM 2. Management's Discussion and Analysis or Plan of Operation.**

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes, and the other financial information included in this report.*

### **Forward-Looking Statements**

This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to the financial condition, results of operations, business strategies, operating efficiencies or synergies, competitive positions, growth opportunities for existing products, plans and objectives of management, markets for stock of Xcorporeal, and other matters. Statements in this report that are not historical facts are "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. Such forward-looking statements, including, without limitation, those relating to the future business prospects, revenues, and income of Xcorporeal, wherever they occur, are necessarily estimates reflecting the best judgment of the senior management of Xcorporeal on the date on which they were made, or if no date is stated, as of the date of this report. These forward-looking statements are subject to risks, uncertainties and assumptions, including those described in the "Risk Factors" described below, that may affect the operations, performance, development, and results of our business. Because the factors discussed in this report could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

### **Overview**

We are a medical device company developing an innovative *extra-corporeal* platform technology to be used in devices to replace the function of various human organs. These devices will seek to provide patients with improved, efficient and cost effective therapy. The platform leads to three initial products:

- A PAK for hospital Renal Replacement Therapy (RRT);

- A PAK for home hemodialysis; and
- A Wearable Artificial Kidney (WAK) for continuous ambulatory hemodialysis.

For the hospital market, we are developing a portable, multifunctional renal replacement device that will offer cost-effective therapy for those patients suffering from Acute Renal Failure (ARF) causing a rapid decline in kidney function. We have completed our functional prototype of the product, which is currently undergoing bench testing, and will submit a 510(k) filing with the FDA next year. We plan to commercialize the product after receiving clearance from the FDA. Timing of FDA clearance is uncertain at this time.

We also plan to commercialize a home hemodialysis device for the End Stage Renal Disease (ESRD) market, comprised of patients in whom the kidneys have ceased to function. We have also completed our functional prototype of the product, which is currently undergoing bench testing, and we will submit a 510(k) with the FDA during 2009. Clinical trials are anticipated to commence as soon as FDA clearance is received.

Our WAK is a device for the chronic treatment of ESRD. We have successfully demonstrated a prototype system that weighs less than 6 kg., is battery operated, and can be worn by an ambulatory patient. Provided that the Technology Transaction described in Part II, Item 1 – Legal Proceedings below closes, we will evaluate the feasibility of furthering our development of this product over the next 12 months.

We are a development stage company, have been unprofitable since our inception, and will incur substantial additional operating losses for at least the next twelve months as we continue to implement commercial operations and allocate significant and increasing resources to research, development, clinical trials, and other activities. Accordingly, our historical operations and financial information are not indicative of our future operating results, financial condition, or ability to operate profitably as a commercial enterprise.

## **Research and Development**

### ***R&D Team***

We have recruited and currently employ a talented interdisciplinary team of scientists and engineers who are developing our products. The team includes engineering leaders from within the dialysis field who provide state of the art as well as historical insights into dialysis equipment. The team also includes seasoned engineers from related medical fields providing us with cutting edge technology in the areas of fluidics, sensors, and electronics. In addition, we have retained a medical device consulting firm, The Aubrey Group, Inc., an FDA-registered third-party contract developer and manufacturer of medical devices, to provide engineering support in the development and build of the PAK thru the end of 2008. In 2009, we will transition into verification and validation of the PAK utilizing our scientists and engineers as well as outside consultants.

We incurred \$12.7 million and \$18.9 million in research and development costs in the three and nine months ended September 30, 2008, respectively, including the August 4, 2008, \$10.2 million fair value accrual for a potential 9.23 million shares issuance to effectuate the Technology Transaction in accordance to the Second Interim Award. Less the accrual for shares issuable, we incurred \$2.5 million and \$8.7 million in research and development costs in the three and nine months ended September 30, 2008, respectively. This compares to \$2.1 million and \$4.8 million incurred in the three and nine months ended September 30, 2007.

