Xcorporeal, Inc. Form 10QSB November 13, 2007

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

#### FORM 10-QSB

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

For the quarterly period ended September 30, 2007

Commission file number 001-31608

#### **XCORPOREAL, INC.**

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

**Delaware** 

75-2242792

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification Number)

11150 Santa Monica Blvd., Suite 340, Los Angeles, California 90025

(Address of principal executive offices)

(310) 481-8986

(Issuer's telephone number)

## CT HOLDINGS ENTERPRISES, INC.

2100 McKinney Avenue, Suite 1500, Dallas, Texas 75201

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

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 R No £

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

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 8, 2007

Common Stock, \$0.0001 par value

14,351,491 shares

-

## **INDEX**

## PART I — FINANCIAL INFORMATION

Item 1. Interim Financial Statements	3
Balance Sheets at September 30, 2007 (unaudited) and December 31, 2006	3
Statements of Operations (unaudited) for the three and nine months ended September 30, 2007 and September 30, 2006 and the period from inception (May 4, 2001) to September 30, 2007	4
Statement of Stockholders Equity (Deficit) for the nine months ended September 30, 2007 and the period from inception (May 4, 2001) to September 30, 2007 (unaudited)	5
Statements of Cash Flows (unaudited) for the nine months ended September 30, 2007 and September 30, 2006 and the period from inception (May 4, 2001) to September 30, 2007	6
Notes to the Interim Financial Statements	7
Item 2. Management's Discussion and Analysis or Plan of Operation	11
Item 3. Controls and Procedures	18
PART II — OTHER INFORMATION	19
Item 1. Legal Proceedings	19
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	24
Item 4. Submission of Matters to a Vote of Security Holders	24
Item 6. Exhibits	24
Signatures	25

#### PART I — FINANCIAL INFORMATION

#### **ITEM 1. Financial Statements**

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

	(	September 30, 2007 (Unaudited)	December 31, 2006
ASSETS			
Current			
Cash and cash equivalents	\$	672,271	\$ 27,440,987
Marketable securities, at fair value		19,609,317	-
Restricted cash		87,996	-
Prepaid Expenses & Other Current Assets		314,163	90,228
Total current assets		20,683,747	27,531,215
Property and equipment, net		196,087	3,328
Other assets		936	1,000
Total Assets	\$	20,880,770	\$ 27,535,543
LIABILITIES			
Current			
Accounts payable	\$	1,314,373	\$ 143,606
Accrued placement agent fees		-	1,348,470
Accrued professional fees		582,668	312,208
Accrued royalties		270,833	83,333
Accrued other liabilities		173,456	121,189
Other current liabilities		115,400	124,676
Total Current Liabilities		2,456,730	2,133,482
Commitments and contingencies			
STOCKHOLDERS' EQUITY			
Preferred Stock, \$0.001 par value, 10,000,000 shares			
authorized, none outstanding		-	-
Common Stock, \$0.0001 par value, 40,000,000 shares			
authorized, 14,000,050 and 14,200,050 outstanding on			
September 30, 2007 and December 31, 2006,			
respectively		1,400	1,420
Additional paid-in capital		35,081,012	29,924,410
Deficit accumulated during the development stage		(16,658,372)	(4,523,769)
Total Stockholders' Equity		18,424,040	25,402,061
Total Liabilities & Stockholders' Equity	\$	20,880,770	\$ 27,535,543

See accompanying notes to these interim financial statements.

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

	Thr	ee Mo	onth	s Ended	Nine Mo	onths	Ended	May 4, 2001 (Date of Inception) to September
		Septei	mbei	r <b>30</b> ,	September 30,			30,
	2007	-		2006	2007		2006	2007
Operating Expenses:								
Selling, general and administrative	\$ 2,664,	405	\$	2,307,727 \$	8,254,693	\$	2,319,517	\$ 11,573,345
Research and development	2,087,	753		917,630	4,775,887		917,630	6,063,209
Depreciation and amortization	9,	243		-	14,626		-	14,721
Loss before interest income and								
income taxes	(4,761,	401)		(3,225,357)	(13,045,206)		(3,237,147)	(17,651,275)
Interest income	290,	677		-	910,603		-	992,903
Loss before income taxes	(4,470,	724)		(3,225,357)	(12,134,603)		(3,237,147)	(16,658,372)
Income taxes				_				_
meonic taxes		_					_	_
Net Loss	\$ (4,470,	724)	\$	(3,225,357)\$	(12,134,603)	\$	(3,237,147)	\$ (16,658,372)
Basic and diluted loss per share	\$ ((	).32)	\$	(0.55)\$	(0.86)	\$	(0.72)	
XX : 1 . 1 1								
Weighted average number of shares outstanding	14,089,	180		5,835,217	14,162,687		4,499,121	

See accompanying notes to these interim financial statements.

# XCORPOREAL, INC. (a Development Stage Company) STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY) For the Period May 4, 2001 (Inception) to September 30, 2007 (Unaudited)

	Comm	on Stock	Additional Paid-in	Deficit Accumulated During Development	
	Shares	Amount	Capital	Stage	Total
Common stock issued for cash at \$0.01 per share	2,500,000	\$ 250	_	\$	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 licence rights	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

Edgar Filing: Xcorporeal, Inc. - Form 10QSB

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	-	-
Warrants granted for consulting			2 222 229		2 222 220
services			2,233,238		2,233,238
Stock-based compensation expense			2,923,344		2,923,344
Net loss for the period				(12,134,603)	(12,134,603)
Balance as of September 30, 2007	14,000,050	\$ 1,400 \$	35,081,012 \$	(16,658,372)\$	18,424,040

See accompanying notes to these interim financial statements.

