ENDOREX CORP
Form 10QSB
August 14, 2001

SEC SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-QSB

(X) QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the Quarterly Period Ended June 30, 2001

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

For the transition period from _____ to _____

Commission File No. 1-14778

ENDOREX CORPORATION
(Exact name of registrant as specified in its charter)

DELAWARE	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
28101 BALLARD DRIVE, SUITE F, LAKE FOREST, IL	60045
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code (847) 573-8990

(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 Securities 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 /X/ No / /

At August 10, 2001, 12,741,858 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

Transitional Small Business Disclosure Format (check one):

Yes / / No /X/

PART I. - FINANCIAL INFORMATION

ITEM 1 - Financial Statements

ENDOREX CORPORATION
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	June 30, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$9,808,676	$10,831,266
Marketable securities - available for sale	0	2,014,984
Related party receivable	26,745	126,538
Prepaid expenses	52,930	58,803
Total current assets	9,888,351	13,031,591
Leasehold improvements and equipment, net of accumulated amortization of $883,409	407,373	384,162
Patent issuance costs, net of accumulated amortization of $13,030	281,845	253,705
Other Assets:		
Prepaid Acquisition Cost	1,004,608	0
TOTAL ASSETS	$11,582,177	$13,669,458
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 674,319	$ 642,440
Accrued compensation	174,616	147,205
Due to joint ventures	2,285,831	2,010,713
Current portion of line of credit	126,611	118,793
Total current liabilities	3,261,377	2,919,151
Long-term liabilities:		
Long-term portion of line of credit	162,754	204,162
Total long-term liabilities	162,754	204,162
Total Liabilities	3,424,131	3,123,313
Series C exchangeable convertible preferred stock, $.05 par value. Authorized 200,000 shares; 97,603 issued and outstanding at liquidation value	10,004,315	9,665,512
Stockholders' equity:		
Preferred stock, $.001 par value. Authorized 4,600,000 shares; none issued and outstanding	--	--
Series B convertible preferred stock, $.05 par value. Authorized 200,000 shares; 100,410 issued & outstanding at liquidation value	10,439,339	10,041,000
Common stock, $.001 par value. Authorized 50,000,000 shares; 12,860,500 issued, and 12,741,858 outstanding	12,861	12,861
Additional paid-in capital	39,633,107	40,365,410
Unearned compensation	(6,350)	(4,852)
Deficit accumulated during the development stage	(51,481,746)	(49,090,111)
Unrealized gain/(loss) on marketable securities	270	75

	(1,402,519)	1,324,383
Less:		
Treasury stock, at cost, 118,642 shares	(443,750)	(443,750)
Total Stockholders' Equity	(1,846,269)	880,633
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,582,177	$ 13,669,458

See accompanying condensed notes to financial statements.

ENDOREX CORPORATION
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Six Months Ended June 30, 2001	2000	Cumulative from February 15, 1985 (date of inception) to June 30, 2001
Revenue:			
SBIR contract revenue	$ --	$ --	$ 100,000
Expenses:			
SBIR contract research and development	--	--	86,168
Proprietary research and development	1,171,494	468,193	16,004,499
General and administrative	908,269	981,521	13,980,313
Total operating expenses	2,079,763	1,449,714	30,070,980
Loss from operations	(2,079,763)	(1,449,714)	(29,970,980)
Equity losses in joint ventures	(577,661)	(1,578,856)	(23,223,912)
Other income	(1,577)	--	253,725
Interest income	294,686	320,965	3,336,274
Interest expense	(27,320)	(23,019)	(340,630)
Net loss	(2,391,635)	(2,730,624)	(49,945,523)
Preferred stock dividends	(737,142)	(687,378)	(4,117,942)
Net loss available to common stockholders	$(3,128,777)	$ (3,418,002)	$(54,063,465)
Basic and diluted net loss per share available to common stockholders	$ (0.25)	$ (0.29)	$ (15.78)
Basic and diluted weighted average common			

shares outstanding	12,741,858	11,646,663	3,416,117

See accompanying condensed notes to financial statements.