### ***Third-party Arrangements***

In July 2007, we entered into an agreement with Aubrey for the design and development of subsystems of the PAK. The PAK will be designed for intermittent hemodialysis or CRRT in a clinical setting as well as for treatments in a home setting. The development is expected to be complete by the end of 2008. At the inception of the agreement, total labor and material costs over the term of the Aubrey agreement was budgeted at approximately \$5.1 million which we anticipate to be under budget at completion. We can terminate the agreement at any time with 30 business days notice.

We also contract with other third parties to assist in our research and development efforts and to supplement our internal resources while we continue to grow our organization.

## **Management's Discussion and Analysis**

### ***Results of Operations for the three and nine months ended September 30, 2008.***

We have not generated any revenues since inception. We incurred a net loss of \$11.1 million and \$22.8 million for the three and nine months ended September 30, 2008, respectively, compared to a net loss of \$4.5 million and \$12.1 million for the three and nine months ended September 30, 2007, respectively. The increase in net loss was primarily due to (i) research, development and other expenses related to advancing our kidney failure treatment technologies, (ii) stock compensation expense related to options and warrants granted to directors, officers, employees, and consultants, (iii) legal fees, (iv) common stock issuances as compensation for consulting services, (v) accruals for alleged licensor expenses and interim awards issued in the arbitration with NQCI, and (vi) increased company personnel. At September 30, 2008, we had positive working capital of \$1.4 million compared to positive working capital of \$15.0 million at the beginning of the year.

***Liquidity and Capital Resources***

We expect to incur operating losses and negative cash flows for the foreseeable future. During the fourth quarter 2006, we raised approximately \$27.3 million (net of placement fees of \$2.1 million) through a private placement. Our ability to execute on our current business plan is dependent upon our ability to develop and market our products, and, ultimately, to generate revenue.

As of September 30, 2008, we had cash, cash equivalents and marketable securities of approximately \$6.0 million. We are currently expending cash at a rate of approximately \$1.1 million per month. In addition, we may become obligated to pay damages, costs or legal fees in connection with the ongoing arbitration described under Part II, Item 1-Legal Proceedings below, in an interim amount of \$1.87 million. At present rates, we will have to raise additional funds during the next several months. We may not be successful in doing so on terms acceptable to us, and the inability to raise capital could require us to curtail our current plans in order to decrease spending, which could have a material adverse effect on our plan of operation. Our ability to execute on our current business plan is dependent upon our ability to obtain equity financing, develop and market our products, and, ultimately, to generate revenue.



We expect to incur negative cash flows and net losses for the foreseeable future. Based upon our current plans, we believe that our existing cash reserves will not be sufficient to meet our operating expenses and capital requirements before we achieve profitability. Accordingly, we may seek to raise additional funds through public or private placement of shares of preferred or common stock or through public or private financing. Our ability to meet our cash obligations as they become due and payable will depend on our ability to sell securities, borrow funds, reduce operating costs, or some combination thereof. We may not be successful in raising necessary funds on acceptable terms, or at all. As a result of these conditions, there is substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Upon receipt of the approximate \$27.3 million raised through private placement in the fourth quarter of 2006, we strategically began our operating activities and research and development efforts which resulted in a net loss of \$17.1 million in 2007 and \$18.2 million in the nine months ended September 30, 2008. In addition, we invested \$25.0 million in high grade money market funds and marketable securities of which we sold \$19.2 million of the investments, leaving a balance of \$5.8 million as of September 30, 2008.

We have focused much of our efforts on development of the PAK, which has not been derived from the technology covered by the License Agreement. Through the productive research and development efforts of the PAK, we have completed functional prototypes of our hospital and home PAKs that we plan to commercialize after 510(k) clearance from the Food and Drug Administration (FDA) which we plan 510(k) submission by next year. Prior to the 510(k) submission to the FDA for clinical use under direct medical supervision, the units will undergo final verification and validation. It generally takes 4 to 12 months from the date of a 510(k) submission to obtain clearance from the FDA, although it may take longer. We expect that our monthly expenditures will increase as we shift resources towards developing a marketing plan for the PAK.