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

	001 (Date of
Nine Months Ended	nception) to eptember
September 30, 2007 2006	30, 2007
Cash flows used in operating activities	
Net Loss for the Period \$ (12,134,603) \$ (3,237,147) \$ (1	16,658,372)
Adjustments to reconcile net loss to net cash used in	
operating activities:	
Non-employee Stock Based Compensation 2,923,344 2,162,611	5,085,955
Stock Based Compensation 2,233,238 -	2,497,489
Depreciation and amortization 14,626 -	14,721
Net Change in assets and liabilities:	
Prepaid Expenses & Other Current Assets (223,935) -	(314,163)
Other Assets	(1,000)
Accounts Payable and Accrued Liabilities 332,524 1,044,143	2,341,329
Other Current Liabilities (9,276) -	115,400
Net Cash Used in Operating Activities (6,864,082) (30,393)	(6,918,641)
Cash Flows from Investing Activities	
Capital Expenditures (207,321)	(210,744)
Restricted Cash (87,996) -	(87,996)
Purchase of marketable securities (21,932,739) - (2	21,932,739)
Sale of marketable securities 2,323,422 -	2,323,422
Net Cash Used in Investing Activities (19,904,634) - (1	19,908,057)
Cash Flows from Financing Activities	
-	27,434,349
Advances from related party - 30,393	64,620
• •	27,498,969
Increase/(decrease) in cash during the period (26,768,716)	672,271
Cash, beginning of the period 27,440,987 -	-
Cash, end of the period \$ 672,271 \$ - \$	672,271
Supplemental disclosure of cash flow information; cash paid for:	
Interest \$ - \$ - \$	_
Income taxes \$ - \$	-

See accompanying notes to these interim financial statements.

## XCORPOREAL, INC.

# (a Development Stage Company) NOTES TO THE INTERIM FINANCIAL STATEMENTS

September 30, 2007 (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. All adjustments are of a normal recurring nature. It is suggested that these interim financial statements be read in conjunction with our December 31, 2006 financial statements.

The results of operations for the period ended September 30, 2007 are not necessarily indicative of the results that can be expected for the year ended December 31, 2007.

#### Note 2 — Nature and Continuance of Operations

On October 12, 2007, pursuant to a merger agreement with Xcorporeal, Inc. (referred to hereinafter as pre-merger Xcorporeal), our newly-formed wholly-owned merger subsidiary merged with and into pre-merger Xcorporeal, which became our wholly-owned subsidiary and changed its name to "Xcorporeal Operations, Inc." We changed our name from CT Holdings Enterprises, Inc. to "Xcorporeal, Inc." and amended our certificate of incorporation and bylaws to read substantially as pre-merger Xcorporeal. 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 pre-merger Xcorporeal common stock was then converted into one share of our common stock. In addition, we assumed all outstanding pre-merger Xcorporeal options and warrants to purchase pre-merger Xcorporeal common stock.

CTHE is considered to be the legal acquirer in this merger. As the former shareholders of pre-merger Xcorporeal own over 97% of the outstanding voting common stock of CTHE after the merger and CTHE is a public shell company, pre-merger Xcorporeal is considered the accounting acquirer and the transaction is considered to be a recapitalization of pre-merger Xcorporeal.

Historical financial statements prior to the merger were restated to be those of pre-merger Xcorporeal. The merger is accounted for as if it were an issuance of the common stock of pre-merger Xcorporeal to acquire our net assets, accompanied by a recapitalization. Historical stockholders' equity of pre-merger Xcorporeal 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 pre-merger Xcorporeal are carried forward at their predecessor carrying amounts. Retained deficiency of pre-merger Xcorporeal is carried forward after the merger. Operations prior to the merger are those of pre-merger Xcorporeal. Earnings per share for periods prior to the merger are restated to reflect the number of equivalent shares received by pre-merger Xcorporeal's stockholders. The costs of the transaction will be expensed to the extent they exceed cash received from CTHE.

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.

#### **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, regulatory and other risks associated with a development stage company, including the potential risk of business failure.

#### Note 4 — Cash Equivalents and Marketable Securities

We invest available cash in short-term commercial paper, certificates of deposit and high grade variable rate securities. Liquid investments with an original maturity of three months or less when purchased are considered to be cash equivalents.

Investments, including auction rate securities and certificates of deposit, with maturity dates greater than three months when purchased, 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. Auction rate securities are recorded at par value, which equals fair market value, as the rate on such securities resets generally every 7, 28 or 35 days.

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

#### Note 5 — Property and Equipment

Property and equipment consist of the following at September 30, 2007:

Property and equipment	\$ 210,744
Accumulated depreciation	(14,657)
Property and equipment, net	\$ 196,087

Depreciation expense for the three and nine months ended September 30, 2007 was \$9,229 and \$14,562, respectively. There was no depreciation expense for the three and nine months ended September 30, 2006.

#### Note 6 — Interest Income

Interest income of \$290,677 and \$910,603 reported for the three and nine months ended September 30, 2007, respectively, are a result of the interest earned on our cash raised from our private placement during the fourth quarter of 2006.

#### **Note 7** — Related Party Transaction

We were charged the following by a former director of pre-merger Xcorporeal:

				May 4, 2001
				(Date of
				Inception) to
	Three months er	nded N	ine months ended	September
	September 30	),	September 30,	30,
	2007 2	006 200	7 2006	2007
Administrative services	\$ — \$	-\$	<b>—</b> \$ 3,0	000 \$ 12,000

On August 7, 2007, CTHE issued 500,000 (60,460 post reverse split) shares of restricted common stock to Steven B. Solomon, CTHE's then Chief Executive Officer, in connection with his services to CTHE and further advances of funds. CTHE issued the restricted common stock in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, pursuant to a transaction to one accredited investor not involving any public offering.

#### Note 8 — License Agreement

On August 31, 2006, we entered into a Contribution Agreement with a company whose sole managing member is our current Chairman. 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. Pre-merger Xcorporeal 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 a minimum annual royalty of \$250,000, or 7% of net sales. We recorded \$270,833 in royalty expenses covering the minimum royalties from commencement of the License Agreement through September 30, 2007. The first minimum royalty payment is due by December 1, 2007. The License Agreement expires in 2105.

#### **Note 9— 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 pre-merger Xcorporeal immediately prior to the merger (see Note 2).

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 that were granted by pre-merger Xcorporeal under its 2006 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.

On August 10, 2007 and August 15, 2007, pre-merger Xcorporeal granted options to purchase an aggregate of 470,000 and 325,000 shares, respectively, of common stock to employees, which we assumed as part of the merger. The options vest ratably over 4 or 5 years, are exercisable at \$7.00 per share, the fair market value of our common stock on the grant date, and expire in 2017. The fair value of such stock options was \$4.8 million.