ENDOREX CORPORATION
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended June 30, 2001	2000
Revenue:		
SBIR contract revenue	$ --	$ --
Expenses:		
SBIR contract research and development	--	--
Proprietary research and development	585,642	217,112
General and administrative	439,515	615,559
Total operating expenses	1,025,157	832,671
Loss from operations	(1,025,157)	(832,671)
Equity losses in joint ventures	(260,603)	(648,779)
Other income	--	--
Interest income	120,317	198,165
Interest expense	(16,728)	(11,221)
Net loss	(1,182,171)	(1,294,506)
Preferred stock dividends	(370,608)	(342,747)
Net loss available to common stockholders	$(1,552,779)	$ (1,637,253)
Basic and diluted net loss per share available to common stockholders	$ (0.12)	$ (0.13)
Basic and diluted weighted average common shares outstanding	12,741,858	12,488,842

See accompanying condensed notes to financial statements.

ENDOREX CORPORATION

(A DEVELOPMENT STAGE ENTERPRISE)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Six Months Ended June 30, 2001	2000	Cumulative Period February 15, 1985 (Inception) to June 30, 2001
NET CASH USED IN OPERATING ACTIVITIES	(1,279,329)	(1,319,747)	(20,401,497)
INVESTING ACTIVITIES:			
Patent issuance cost	(30,201)	(33,454)	(789,426)
Investment in joint ventures	(577,661)	(964,064)	(20,541,544)
Organizational costs incurred	--	--	(135)
Purchases of leasehold improvements	(7,098)	--	(702,711)
Purchases of office and lab equipment	(87,893)	(52,236)	(1,085,354)
Proceeds from assets sold	--	--	4,790
Purchases of marketable securities--available for sale	(3,973,724)	(3,456,799)	(14,977,804)
Proceeds from sale of marketable securities--available for sale	5,988,708	3,000,000	15,088,123
Prepaid acquisition cost	(1,004,608)	--	(1,004,608)
NET CASH USED IN INVESTING ACTIVITIES	307,524	(1,506,553)	(24,008,668)
FINANCING ACTIVITIES:			
Net proceeds from issuance of common stock	0	7,797,238	37,799,270
Net proceeds from issuance of preferred stock	--	--	16,325,712
Proceeds from exercise of options	--	215,888	417,092
Proceeds from borrowings under line of credit	0	45,621	1,196,534
Repayment of borrowings under line of credit	(50,785)	(57,971)	(924,364)
Repayment of long-term note receivable	--	--	50,315
Repayment of note payable issued in exchange for legal service	--		(71,968)
Purchase and retirement of common stock	--	--	(130,000)
Purchase of treasury stock	--	--	(443,750)
NET CASH PROVIDED BY(USED IN) FINANCING ACTIVITIES	(50,785)	8,000,776	54,218,841
NET INCREASE(DECREASE) IN CASH AND CASH EQUIVALENTS	(1,022,590)	5,174,476	9,808,676
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,831,266	4,995,906	--
CASH AND CASH EQUIVALENTS - END OF PERIOD	$ 9,808,676	$10,170,382	$ 9,808,676

SUPPLEMENTAL DISCLOSURE OF CASH FLOW:			
Cash paid for interest.....	$ 27,321	$ 23,020	$ 187,662
NON-CASH TRANSACTIONS			
Issuance of common stock dividends in kind.....	$ --	--	$ 1,536,223
Issuance of preferred stock dividends in kind.....	737,142	687,378	(4,117,942)

The accompanying notes are an integral part
of the consolidated financial statements

ENDOREX CORPORATION
(A DEVELOPMENT STAGE ENTERPRISE)
CONDENSED NOTES TO FINANCIAL STATEMENTS

We prepared these unaudited interim consolidated financial statements under the rules and regulations for reporting on Form 10-QSB. Accordingly, we omitted some information and footnote disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with the consolidated financial statements and their notes included in our latest annual report on Form 10-KSB, as amended. It is our opinion that the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

NET LOSS PER SHARE

Net loss per share is presented on the Consolidated Statements of Operations in accordance with SFAS No. 128 for the current and prior periods. Endorex had a net loss for all periods being presented, which resulted in diluted and basic earnings per share being the same for all periods presented. The potential impact of warrants and stock options outstanding was not included in the calculation because their inclusion would have been anti-dilutive.