We have used some of our resources for the development of the WAK which we have demonstrated a feasibility prototype. Commercialization of the WAK will require development of a functional prototype and likely a full pre-market approval by the FDA, which could take several years. Our rights to the WAK derive in part from a License Agreement dated September 1, 2006 between Operations and National Quality Care, Inc, pursuant to which we obtained the exclusive rights to the technology designated therein. Once the Technology Transaction has closed and the results of the arbitration proceeding are final, we will determine whether to devote additional resources to development of the WAK.

If we ever become obligated to pay all or a substantial portion of the \$690,000 in alleged expenses related to the License Agreement and the interim award of \$1.87 million in attorneys' fees pursuant to the NQCI arbitration, doing so could have a material adverse effect on our liquidity and financial ability to continue with ongoing operations as currently planned.

Because neither the PAK nor the WAK is yet at a stage where it can be marketed commercially, we are not able to predict the portion of our future business which will be derived from each.

## **Research and Development**

We employ an interdisciplinary team of scientists and engineers who are developing the PAK and a separate, interdisciplinary team developing the WAK. In addition, we have retained Aubrey to assist with the engineering of the PAK. The PAK will be engineered to perform both hemodialysis, hemofiltration and ultrafiltration under direct medical supervision. A variation of this device will be developed for chronic home hemodialysis. An initial laboratory prototype of the PAK, capable of performing the functions of a hemodialysis machine, and demonstrating our unique new fluidics circuit, was completed at the end of 2007. The first physical prototype including industrial design of the PAK was completed in October 2008. Further refinements to this prototype are now in progress. The final product

design of the PAK will be completed shortly and units will undergo final verification and validation prior to a 510(k) submission for clinical use under direct medical supervision. A clinical study is not required for this submission.

In a clinical feasibility study conducted in London in March 2007, a research prototype of the WAK was successfully demonstrated in eight patients with end-stage renal disease. Patients were successfully treated for up to 8 hours with adequate clearances of urea and creatinine. The device was well tolerated and patients were able to conduct activities of normal daily living including walking and sleeping. There were no serious adverse events although clotting of the dialyzer occurred in two patients. To our knowledge, this is the first successful demonstration of a wearable artificial kidney in man. Provided that the Technology Transaction closes, we will be making substantial improvements to the WAK. This work will result in a WAK Generation 2.0. Pending the FDA approval of an investigational Device Exemption (IDE), additional clinical studies will be conducted upon completion of the Generation 2.0 WAK prototype.

We incurred \$12.7 million and \$18.9 million in research and development costs in the three and nine months ended September 30, 2008, respectively, including the August 4, 2008, \$10.2 million fair value accrual for a potential 9.23 million shares issuance to effectuate the Technology Transaction in accordance to the Second Interim Award. As such, less the accrual for the shares issuable, we incurred \$2.5 million and \$8.7 million in research and development costs in the three and nine months ended September 30, 2008, respectively. This compares to \$2.1 million and \$4.8 million incurred in the three and nine months ended September 30, 2007.

**Contractual Obligations and Commercial Commitments**

Contractual Obligations:	Total	Less than 1			More than 5
		year	1 - 3 years	3 - 5 years	
<b>Capital Lease Obligations</b>	\$ -	\$ -	\$ -	\$ -	-
<b>Operating Lease Obligations (1)</b>	1,176,889	107,113	786,199	283,576	-
<b>Research &amp; Development</b>					
<b>Contractual Commitments</b>	77,996	77,996	-	-	-
<b>Other Liabilities</b>	12,167	12,167	-	-	-
	\$ 1,267,051	\$ 197,276	\$ 786,199	\$ 283,576	\$ -

(1) Operating lease commitments for our corporate office facility, product development facility, Dr. Gura's office which is a related party transaction, and two corporate apartments as well as for copiers and T1 access.