In connection with his August 10, 2007 resignation as an officer, Daniel Goldberger forfeited options to purchase 200,000 shares of common stock. He will retain his remaining 200,000 options as he continues to serve as a member of the board of directors.

We reported \$1.0 million and \$2.2 million in stock-based compensation expense for employees, officers and directors for the three and nine month period ended September 30, 2007, respectively. No such stock-based compensation expense was reported for the three and nine month period ended September 30, 2006.

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, 2007
Expected dividend yields	zero
Expected volatility	110%
Risk-free interest rate	4.68%
Expected terms in years	6.25-6.50

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

On August 10, 2007 and August 15, 2007, pre-merger Xcorporeal also issued stock options to two consultants to purchase 20,000 and 10,000 shares of common stock, respectively, in exchange for consulting services, which we also assumed. These stock options vest ratably over 5 years so long as the consultant continues to provide services, are exercisable at \$7.00 per share, the fair market value of our common stock on the grant date and expire 2017. The resulting fair value of such stock options was \$0.2 million.

We reported \$0.1 million and \$2.9 million in stock-based compensation expense for consultants for the three and nine month period ended September 30, 2007, respectively. Stock-based compensation expense in the amount of \$2.2 million was reported for the three and nine month period ended September 30, 2006.

Compensation for options granted to non-employees has been determined in accordance with SFAS No. 123, 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:

	September
	30, 2007
Expected dividend yields	zero
Expected volatility	135%
Risk-free interest rate	4.59%
Expected terms in years	9.86

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, 2007:

	Stock	
	Options	
	and	Unamortized
	Warrants	Compensation
	Outstanding	Expense
January 1, 2007	2,054,221	\$ 10,002,154
Granted in the period	2,985,000	18,321,060
Forfeited in the		
period	(405,000)	(2,721,499)
Expensed in the		
period		(5,156,582)
September 30, 2007	4,634,221	\$ 20,445,133

Options and Warrants	E	Weighted Average Exercise Price	
2.054.221	¢	4.50	
	and Warrants	and E	

Edgar Filing: Xcorporeal, Inc. - Form 10QSB

Granted	2,985,000 \$	7.00
Exercised	- \$	-
Forfeited	(405,000) \$	6.01
Balance at		
September 30, 2007	4,634,221 \$	5.98
Options and warrants		
exercisable at		
September 30, 2007	4,634,221 \$	5.98

#### Note 10 — Stockholders' Equity

On August 7, 2007, Steven B. Solomon, CTHE's then Chief Executive Officer, was issued 500,000 (60,460 post reverse split) shares of CT Holdings Enterprises, Inc. common stock for providing services and cash to fund operating expenses of the Company. Steven Solomon is a 50% owner of CITN Investment Inc. (CII) which owns 1,014,286 (122,647 post reverse split) shares of CT Holdings Enterprises common stock. Lawrence Lacerte, the other owner of CII transferred 100,000 (12,092 post reverse split) of such shares to Steven Solomon.

On August 10, 2007, pre-merger Xcorporeal cancelled 200,000 shares of common stock pursuant to a settlement agreement with one of our stockholders.

#### **Note 11 — 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 are estimated at approximately \$5.1 million over the term. The agreement can be terminated at any time with 30 business days notice.

#### **Note 12 — Subsequent Events**

Effective October 12, 2007 and pursuant to a merger agreement executed on August 10, 2007, our merger subsidiary merged with and into pre-merger Xcorporeal, with pre-merger Xcorporeal being the surviving corporation and becoming our wholly-owned subsidiary. Each share of pre-merger Xcorporeal common stock outstanding immediately prior to the effective time of the merger was converted into one share of our common stock. In addition, we assumed all outstanding pre-merger Xcorporeal options and warrants.

We changed our name to "Xcorporeal, Inc." and our certificate of incorporation and bylaws were amended and restated to read substantially as pre-merger Xcorporeal. Pre-merger Xcorporeal's certificate of incorporation were amended to change its name to "Xcorporeal Operations, Inc." All of our former officers and directors resigned, and all of the officers and directors of pre-merger Xcorporeal became our officers and directors effective as of October 12, 2007.

Immediately prior to the effectiveness of the merger, we caused a reverse split of our common stock, whereby each 8.27 issued and outstanding shares of our common stock were converted into one share of common stock.

We also adopted a new 2007 Incentive Compensation Plan substantially identical to pre-merger Xcorporeal's 2006 Incentive Compensation Plan.

#### 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**

The forward-looking comments contained in this report involve risks and uncertainties. Our actual results may differ materially from those discussed here due to factors such as, among others, limited operating history, difficulty in developing, exploiting and protecting proprietary technologies, results of clinical studies, intense competition and substantial regulation in the healthcare industry. Additional factors that could cause or contribute to such differences can be found in the following discussion and in the "Risks Factors" set forth below.

#### **Plan of Operation**

#### Overview

We are a medical device company actively researching and developing an *extra-corporeal* platform to perform functions of various human organs. Our prototype systems apply modern electronics and engineering principals to reduce the size, cost and power requirements of conventional extra-corporeal therapies including acute and chronic renal replacement therapies (kidney dialysis). Our platform may also improve the quality of therapy ultimately delivered leading to better patient outcomes and reduced healthcare costs. The products we plan to bring to market include:

- · Portable Artificial Kidney (PAK) dialysis device for use in the hospital for the treatment of acute renal failure
  · PAK for use in the home for chronic treatment of End Stage Renal Disease (ESRD)
  - · Wearable Artificial Kidney (WAK) for chronic treatment of ESRD.

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 activities to date are not as broad in depth or scope as the activities we will undertake in the future, and 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.

Since we began implementing our current business model on August 31, 2006, we have accomplished the following milestones:

- Raised over \$29 million in equity financing in the fourth quarter of 2006 selling shares of Xcorporeal common stock at \$7.00 per share.
- Recruited experienced independent board members
- · Recruited top industry management team and scientific staff
- Advanced the clinical studies for our technology
- Paid in excess of \$1 million in licensed product development expenses.

For the coming year we plan to test and develop the technology for our extra-corporeal platform and other medical devices. We will also plan our Validation and Verification strategy including bench testing, clinical testing, and regulatory strategy in the U.S. and abroad. Some of our products may qualify for the 510(k) regulatory process in the U.S. based on the existence of predicate devices. Other products, for example our WAK, are likely to require a full PMA review which will be longer and more expensive.