JOINT VENTURE ESTIMATES

The preparation of the quarterly consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts related to the activities of InnoVaccines Corporation, or InnoVaccines and Endorex Newco, Ltd., or Newco, our joint ventures with Elan Corporation, plc, or "Elan", including the reported net liabilities related to the joint ventures and the reported amounts of equity in losses from joint ventures. Actual results could differ from those estimates.

UNAUDITED CONDENSED FINANCIAL STATEMENTS FOR UNCONSOLIDATED JOINT VENTURES

Condensed, unaudited financial statement information of the joint ventures is stated below. The joint ventures had no revenues. Net expenses equaled the net loss for all periods.

	For the six months ended June 30, 2001	2000
InnoVaccines, net of Endorex mark up on billings to InnoVaccines	$ (482,202)	$(2,077,843)
Newco, net of Endorex mark up on billings to Newco	(230,825)	(131,496)
Total net loss	$ (713,027)	$(2,209,339)
Reconciliation to equity in losses from joint ventures:		
Total joint venture net losses	$ (713,027)	$(2,209,339)
Less: Elan minority interest	135,366	630,454
Equity in losses from joint ventures	$ (577,661)	$(1,578,885)

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes and our most recent Annual Report on Form 10-KSB, as amended. This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, and is subject to the safe-harbors created by those sections. These forward-looking statements are subject to significant risks and uncertainties, including those identified in Exhibit 99 "Risk Factors" of this Form 10-QSB, which may cause actual results to differ materially from those discussed in any forward-looking statements. The forward-looking statements within this Form 10-QSB are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions. However, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections, or other characterizations of future events or circumstances are forward-looking statements. We undertake no obligation to publicly release the results of any revisions to forward-looking statements that may be made to reflect events or circumstances occurring subsequent to the filing of this Form 10-QSB with the SEC. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks and factors that may affect our business.

Endorex is a development stage enterprise and expects no significant revenue from the sale of products in the near future.

MATERIAL CHANGES IN RESULTS OF OPERATIONS

For the second quarter ended June 30, 2001, the Company had a net loss available to common shareholders of $1,552,779, or a decrease of 5 percent, as compared to a loss of $1,637,253 for the second quarter ended June 30,

2000. Net loss included preferred stock dividends, which are paid-in-kind in shares of preferred stock.

Research and development, or R&D expenditures for the second quarter ended June 30, 2001 were $585,642, a 170 percent increase when compared with $217,112 for the corresponding period ended June 30, 2000. This increase in R&D expenditures was due to the hiring of additional R&D personnel and expansion of proprietary pre-clinical R&D drug delivery activities.

General and administrative expenses for the second quarter ended June 30, 2001 were $439,515 compared to $615,559 for the same period ended June 30, 2000, a 29 percent decrease. General and administrative expenses during the second quarter of 2001 were lower due to higher legal and accounting expenses as well as the payment of SEC filing fees related to the Company's private placement during this period last year.

Total Operating expenses of $1,025,157 for the second quarter of 2001 increased 23 percent compared to $832,671 for the same period last year, due to the increased spending in R&D pre-clinical drug delivery activities.

Operating expense increases were offset by reductions in equity losses in joint ventures of $260,603 for the second quarter of 2001 compared with losses of $648,779 during the same period in 2000. These losses pertain to the two joint ventures with Elan. InnoVaccines, the oral/mucosal vaccine delivery joint venture, has been developing several delivery systems for oral and mucosal vaccines. Newco has been developing Elan's Medipad(R), a small, disposable microinfusion pump, for the delivery of iron chelation drugs to treat a type of genetic blood disease known as iron overload disorders (e.g. Cooley's anemia, and sickle cell anemia). Our share of the research, development and business expenditures through these joint ventures is recorded as equity losses in joint ventures. The decrease in expenses represents a reduction of activities in each joint venture. Although activities to evaluate the efficacy of selected oral vaccines is still underway in Innovaccines, both partners in the joint venture are in discussions regarding the future direction of this joint venture and its possible termination. The Newco joint venture has recently met with Watson Pharmaceuticals, or Watson, which acquired Schein Pharmaceutical Inc. or Schein, during 2000, as well as Schein's licensing rights to the Medipad(R) device for iron chelation therapy. Watson has indicated to Newco its intention to discontinue its iron chelation program. Such action may require the modification, or termination of Watson's agreement with Newco. Newco is also evaluating other commercialization alternatives.