The table excludes the agreement with Aubrey in relation to the PAK development which can be terminated at any time with 30 business days notice. Due to development efficiencies not anticipated at the inception of the Aubrey agreement, we will incur less actual costs and expenses than the \$5.1 million budgeted amount. With the expected completion by end of 2008, we estimate we will incur a total cost of \$3.3 million under this agreement.

**Off-Balance Sheet Arrangements**

As of September 30, 2008, we had no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations or cash flows.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. Generally accepted accounting principles require management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. We base our estimates on experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that may not be readily apparent from other sources. Our actual results may differ from those estimates.

We consider our critical accounting policies to be those that involve significant uncertainties, require judgments or estimates that are more difficult for management to determine or that may produce materially different results when using different assumptions. We consider the following accounting policies to be critical:

**Marketable Securities**

We classify investments with maturity dates greater than three months when purchased as marketable securities. Investments, including certificates of deposit with maturity dates greater than three months when purchased and which have readily determined fair values, are classified as available-for-sale investments and reflected in current assets as marketable securities at fair market value. Our investment policy requires that all investments be investment grade quality and no more than ten percent of our portfolio may be invested in any one security or with one institution.

Short-term investments classified as available-for-sale were as follows:

	September 30, 2008		
Aggregate Fair	Gross Unrealized	Estimated Fair	

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	<b>Value</b>	<b>Gains / (Losses)</b>	<b>Value</b>
Commercial paper	\$ 3,708,821	\$ -	\$ 3,708,821
Corporate securities fixed rate	651,811	-	651,811
<b>Total</b>	<b>\$ 4,360,632</b>	<b>\$ -</b>	<b>\$ 4,360,632</b>

Xcorporeal reviews impairments associated with the above in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and FASB Staff Position FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," to determine the classification of the impairment as temporary or other-than-temporary. Xcorporeal considers these investments not to be impaired as of September 30, 2008.

There were no gross unrealized gains or losses as of September 30, 2008.

#### *Shares Issuable*

Pursuant to the Second Interim Award, stating that, if the Technology Transaction is submitted to and approved by our stockholders, 9,230,000 shares of our common stock should be issued to NQCI to effectuate the transaction, we accrued for the 9.23 million shares of our common stock. As the Second Interim Award states that a registration statement for any issued shares must be declared effective within 90 days, and such contingency is not within our control, we have recorded the issuance as a liability, rather than as equity. The fair value of the 9.23 million shares was measured using the closing price of our common stock on August 4, 2008, the date of the Second Interim Award, and revalued, marked to market, as of the end of this interim reporting period, September 30, 2008. The fair value of the accrued shares on August 4, 2008, was \$10,153,000 which was revalued at \$4,615,000 as of September 30, 2008, resulting in a \$5,538,000 non-operating gain to the statement of operations for the three and nine months ended September 30, 2008. The net fair value of \$4,615,000 was accrued under "Shares issuable" as of September 30, 2008. Stockholders' approval and issuance of the shares are pending to date. The shares issuable liability will be marked to market until a determination is made that the Technology Transaction will not be submitted to our stockholders, the stockholders vote not to approve the transaction, or they vote to approve the transaction and the shares are issued and registered. The price of our stock has declined since September 30, 2008, and as of November 18, 2008, the closing price was \$0.27 per share, reducing the shares issuable liability from \$4.6 million to approximately \$2.5 million as of that date. We anticipate that we will continue to incur losses, which will continue to increase the shareholder deficit.

Although we may seek stockholder approval for the issuance of the 9.23 million shares of our common stock to effectuate the Technology Transaction, we are uncertain whether the SEC will approve a form of proxy to solicit stockholder approval of the transaction, our stockholders will vote to approve the transaction, shares will be issued to NQCI, or the SEC will declare effective a registration statement to register the shares for resale. If the Technology Transaction does not close, the arbitrator may issue alternative relief. In the event of an alternate award, the above accrual may be adjusted and the accrual or the actual settlement will be recorded to coincide with the alternate award. If the Technology Transaction is approved and the shares are issued and registered or the registration requirement is eliminated or waived, that would eliminate the shares issuable liability, and increase stockholders equity by the amount of the liability.