Our system can also be configured into a portable ultrafiltration device to treat fluid overload in Congestive Heart Failure (CHF) patients. We intend to focus initially on the renal replacement device applications described above, and may eventually exploit our technology's CHF applications through licensing or strategic arrangements.

#### **Product Applications**

Our WAK is a breakthrough technology 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. Increasing the weekly prescribed dose of dialysis therapy has previously been shown to reduce morbidity and improve quality of life in ESRD patients. Our WAK is the first practical device to provide continuous, chronic therapy, because:

- Its reduced size, weight, and power consumption allows us to deploy a wearable package so that the treatment does not interfere with normal activities of daily life.
- Its utilization of sorbents to regenerate the dialysate fluid and thus afford a considerable reduction in the amount of dialysate required for each treatment.

The same attributes (portability, size, weight, fluid and power reduction) will be applied to develop a PAK that will be able to provide Continuous Renal Replacement Therapy (CRRT) and/or acute intermittent hemodialysis to hospitalized patients with acute renal failure. This device will also be modified to provide home hemodialysis to patients with ESRD.

#### **Research and Development**

#### R&D Team

We acquired the exclusive license to our platform technology on September 1, 2006, and have commenced planning and implementing our research and development efforts. We have recruited an experienced scientific team to execute our research and development plan. The goals of our research and development efforts will include:

- Improving the chemicals used in the regeneration of the dialysis fluid. The current chemicals have been used for decades. We believe new chemicals that last longer and can be used in smaller quantities would further reduce the cost and weight of our product.
- Developing software to allow physicians to customize the function of the device to meet the specific dialysis needs of each patient.
- Adapting the extra-corporeal platform technology underlying our Wearable Artificial Kidney to
  other medical uses. We believe our technology is a platform for a number of other devices that can
  be used to treat other diseases and will offer substantive value propositions for patients and
  healthcare providers.
- Expanding our recruiting and retaining an experienced team of scientists and engineers.

#### Clinical Studies

The feasibility of the WAK prototype was demonstrated in a porcine model during 2004 and 2005. The feasibility of the WAK prototype for treatment of fluid overload in humans was demonstrated by the treatment of six volunteers in Vicenza, Italy in July and August 2006. We demonstrated the feasibility of the WAK prototype for dialysis treatment in humans by the treatment of eight volunteers in London in March 2007. We are planning over the next few years to conduct a pivotal study to support a regulatory submission.

We incurred approximately \$2.1 million and \$4.8 million in research and development expenses for the three and nine months ended September 30, 2007, respectively. This compares to \$1.3 million incurred during the year ended December 31, 2006. We expect our research and development expenses to increase as a result of additional headcount in the areas of product development and quality assurance and regulatory affairs, a higher level of third-party consulting activity and related expenses.

#### Third-party Arrangements

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 PAK. The PAK will be designed for use as a Continuous Renal Replacement Therapy (CRRT) in either a hospital (with medical supervision) or home setting. The development is expected to be completed by the end of 2008 and projected labor and material costs are estimated at approximately \$5.1 million over the term. The agreement can be terminated 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.

#### **Government Regulation**

#### **US Regulation**

We are subject to extensive government regulation relating to the development and marketing of our products. Due to the relatively early nature of our development efforts, we have not yet confirmed with the FDA its view of the regulatory status of the submissions we intend to make. However, we anticipate that regardless of regulatory pathway, we will need to conduct clinical studies involving human subjects before being able to market our products in the US.

To support a regulatory submission, the FDA commonly requires clinical studies to show safety and effectiveness. While we cannot currently state the nature of the studies the FDA may require due to our early stage of product development, it is likely any product we attempt to develop will require time-consuming studies in order to secure approval.

Outside the US, our ability to market potential products is contingent upon receiving market application authorizations from the appropriate regulatory authorities. These foreign regulatory approval processes may involve differing requirements than those of the FDA, but also generally include many, if not all, of the risks associated with the FDA approval process described above, depending on the country involved.

In the US, medical devices are classified into three different classes, Class I, II and III, on the basis of controls deemed reasonably necessary to ensure the safety and effectiveness of the device. Class I devices are subject to general controls, including labeling, pre-market notification and adherence to the FDA's Good Manufacturing Practices (GMP), Class II devices are subject to general and special controls, including performance standards, post-market surveillance, patient registries and FDA guidelines, and Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness, that is, life-sustaining, life-supporting and implantable devices, or new devices, which have been found not to be substantially equivalent to legally marketed devices. Because of their breakthrough nature, some of our devices may be considered Class III.

Before new medical devices such as our products can be marketed, marketing clearance must be obtained through a pre-market notification under Section 510(k) of the Federal Food, Drug and Cosmetic (FDC) Act. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to authorize the marketing of new products or to allow us to enter into supply contracts and criminal prosecution. A 510(k) clearance will typically be granted by the FDA, if it can be established that the device is substantially equivalent to a "predicate device," which is a legally marketed Class I or II device or a pre-amendment Class III device (that is, one that has been marketed since a date prior to May 28, 1976), for which the FDA has not called for pre-market approval (PMA). The FDA has been requiring an increasingly rigorous demonstration of substantial equivalence, which may include a requirement to submit human clinical trial data. It generally takes 4 to 12 months from the date of a 510(k) submission to obtain clearance, but it may take longer.

If clearance or approval is obtained, any device manufactured or distributed by us will be subject to pervasive and continuing regulation by the FDA. We will be subject to routine inspection by the FDA and will have to comply with the host of regulatory requirements that usually apply to medical devices marketed in the U.S. including labeling regulations, GMP requirements, Medical Device Reporting (MDR) regulation which requires a manufacturer to report to the FDA certain types of adverse events involving its products, and the FDA's prohibitions against promoting products for unapproved or "off-label" uses.

#### **European Community**

The primary regulatory environment in Europe is that of the European Union (EU), which consists of 25 countries encompassing most of the major countries in Europe. The EU requires that manufacturers of medical products obtain the right to affix the CE mark to their products before selling them in member countries of the EU. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE mark on its products and commercially distribute those products throughout the European Union.