Interest income for the second quarter of 2001 of $120,317 decreased 39 percent compared to $198,165 for the same period last year reflecting the reduction in interest rates as well as a reduction in the available cash investment balance generated by the April 2000 equity financing.

Net loss for the six months ended June 30, 2001 of $3,128,777 decreased 8% as compared to a loss of $3,418,002 for the same period in 2000.

The decrease in net loss year to date versus the prior year reflects an overall decrease in joint venture R&D activities as we redirected our activities towards more proprietary drug delivery research and development. Additionally, the expenses related to our private placement incurred during the first and second quarter of 2000 which were not reflected in our 2001 activity.

PLAN OF OPERATION AND FINANCIAL CONDITION

On July 31, 2001, Endorex and Corporate Technology Development, Inc., or CTD, a privately held, development-stage specialty pharmaceutical company developing novel oral and mucosal formulations for therapeutic indications of small molecule drugs, based in Miami, Florida, entered into a definitive merger agreement, whereby we will acquire all of the outstanding capital stock of CTD in a stock-for-stock merger. This acquisition will broaden our product pipeline by the addition of two drug candidates currently in various stages of clinical development as well as other products in pre-clinical development.

CTD's lead product, orBec(TM), is currently in a multi-center phase III clinical trial, and is being developed for the treatment of intestinal graft-versus-host disease, or GVHD, a life-threatening complication affecting the skin, liver, and the gastrointestinal tract, or GI, following bone marrow transplantation. According to the International Bone Marrow Transplant Registry & Autologous Blood and Marrow Transplant Registry, there were 17,000 allogeneic bone marrow transplants (transplants of blood or bone marrow cells from another person) worldwide in 1998. It is estimated that intestinal GVHD affects approximately

15-30 percent, or approximately 2500 to 5100, of these patients per year worldwide, resulting in a high mortality rate. Allogeneic transplants remain a viable treatment strategy for a variety of cancers. CTD is also planning other phase II clinical trials for the treatment of other GI related disorders, which represent larger market segments.

The FDA has granted orBec(TM) "fast track" status for the treatment of intestinal GVHD, allowing for an expedited review process. orBec(TM) has also been designated as an "orphan drug" by the FDA for the prevention of Intestinal GVHD.

orBec(TM) is an oral dual-release formulation of beclomethasone dipropionate, or "BDP," a potent site-active corticosteroid drug. BDP has already been approved by the FDA and is sold by GlaxoSmithKline, as Beconase(R), in an inhaled and nasal formulation for the treatment of asthma, allergic rhinitis, and nasal polyposis. orBec(TM) allows for larger doses of BDP to be delivered to the afflicted GI area without systemic side effects associated with other steroids used to treat intestinal GVHD.

CTD's second clinical-stage compound is Oraprine(TM), a liquid formulation of a commonly prescribed immunosuppressant, azathioprine, the active pharmaceutical ingredient in Imuran(R). Imuran(R) is currently marketed in tablet form for the treatment of transplant rejection by Faro Pharmaceuticals, Inc. in North America and GlaxoSmithKline worldwide. Oraprine(TM) has recently completed a phase I bioequivalency trial which demonstrated that Oraprine(TM) is equivalent to Imuran(R). In addition, a pilot phase I/II trial has been completed for the treatment of chronic oral autoimmune diseases, such as oral GVHD. Oraprine(TM) has been designated an "orphan drug" for the treatment of oral GVHD.