#### *Stock-Based Compensation*

Statements of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) and Securities and Exchange Commission issued Staff Accounting Bulletin (SAB) No. 107 (SAB 107) require the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

In determining stock based compensation, we consider various factors in our calculation of fair value using a Black-Scholes pricing model. These factors include volatility, expected term of the options, and forfeiture rates. A change in these factors could result in differences in the stock based compensation expense.

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

We invest our cash in short term high grade commercial paper, certificates of deposit, money market accounts, and marketable securities. We consider any liquid investment with an original maturity of three months or less when purchased to be cash equivalents. We classify investments with maturity dates greater than three months when purchased as marketable securities, which have readily determined fair values and are classified as available-for-sale securities. Our investment policy requires that all investments be investment grade quality and no more than ten

percent of our portfolio may be invested in any one security or with one institution.

Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk arising from changes in the level or volatility of interest rates; however, interest rate movements do not materially affect the market value of our portfolio because of the short-term nature of these investments. A reduction in the overall level of interest rates may produce less interest income from our investment portfolio. The market risk associated with our investments in debt securities is substantially mitigated by the frequent turnover of our portfolio.

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

##### ***Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (September 30, 2008), as is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officer, to allow timely decisions regarding required disclosures.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. Our management has concluded that the financial statements included in this report present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events.

***Changes in Internal Control***

There have been no changes in our internal control over financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

## PART II — OTHER INFORMATION

### ITEM 1. Legal Proceedings.

On September 1, 2006, Operations entered into a Merger Agreement with NQCI which contemplated that we would acquire NQCI as a wholly owned subsidiary pursuant to a triangular merger, or we would issue shares of our common stock to NQCI stockholders in consideration of the assignment of the technology relating to our WAK and other medical devices which, as listed under “Technology” on the License Agreement, are “all existing and hereafter developed Intellectual Property, Know-How, Licensor Patents, Licensor Patent Applications, Derivative Works and any other technology, invented, improved or developed by Licensor, or as to which Licensor owns or holds any rights, arising out of or relating to the research, development, design, manufacture or use of (a) any medical device, treatment or method as of the date of this Agreement, (b) any portable or continuous dialysis methods or devices, specifically including any wearable artificial kidney, or Wearable Artificial Kidney, and related devices, (c) any device, methods or treatments for congestive heart failure, and (d) any artificial heart or coronary device” (the “Technology Transaction”). The agreement provided that Operations had no obligation to issue or deliver any shares after December 31, 2006, unless the Parties mutually agreed to extend such date, which they did not. In addition, on December 29, 2006, NQCI served us with written notice that it was terminating the Merger Agreement, which we accepted. Accordingly, the merger was not consummated. Copies of the License Agreement and the Merger Agreement are attached as Appendix B and Appendix C, respectively, to the preliminary proxy statement filed October 31, 2008, with the Securities and Exchange Commission.

On December 1, 2006, Operations initiated arbitration proceedings against NQCI for its breach of the License Agreement, which remains pending. NQCI claimed the License Agreement was terminated, and we sought a declaration that the License Agreement remained in effect until the Closing of the Merger or Technology Transaction. We later amended our claims to seek damages for NQCI’s failure to perform its obligations under the License Agreement. NQCI filed counterclaims seeking to invalidate the License Agreement and claiming monetary damages against us. NQCI also filed claims against Dr. Gura, claiming he breached his obligations to NQCI by agreeing to serve on our board of directors. Following a hearing and extensive briefing, the arbitrator denied both parties’ claims for damages. Although NQCI never filed an amendment to its counterclaims to seek specific performance, on June 9, 2008, the arbitrator issued an Interim Award granting specific performance of the Technology Transaction.