International Organization for Standards (ISO) standards were developed by the EU as a tool for companies interested in increasing productivity, decreasing cost and increasing quality. The EU uses ISO standards to provide a universal framework for quality assurance and to ensure the good quality of products and services across borders. The ISO standards (it is now ISO13485) have facilitated trade throughout the EU, and businesses and governments throughout the world are recognizing the benefit of the globally accepted uniform standards. Manufacturers we utilize for

purposes of producing our products (including us, if we manufacture any of our own products) will be required to obtain ISO certification to facilitate the highest quality products and the easiest market entry in cross-border marketing. This will enable us to market our products in all of the member countries of the EU. We also will be required to comply with additional individual national requirements that are outside the scope of those required by the European Economic Area.

Any medical device that is legally marketed in the US may be exported anywhere in the world without prior FDA notification or approval. The export provisions of the FDC Act apply only to unapproved devices. While FDA does not place any restrictions on the export of these devices, certain countries may require written certification that a firm or its devices are in compliance with US law. In such instances FDA will accommodate US firms by providing a Certificate for Foreign Government. In cases where there are devices which the manufacturer wishes to export during the interim period while their 510(k) submission is under review, exporting may be allowed without prior FDA clearance under certain limited conditions.

#### Competition

We compete directly and indirectly with other biotechnology and healthcare equipment businesses, including those in the dialysis industry. The major competitors for the *Xcorporeal* platform technology are those companies manufacturing and selling dialysis equipment and supplies. Xcorporeal will compete with these companies in the critical care markets as well as the home application markets. In many cases, these competitors are larger and more firmly established than we are. In addition, our competitors have greater marketing and development budgets and greater capital resources than our company. We anticipate that some of our primary competitors will be companies such as Baxter, Fresenius, Gambro, NxStage, and Nephros.

#### **License Agreement**

On September 1, 2006, we entered into the License Agreement pursuant to which we obtained exclusive rights to our technology relating to the treatment of kidney failure and other applications, with no geographic restrictions, that will last for a period of ninety-nine years or until the expiration of its proprietary rights in each item of intellectual property, if earlier. As consideration for granting the license, we agreed to reimburse designated costs and expenses of our licensor, and pay a minimum royalty of 7% of net sales, with an annual minimum royalty of \$250,000.

#### **Patents and Trademarks**

We have exclusive license rights to two issued US patents, No. 20050101901 "Wearable continuous renal replacement therapy device," and No. 20040254514 "Wearable ultrafiltration device" from the US Patent & Trademark Office. We also have exclusive rights to a pending application specifically for the pump, the most critical part of all three devices, "Dual-Ventricle Pump Cartridge," and another proposed patent for "Method For Installing and Servicing a Wearable Continuous Renal Replacement Therapy Device" which is aimed to prevent entry into the wearable device market. We are actively developing our intellectual property, and plan to continually expand our patent portfolio.

In addition, we are actively developing additional intellectual property that in part supersedes the rights licensed under the License Agreement. We are filing patent applications to protect and improve the inventions that are commercially important for the development of our business and we plan to continually expand our patent portfolio.

We have pending applications to register our trademarks "Xcorporeal" and "Xcorporeal WAK."

#### **Employees**

We have 17 full-time employees, comprised of our Chief Operating Officer, Chief Financial Officer, Chief Medical and Scientific Officer, Senior Vice President of Quality Assurance and Regulatory Affairs, and seven other personnel in research and development and administration. During 2007, we plan to add additional employees, particularly in the areas of product development, regulatory affairs, and quality assurance. Our headcount is expected to exceed 25 employees by the end of the year. We also utilize, whenever appropriate, contract and part-time professionals in order to conserve cash and resources.

#### **Business Development**

#### Formation, Merger and Name Change

We were incorporated in the State of Delaware in 1992 as Lonestar Hospitality Corp. Effective October 12, 2007 and pursuant to the merger agreement executed on August 10, 2007, our newly-formed merger subsidiary with and into pre-merger Xcorporeal, with pre-merger Xcorporeal being the surviving corporation and becoming our wholly-owned

subsidiary.

Pursuant to the merger, we changed our name from "CT Holdings Enterprises, Inc." to "Xcorporeal, Inc." and amended and restated the certificate of incorporation and bylaws to read substantially as pre-merger Xcorporeal. Pre-merger Xcorporeal's certificate of incorporation were amended to change its name to "Xcorporeal Operations, Inc." All of our former officers and directors resigned, and all of the officers and directors of pre-merger Xcorporeal became our officers and directors effective as of October 12, 2007.

On August 31, 2006, pre-merger Xcorporeal entered into a Contribution Agreement with Consolidated National, LLC (CNL), which is owned and controlled by our current Executive Chairman, giving us the right to enter into a License Agreement with NQCI. We issued 9,600,000 shares of common stock, a 96% voting interest in our company, to CNL in exchange for all of our right, title, and interest to the name "Xcorporeal" and related trademark applications and domain names, and the right to enter into the License Agreement. Prior to the August 31, 2006 transaction, pre-merger Xcorporeal was a shell corporation.

On September 1, 2006, pre-merger Xcorporeal entered into a License Agreement with NQCI, pursuant to which we obtained the exclusive rights to the technology relating to our congestive heart failure treatment, kidney failure treatment, and other medical devices. As a result, we have become a developmental stage company focused on researching, developing, and commercializing technology and products related to the treatment of kidney failure and congestive heart failure.

On December 1, 2006, we initiated arbitration proceedings against NQCI for its breach of the License Agreement, which remains pending. On December 29, 2006, NQCI served us with a written notice purporting to terminate the License Agreement for unspecified alleged breaches. On January 2, 2006, we advised NQCI that we did not consent to termination of the License Agreement, that we have not breached the License Agreement, and that NQCI has no right to unilaterally terminate the License Agreement in any event. Accordingly, the License Agreement cannot be terminated.

#### **Terminated Merger Agreement**

On September 1, 2006, we 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 to NQCI shares of our common stock in consideration of the assignment of the technology relating to our WAK and other medical devices.

The merger was not consummated, and the Merger Agreement expired by its own terms on December 31, 2006. In addition, on December 29, 2006, NQCI served written notice that it was terminating the Merger Agreement, and on January 2, 2006, we consented to the termination. Accordingly, the Merger Agreement is now terminated. We will not be proceeding with any merger with NQCI.