Upon closing, CTD's Chairman, Colin Bier, Ph.D., will join our organization as Chairman of the Board and Chief Executive Officer. The current Chairman, Kenneth Tempero, M.D., Ph.D., will continue to serve as a director on our board. Michael S. Rosen, our current President and Chief Executive Officer, will remain as President and assume the newly created position of Chief Operating Officer. Steve H. Kanzer, currently CTD's President and Chief Executive Officer and an Endorex director, will remain on our board. Additionally, three members of the CTD board, including Dr. Bier, will become members of our board.

As of June 30, 2001, CTD had approximately $5 million in cash and no debt. CTD

believes this will be sufficient to fund development of their two primary products in the near term as well as to take orBec(TM), its lead drug candidate in phase III clinical trials, through the FDA approval process.

Our proprietary drug delivery activities include preclinical testing (IN VITRO and IN VIVO) of the Orasome(TM) and other delivery systems for the oral and mucosal delivery of macromolecular drugs based on proteins and peptides. Endorex believes that the acquisition of CTD provides us with a product pipeline of both clinical and preclinical oral and mucosal drug candidates covering both small molecule and macromolecule drugs. We have expanded the number of macromolecular drugs under evaluation for delivery beyond insulin, human growth hormone and vaccines. We continue to collaborate with Novo Nordisk on the development of an oral human growth hormone. We believe that Novo Nordisk will determine whether to license our Orasome(TM) technology for its human growth hormone product, Norditropin(R), later in 2001.

The recent announced merger between Endorex and CTD and the renewed focus on proprietary R&D activities have prompted a review of our existing joint ventures to determine the progress to date.

The InnoVaccine development activities during the second quarter included further evaluation of development work of the Orasome(TM) delivery system for oral and mucosal delivery of the tetanus and influenza vaccines and the development of mucosal tissue targeting technology for this delivery system. Work in this area has been focused on the PLGA microparticle system licensed from the Southern Research Institute.

Newco is in the process of assessing its relationship with Watson. Watson, the marketing and development partner to the joint venture, has recently verbally expressed its desire to discontinue its iron chelation therapy program with the Medipad(R) device. As a result, the joint venture partners are reviewing their commercialization agreements in light of this development with Watson. Newco is also evaluating other commercialization partners for its iron chelation delivery system, as well as the future direction of this joint venture.

On June 30, 2001 and December 31, 2000, Endorex had cash, cash equivalents, and marketable securities of approximately $9.8 million and $12.8 million, respectively, and working capital of approximately $6.6 million and $10.1 million, respectively. We believe that our cash and cash equivalents are sufficient to satisfy our cash requirements for the next two years. We intend, from time to time in the future, to seek to expand our research and development activities into other drug delivery technologies and/or products that we either may license from other persons or develop. Any such activities may require the expenditure of funds not presently available and may deplete our cash resources sooner than anticipated. We also may seek to obtain funds from possible future public or private sales of our securities or other sources. See Exhibit 99--"Risk Factors."

PART II. - OTHER INFORMATION

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

(a)	EXHIBIT NO.	DESCRIPTION

2.1	Agreement and Plan of Merger and Reorganization, dated as of July 31, 2001 by and among Endorex Corporation, Roadrunner Acquisition, Inc. and Corporate Technology Development, Inc.
10.1	Voting Agreement dated as of July 31, 2001 by and among Endorex Corporation, Roadrunner Acquisition, Inc. and Corporate Technology Development, Inc. and certain stockholders of Corporate Technology Development, Inc.
99.1	Risk Factors

(b) On August 1, 2001, Endorex filed a Current Report on Form 8-K, reporting under Item 5 thereof, Endorex's execution of the Agreement and Plan of Merger and Reorganization dated as of July 31, 2001 by and among Endorex, Roadrunner Acquisition Inc. and Corporate Technology Development Inc. ("CTD") and filing as an exhibit under Item 7 thereof the press release issued by Endorex and CTD regarding the execution of the agreement.

SIGNATURES

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

ENDOREX CORPORATION

August 14, 2001 /s/ MICHAEL S. ROSEN

Michael S. Rosen
President and Chief Executive Officer
(Principle executive officer)

August 14, 2000 /s/ STEVE KOULOGEORGE

Steve Koulogeorge
Controller
(Principle financial officer)