The Interim Award stated that the total aggregate shares of stock to be received by NQCI stockholders at the Closing should equal 48% of all Operations shares outstanding as of the date of the Merger Agreement. On September 1, 2006, there were 10,000,000 shares of Operations common stock outstanding. NQCI proposed four possible share interest awards, arguing that it was entitled to between 9,600,000 and 17,130,293 shares, representing a 48% or 54% interest based on Operations shares outstanding at the time of the Merger Agreement or our present number of outstanding shares.

On August 4, 2008, the arbitrator issued a Second Interim Award, modifying the initial Interim Award, stating that, if we desire to close the Technology Transaction, we must obtain approval from a majority of our stockholders and issue 9,230,000 shares of our common stock. Although the first Interim Award stated that 48% of the outstanding shares should be issued, the Second Interim Award states that the number of shares issued should be 48% of 19,230,000 shares, the total number of shares necessary to put our 52% interest at 10,000,000 shares. As of October 31, 2008, there were 14,704,687 shares of our common stock issued and outstanding. Accordingly, following Closing of the Technology Transaction, NQCI stockholders would own approximately 39% of our total outstanding shares, making NQCI our largest stockholder. The arbitrator found that, with the exception of shareholder approval, virtually all conditions to Closing the Technology Transaction have been waived, including virtually all of NQCI’s representations and warranties concerning the Technology. Upon Closing of the Technology Transaction, all of the Technology will be our sole and exclusive property.



The Second Interim Award also states that, contrary to the assertions made by NQCI, the License Agreement will remain in full force and effect until the Technology Transaction closes or the arbitrator determines that it will never close. Upon Closing of the Technology Transaction, the License Agreement will terminate, and we will own all of the Technology.

On January 3, 2008, the arbitrator issued an order denying NQCI's motion to amend its counterclaim to add us as a successor company following the merger. However, in the Second Interim Award, the arbitrator found that we are the successor to Operations as a result of the merger, even though we are not a party to any of the agreements or the arbitration, and ordered that our shares should be issued to NQCI rather than shares of Operations.

The arbitrator has not ordered us to close the Technology Transaction. However, the Second Interim Award states that, if our stockholders fail to approve the issuance of stock to effectuate the Technology Transaction, all of the Technology covered by the License shall be declared the sole and exclusive property of NQCI, and the arbitrator shall schedule additional hearings to address two questions: whether the PAK technology is included within that Technology, and whether NQCI is entitled to compensatory damages and the amount of damages under these circumstances. During the arbitration, NQCI took the position that we had misappropriated trade secrets regarding the WAK and used them to create the PAK. The arbitrator found that we had not misappropriated NQCI's trade secrets. However, should the Technology Transaction not close for any reason, and the arbitrator rules that the licensed Technology must be returned to NQCI, the arbitrator could find that the PAK is derived in whole or in part from the licensed Technology, and could rule that Operations must "return" the PAK technology to NQCI or that NQCI is entitled to compensatory damages or both.

On August 15, 2008, the arbitrator awarded NQCI \$1.87 million of over \$4 million it claimed in attorneys' fees and costs, stating that NQCI's lack of success and other factors warranted a substantial reduction in the sums claimed. The arbitrator stated in pertinent part: "National's success in the arbitration has been only partial and this is directly relevant to the question of the quantum of attorneys' fees which should be awarded. ... National sought eight or nine figure damages, but was awarded none. ... Further, National asserted claims for fraud, interference with contract, and other torts, all of which were rejected. His lack of success warrants a substantial reduction in the sums claimed." NQCI asked for a total of \$4.04 million in attorneys' fees and costs. The arbitrator awarded NQCI a total of \$1.87 million.

In an August 29, 2008 Order Re Issuance of Xcorporeal Shares, the arbitrator stated that the shares should be issued directly to NQCI's stockholders. However, on September 4, 2008, the arbitrator issued an order that we should issue and deliver the 9,230,000 shares directly to NQCI, rather than directly to NQCI stockholders, if we obtain stockholder approval and elect to proceed with the Technology Transaction.