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

#### Results of Operations for the three and nine months ended September 30, 2007

We have not generated any revenues since inception. We incurred net loss of \$4.7 million and \$12.4 million for the three and nine months ended September 30, 2007, compared to a net loss of \$3.2 million for the three and nine months ended September 30, 2006. The net loss for the three and nine months ended September 30, 2007 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, officer, employees and consultants, and (iii) legal and audit fees. The net loss for the three and nine months ended September 30, 2006, was the result of (i) stock compensation expense related to warrants granted to three consultants and (ii) research and development expenses. At September 30, 2007, we had positive working capital of \$18.2 million compared to positive working capital of \$25.4 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.

At September 30, 2007 we had cash, cash equivalents and marketable securities of approximately \$20.3 million. We are currently expending cash at a rate of approximately \$1.0 million per month. At present rates, we will not have to raise additional funds in the next twelve months.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2007, 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.

#### Legal Proceedings

We are involved in arbitration against NQCI as described above. From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. As of the date of this report, we are not currently involved in any legal proceeding that we believe would have a material adverse effect on our business, financial condition or operating results.

#### 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 auction rate securities and 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. Auction rate securities are recorded at cost, which equals fair market value, as the rate on such securities generally resets every 7, 28 or 35 days. 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.

#### Identifiable Intangibles

Certain costs associated with obtaining and licensing patents and trademarks are capitalized and amortized on a straight-line basis over the shorter of their estimated useful lives or their legal lives of 17 to 20 years. Amortization of such costs begins once the patent or trademark has been issued. We evaluate the recoverability of our patent costs and trademarks quarterly based on estimated undiscounted future cash flows.

#### 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 its adoption of SFAS 123(R).

In determining stock based compensation the Company considers various factors in its 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.

#### **Recent Accounting Pronouncements**

In July 2006, the FASB released FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. This Interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. This statement is effective for fiscal years beginning after December 15, 2006. We have adopted FIN 48 in January 2007. There was no impact on our results of operations and financial position upon adoption.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are required to adopt the provision of SFAS 157, as applicable, beginning in fiscal year 2008. We are currently in the process of evaluating the expected effect of SFAS 157 on our results of operations and financial position.

In February 2007, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities" ("SFAS No. 159"). SFAS No. 159 permits an entity to choose to measure many financial instruments and certain items at fair value. The objective of this standard is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reporting earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. Entities will report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007, which for us would be our fiscal year beginning January 1, 2008. Early adoption is permitted as of the beginning of the previous fiscal year provided that the entity makes that choice in the first 120 days of that fiscal year and also elects to apply to provision of FASB Statement No. 157, "Fair Value Measurements." We are currently evaluating the impact that the adoption of SFAS No. 159 will have on our consolidated financial statements.

#### **ITEM 3. Controls and Procedures**

We conducted an evaluation, under the supervision and with the participation of our Chief Operating Officer (principal executive officer) and Chief Financial Officer (principal financial officer), of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2007. Based upon this evaluation, our Chief Operating Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that required material information is included in this quarterly report for the period ended September 30, 2007.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II — OTHER INFORMATION

#### ITEM 1. Legal Proceedings.

On December 1, 2006, we initiated arbitration against National Quality Care, Inc. (NQCI) for its failure to fully perform its obligations under our License Agreement. On December 29, 2006, NQCI filed suit against us in Los Angeles County Superior Court entitled *National Quality Care, Inc. v. Victor Gura, M.D., et al.*, Case No. BC364140. We do not believe there is any reasonable likelihood that NQCI can prevail on its claims. On January 5, 2007, we filed a petition to compel arbitration, and NQCI subsequently stipulated to resolve all claims in the pending arbitration. On March 20, 2007, the lawsuit was dismissed without prejudice.

#### ITEM 1A. Risk Factors.

Our results of operations and financial condition are subject to numerous risks and uncertainties. You should carefully consider these risk factors in conjunction with the other information contained in this report. Should any of these risks materialize, our business, financial condition and future prospects could be negatively impacted.

#### RISKS RELATING TO OUR BUSINESS

#### Our limited operating history may make it difficult to evaluate our business to date and our future viability.

We are in the early stage of operations and development, and have only a limited operating history on which to base an evaluation of our business and prospects, having just commenced operations in August 2006 in accordance with our new business plan and entry into the medical devices industry. In addition, our operations and developments are subject to all of the risks inherent in the growth of an early stage company. We will be subject to the risks inherent in the ownership and operation of a company with a limited operating history such as regulatory setbacks and delays, fluctuations in expenses, competition, the general strength of regional and national economies, and governmental regulation. Any failure to successfully address these risks and uncertainties would seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we will face. The likelihood of our success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new technology, and the competitive and regulatory environment in which we operate or may choose to operate in the future. We have generated no revenues to date, and there can be no assurance that we will be able to successfully develop our products and penetrate our target markets.

# We expect to continue to incur operating losses, and if we are not able to raise necessary additional funds we may have to reduce or stop operations.

We have not generated revenues or become profitable, may never do so, and may not generate sufficient working capital to cover the cost of operations. No party has guaranteed to advance additional funds to us to provide for any operating deficits. Until we begin generating revenue, we may seek funding through the sale of equity, or securities convertible into equity, further dilution to our then existing stockholders may result. If we raise additional capital through the incurrence of debt, our business may be affected by the amount of leverage we incur, and our borrowings may subject us to restrictive covenants. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce or stop operations, any of which would have a material adverse effect on our business.

Our success will depend on our ability to retain our managerial personnel and to attract additional personnel.

Our success will depend largely on our ability to attract and retain managerial personnel.

Competition for desirable personnel is intense, and we cannot guarantee that we will be able to attract and retain the necessary staff. The loss of members of managerial, sales or scientific staff could have a material adverse effect on our future operations and on successful development of products for our target markets. The failure to maintain our management, particularly our Executive Chairman, Chief Operating Officer, Chief Financial Officer, and Chief Medical and Scientific Officer, and to attract additional key personnel could materially adversely affect our business, financial condition and results of operations. Although we intend to provide incentive compensation to attract and retain our key personnel, we cannot guarantee that these efforts will be successful.