The Second Interim Award requires that we file a registration statement under the Securities Act to register for resale the shares to be issued to NQCI within 30 days after the closing of the Technology Transaction. The arbitrator acknowledged that our obligation is to file the registration statement and to use reasonable efforts to have the shares registered and not to guarantee registration and resultant actual public tradability. However, the arbitrator nevertheless ordered that the registration statement must be declared effective within 90 days. We have no control over whether the registration statement will be declared effective by the Securities and Exchange Commission, and no way to predict what further action, if any, the arbitrator may order if it is not declared effective.

The arbitrator has stated that he has not yet issued a final award that may be confirmed or challenged in a court of competent jurisdiction. A party to the arbitration could challenge the interim award in court, even after stockholders approve the transaction. In addition, the arbitrator could again change the award by granting different or additional remedies, even after stockholders approve the transaction. We cannot guarantee that the arbitrator would order that stockholders be given another opportunity to vote on the transaction, even if such changes are material. Arbitrators have broad equitable powers, and arbitration awards are difficult to challenge in court, even if the arbitrator makes rulings that are inconsistent or not in accordance with the law or the evidence.

### ***Shares to be issued***

We intend to seek approval from our stockholders to issue 9,230,000 shares of our common stock to NQCI in order to close the Technology Transaction and obtain ownership of intellectual property rights described above. As of November 17, 2008, there were 14,704,687 shares of our common stock issued and outstanding. Accordingly, following Closing of the Technology Transaction, NQCI would own approximately 39% of our total outstanding shares.

As a result, NQCI may have the ability to substantially influence the outcome of issues submitted to our stockholders. The interests of NQCI may not coincide with our interests or the interests of other stockholders, and it may act in a manner that advances its best interests and not necessarily those of other stockholders. One consequence to this substantial interest is that it may deter unsolicited takeovers, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

### ***The Technology***

The Merger Agreement provides that, at the Closing of the Technology Transaction, NQCI shall absolutely, unconditionally, validly and irrevocably sell, transfer, grant and assign to Operations all of the Technology, including, but not limited to, the inventions embodied or described in the Licensor Patents and Patent Applications as defined in the License Agreement.

Under the License Agreement, NQCI grants to us an exclusive license for 99 years (or, if earlier, until the expiration of NQCI's proprietary rights in the Technology) for an annual royalty of 7% of net sales, with a minimum annual royalty of \$250,000. We are required to "make commercially reasonable efforts to develop and commercially exploit the Technology to generate revenues" during the term of the License Agreement. The License Agreement does not provide for termination in the event the Merger Agreement is terminated; instead it provides for an adjustment of the royalty to 6.5%, 7.5%, or 8.5% depending on the grounds on which the Merger Agreement was terminated. Either party has the right to terminate the License Agreement in the event of a material breach by the other party which remains uncured for a period of 30 days after notice. In the event of a termination of the License Agreement, we are required to cease all use of the Technology and return all "Licensee Confidential Information" to NQCI. The Technology relates primarily to the WAK.

### **ITEM 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. In addition to the information in this report, you should carefully consider the risks described under Risk Factors in Part I, Item 1 of our Annual Report on Form 10-KSB for the year ended December 31, 2007, and the revised risk factors noted below. If any of such risks actually occurs, our business, results of operations and financial condition will likely suffer. As a result the trading price of our common stock may decline, and you might lose part or all of your investment*

**An unfavorable result in the pending arbitration could have a material adverse effect on our capital structure, business and financial condition.**

We consider the protection of our proprietary technology for treatment of kidney failure, which we have licensed and are developing, to be critical to our business prospects. We obtained the rights to the wearable artificial kidney (WAK) through a License Agreement with National Quality Care, Inc. (NQCI). On December 1, 2006, Operations initiated arbitration against NQCI for failure to fully perform its obligations under our License Agreement. NQCI filed counterclaims seeking to invalidate the License Agreement and claiming monetary damages against us. In interim awards, the arbitrator has found that the License Agreement will not survive if the Technology Transaction contemplated by the Merger Agreement entered into concurrently with the License Agreement fails to close. If this determination were upheld by a court of competent jurisdiction, we could be prevented from using the WAK technology we licensed from it. In addition, if it were found that our rights to the portable artificial kidney (PAK) are derived from the licensed technology, that could significantly impact our ability to develop, manufacture and sell our PAK, which would have a material adverse effect on our business and results of operations.

The interim awards state that NQCI is entitled to reimbursement for reasonable attorneys' fees. NQCI has made a claim for approximately \$3.9 million in such fees, which we have opposed and a lower amount of \$1.87 million awarded by the arbitrator. The interim settlement of legal fees has been accrued in the three and nine months ending September 30, 2008. NQCI has also made a claim for reimbursement of approximately \$690,000 in alleged expenses related to the License Agreement which has been accrued at June 30, 2008. If we ever become obligated to pay all or a substantial portion of such amounts, doing so could have a material adverse effect on our liquidity and financial ability to continue with ongoing operations as currently planned.

The interim awards also state that 9,230,000 shares of our common stock would have to be issued to effectuate the Technology Transaction, if Closing such a transaction were to be approved by our stockholders. The issuance of such shares would result in NQCI owning approximately 39% of our total outstanding shares, diluting current stockholders and giving it the ability to substantially influence the outcome of matters submitted to stockholders.

**We expect to incur negative cash flows and net losses for the foreseeable future and may not be able to continue as a going concern.**

As a result of our expectation of negative cash flows and net losses for the foreseeable future, based on our current plans, we believe our existing cash reserves will not be sufficient to meet our operating expenses and capital requirements before we achieve profitability. Our ability to meet our cash obligations as they become due will depend on our ability to secure financing on acceptable terms. Unless we are able to raise capital sufficient to support our operations there will be substantial doubt of our ability to continue as a going concern.

**Approximately 42% of our stock is controlled by a single stockholder who has the ability to substantially influence the election of directors and the outcome of matters submitted to stockholders.**

As of September 30, 2008, CNL, a limited liability company whose managing member is a member of our board of directors, directly owned 6,232,596 shares, which represent approximately 42.4% of our 14,704,687 shares of outstanding common stock. As a result, CNL presently and is expected to continue to have the ability to determine the outcome of issues submitted to our stockholders. The interests of this stockholder may not always coincide with our interests or the interests of other stockholders, and it may act in a manner that advances its best interests and not necessarily those of other stockholders. One consequence to this substantial stockholder's interest is that it may be difficult for investors to remove management of the company. It could also deter unsolicited takeovers, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

**Sales of common stock by our existing stockholders, or the perception that such sales may occur, could depress our stock price.**

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, our existing stockholders, including stockholders who recently purchased their shares from CNL. Most of our outstanding shares were registered on a Form S-4 registration statement in connection with our October 2007 merger, and are eligible for public resale. Approximately half of our shares of common stock are currently held by our affiliates and may be sold pursuant to an effective registration statement or in accordance with the volume and other limitations of Rule 144 under the Securities Act of 1933, as amended, or pursuant to other exempt transactions. Future sales of common stock by significant stockholders, including those who acquired their shares in private placements or who are affiliates, or the perception that such sales may occur, could depress the price of our common stock.

**ITEM 2. Unregistered Sales of Equity Securities; Use of Proceeds from Registered Securities.**

For the three months ended September 30, 2008, we did not have unregistered sales of equity securities or use of proceeds from registered securities.

**ITEM 6. Exhibits.**

<b>No.</b>	<b>Description of Exhibit</b>
10.1	Lease for Operating Facility
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

24

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**SIGNATURES**

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

Date: November 19, 2008

By: /s/ Robert Weinstein  
Robert Weinstein  
Chief Financial Officer  
(Principal Financial Officer and Principal  
Accounting Officer)

25

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