We will need to expand our finance, administrative, product development, sales and marketing, and operations staff. There are no assurances that we will be able to make such hires. In addition, we may be required to enter into relationships with various strategic partners and other third parties necessary to our business. Planned personnel may not be adequate to support our future operations, management may not be able to hire, train, retain, motivate and manage required personnel or management may not be able to identify, manage and exploit existing and potential strategic relationships and market opportunities. If we fail to manage our growth effectively, it could have a material adverse effect on our business, results of operations and financial condition.

# We need to develop our financial and reporting processes, procedures and controls to support our anticipated growth.

We have not historically invested significantly in our financial and reporting systems. To comply with our public reporting requirements, and manage the anticipated growth of our operations and personnel, we will be required to improve existing or implement new operational and financial systems, processes and procedures, and to expand, train and manage our employee base. Our current and planned systems, procedures and controls may not be adequate to support our future operations.

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with any new rules and regulations, or if compliance can be achieved.

# We cannot assure you that we will be able to complete development and obtain necessary approvals for our proposed products even if we obtain sufficient funding.

Even if we obtain sufficient funding, no assurance can be given that we will be able to design or have designed parts necessary for the manufacture of our products or complete the development of our proposed products within our anticipated time frames, if at all. Such a situation could have a material adverse effect upon our ability to remain in business.

# The success of our business will depend on our ability to develop and protect our intellectual property rights, which could be expensive.

Patent and other proprietary rights are essential to our business. Our success depends to a significant degree on our ability to obtain and enforce patents and licenses to patent rights, both in the U.S. and in other countries. We cannot be certain that the patents that we license from others will be enforceable and afford protection against competitors. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Even if such patents are valid, we cannot guarantee that competitors will not independently develop alternative technologies that duplicate the functionality of our technology.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive positions. While we protect our proprietary rights to the extent possible, we cannot guarantee that third parties will not know, discover or develop independently equivalent proprietary information or techniques, that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation of our intellectual property would have an adverse effect on our competitive position and may cause us to incur substantial litigation costs.

## We may be subject to claims that we infringe the intellectual property rights of others, and unfavorable outcomes could harm our business.

Our future operations may be subject to claims, and potential litigation, arising from our alleged infringement of patents, trade secrets or copyrights owned by other third parties. We intend to fully comply with the law in avoiding such infringements. However, within the medical devices industry, established companies have actively pursued such

infringements, and have initiated such claims and litigation, which has made the entry of competitive products more difficult. We may experience such claims or litigation initiated by existing, better-funded competitors. Court-ordered injunctions may prevent us from bringing new products to market, and the outcome of litigation and any resulting loss of revenues and expenses of litigation may substantially affect our ability to meet our expenses and continue operations.

We compete against other dialysis equipment manufacturers with much greater financial resources and better established products and customer relationships, which may make it difficult for us to penetrate the market and achieve significant sales of our products.

Our proposed products will compete directly against equipment produced by Fresenius Medical Care AG, Baxter Healthcare Corporation, Gambro AB, NxStage Medical, Inc. and others, each of which markets one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure.

Each of these competitors offers products that have been in use for a longer time than our products and are more widely recognized by physicians, patients and providers. Most of our competitors have significantly more financial and human resources, more established sales, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy. Most of these companies manufacture additional complementary products enabling them to offer a bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our proposed products. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better safety, convenience or effectiveness or are offered at lower prices. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

# We have not commissioned or obtained marketing studies which support the likelihood of success of our business plan.

No independent studies with regard to the feasibility of our proposed business plan have been conducted by any independent third parties with respect to our present and future business prospects and our capital requirements. In addition, there can be no assurances that our products or our treatment modality for ESRD will find sufficient acceptance in the marketplace to enable us to fulfill our long and short term goals, even if adequate financing is available and our products are approved to come to market, of which there can be no assurance.

# Material weaknesses in our internal control over financial reporting may make it difficult to accurately evaluate our results of operations and financial condition.

In pre-merger Xcorporeal's annual report for the year ended December 31, 2006, we reported material weaknesses in the effectiveness of our internal controls over financial reporting related to the application of generally accepted accounting principles arising from (a) our accounting for the transaction by which we ceased to be a shell corporation, (b) the assumptions used in estimating the fair value of warrants issued to consultants, (c) our accounting for research, development and other expenses incurred pursuant to the License Agreement, and (d) the calculation of the weighted average number of share outstanding. Despite our substantial efforts to ensure the integrity of our financial reporting process, we cannot guarantee that we will not identify additional weaknesses as we continue to work with the new systems that we have implemented. Any continuing material weaknesses in our internal control over financial reporting could result in errors in our financial statements, which could erode market confidence in our company, and make it more difficult to raise needed additional funds, and adversely affect the market price of our common stock, if such a market ever develops.

#### An unfavorable result in the pending arbitration could have a material adverse effect on our business.

We consider the protection of our proprietary technology for treatment of kidney failure and congestive heart failure to be critical to our business prospects. We obtained the rights to some of our most significant patented and patent-pending technologies through a License Agreement with National Quality Care, Inc. (NQCI). On December 1, 2006 we initiated arbitration against NQCI for failure to fully perform its obligations under our License Agreement. NQCI has filed counterclaims seeking to invalidate the License Agreement and claiming monetary damages against us. If NQCI were to prevail on some or all of its claims, we could be prevented from using some or all of the patented technology we licensed from it. That could significantly impact our ability to use and develop our technologies, which would have a material adverse effect on our business and results of operations.

#### RISKS RELATED TO OUR INDUSTRY

Our business will always be strictly regulated by the federal and other governments, and we cannot assure you that we will remain in compliance with all applicable regulation.

Clinical testing, manufacture, promotion and sale of our proposed products are subject to extensive regulation by numerous governmental authorities in the U.S., principally the FDA, and corresponding foreign regulatory agencies. Changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. We cannot assure you that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, or at all, or that we will not be required to incur significant costs in obtaining or maintaining such foreign regulatory approvals. Delays in receipt of, or failure to receive, such approvals or clearances, the loss of previously obtained approvals or clearances or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Any enforcement action by regulatory authorities with respect to past or future regulatory noncompliance could have a material adverse effect on our business, financial condition and results of operations. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to authorize the marketing of new products or to allow us to enter into supply contracts and criminal prosecution.

Even if our proposed products are approved for market, we will be subject to continuing regulation. We will continuously be subject to routine inspection by the FDA and will have to comply with the host of regulatory requirements that usually apply to medical devices marketed in the U.S. including labeling regulations, Quality System requirements, MDR regulations (which requires a manufacturer to report to the FDA certain types of adverse events involving its products), and the FDA's prohibitions against promoting products for unapproved or "off-label" uses. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, failure to comply with applicable international regulatory requirements can result in fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspensions of production, refusals by foreign governments to permit product sales and criminal prosecution. Furthermore, changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, or at all, or that we will not be required to incur significant costs in obtaining or maintaining such foreign regulatory approvals. Delays in receipt of, or failure to receive, such approvals or clearances, the loss of previously obtained approvals or clearances or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Any enforcement action by regulatory authorities with respect to past or future regulatory noncompliance could have a material adverse effect on our business, financial condition and results of operations.

Our failure to respond to rapid changes in technology and its applications and intense competition in the medical devices industry could make our treatment system obsolete.

The medical devices industry is subject to rapid and substantial technological development and product innovations. To be successful, we must respond to new developments in technology, new applications of existing technology and new treatment methods. Our response may be stymied if we require, but cannot secure, rights to essential third-party intellectual property. We may compete against companies offering alternative treatment systems to ours, some of which have greater financial, marketing and technical resources to utilize in pursuing technological development and

new treatment methods. Our financial condition and operating results could be adversely affected if our medical device products fail to compete favorably with these technological developments, or if we fail to be responsive on a timely and effective basis to competitors' new devices, applications, treatments or price strategies.

#### Product liability claims could adversely affect our results of operations.

The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. In an effort to minimize our liability we purchase product liability insurance coverage. In the future we may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for mandatory damages could exceed the amount of our coverage. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

#### RISKS RELATED TO OUR COMMON STOCK

#### If a market for our common stock does not develop, our stockholders may be unable to sell their shares.

There is currently no market for our common stock and we can provide no assurance that a market will develop. If no market is ever developed for our shares, it will be difficult for stockholders to sell their stock. In such a case, stockholders may find that they are unable to achieve benefits from their investment.

#### If a market for our common stock develops, our stock price may be volatile.

If a market for our common stock develops, the price at which our common stock will trade may be highly volatile and may fluctuate as a result of a number of factors, including the number of shares available for sale in the market, quarterly variations in our operating results, actual or anticipated announcements of new data, studies, products or services by us or competitors, regulatory investigations or determinations, acquisitions or strategic alliances by us or our competitors, recruitment or departures of key personnel, the gain or loss of significant customers, changes in the estimates of our operating performance, market conditions in our industry and the economy as a whole.

## Over 66% 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 November 2, 2007, Consolidated National, LLC (CNL), a limited liability company whose managing member is our Executive Chairman, directly owned 9,600,000 shares, which represent approximately 66.9% of our 14,351,491 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.

# Investors' interests in our company will be diluted and investors may suffer dilution in their net book value per share if we issue additional shares or raise funds through the sale of equity securities.

In the event that we are required to issue any additional shares or enter into private placements to raise financing through the sale of equity securities, investors' interests in our company will be diluted and investors may suffer dilution in their net book value per share depending on the price at which such securities are sold. If we issue any such additional shares, such issuances also will cause a reduction in the proportionate ownership and voting power of all other stockholders. Further, any such issuance may result in a change in our control.

#### We have never paid cash dividends and do not intend to do so.

We have never declared or paid cash dividends on our common stock. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.

#### We will need additional financing.

We will need additional financing to maintain and expand its business, and such financing may not be available on favorable terms, if at all. We intend to finance our business through the private placement and public offering of equity and debt securities. Additional financing may not be available on favorable terms, if at all. If we need funds and cannot raise them on acceptable terms, we may not be able to execute or business plan, and our shareholders may lose substantially all of their investment.

We became a publicly traded company through a merger with a public shell company, and we could be liable for unanticipated liabilities of our predecessor entity.

We became a publicly traded company through a merger effective October 12, 2007 between Xcorporeal, Inc. and CT Holdings Enterprises, Inc., the a publicly traded shell company that had previously provided management expertise including consulting on operations, marketing and strategic planning and a single source of capital to early stage technology companies. Although we believe the shell company had substantially no assets and liabilities as of the merger, we may be subject to claims related to the historical business of the shell, as well as costs and expenses related to the merger.

#### ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On August 7, 2007, the Company issued 500,000 (60,460 post reverse split) shares of restricted common stock to Steven B. Solomon, the Company's then Chief Executive Officer, in connection with his services to the Company and further advances of funds. The Company issued the restricted common stock in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, pursuant to a transaction to one accredited investor not involving any public offering.

#### ITEM 4. Submission of Matters to a Vote of Security Holders.

As of September 21, 2007, holders of 2,086,689 shares, or approximately 72% of the issued and outstanding common stock, considered, voted on and adopted the proposal to approve entering into the transactions contemplated by the August 10, 2007 merger agreement with pre-merger Xcorporeal, and to approve the merger, reverse stock split, and incentive compensation plan. This consent of stockholders was sufficient to approve entering into the transactions.

#### ITEM 6. Exhibits.

#### No. Description of Exhibit

- 2.1 Merger Agreement
- 3.1 Amended and Restated Certificate of Incorporation
- 3.2 Bylaws
- 4.1 Specimen of common stock certificate
- 10.1\* Form of Indemnification Agreement for directors
- 10.2\* Form of 2007 Incentive Compensation Plan
- 10.3 License Agreement
- 10.4 Contribution Agreement
- 10.5\* Employment Agreement of Victor Gura, M.D.
- 10.6 Form of Innovation, Proprietary Information and Confidentiality Agreement
- 10.7\* Executive Chairman Agreement of Terren S. Peizer
- 10.8\* Employment Agreement of Robert Weinstein
- 10.9 Consulting Agreement of Dr. Hans-Dietrich Polaschegg
- 10.10 Services Agreement with Aubrey Group, Inc.
- 14.1 Code of Ethics
- 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

<sup>\*</sup> Management contracts, compensatory plans or arrangements

#### **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 12, 2007 By: /s/ ROBERT WEINSTEIN

Robert Weinstein Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)