

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-QSB

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

For the quarterly period ended September 30, 1998

or

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

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

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

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3171943
(I.R.S. Employer
Identification No.)

350 South Main Street, Suite 307
Doylestown, Pennsylvania
(Address of principal executive offices)

18901
(Zip Code)

Registrants' telephone number, including area code: (215) 340-4699

Securities registered under Section 12 (b) of the Exchange Act: None

Securities registered under Section 12 (g) of the Exchange Act:

Common Stock, par value \$.001 per share

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

As of November 13, 1998, 4,407,658 shares of the Registrant's common stock, par value \$.001 per share, were outstanding.

Documents incorporated by reference: None.

Transitional Small Business Disclosure Format: Yes No

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Consolidated Balance Sheets
(Unaudited)

	September 30, 1998 ----	December 31, 1997 ----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,701,000	\$ 6,297,000
Investments	2,926,000	4,957,000
Prepaid expenses	200,000	190,000
	-----	-----
Total current assets	5,827,000	11,444,000
Furniture and equipment, net of depreciation	168,000	181,000
Security deposits	33,000	30,000
	-----	-----
	\$ 6,028,000	\$ 11,655,000
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 939,000	\$ 565,000
	-----	-----
Dividends payable on preferred stock		238,000
	-----	-----
Minority interest in preferred stock of subsidiary		2,039,000
	-----	-----
Stockholders' Equity:		
Preferred Stock, \$.001 par value; 5,000,000 shares authorized:		
Series C Redeemable;	2,226,000	\$
2,039 shares issued and outstanding (liquidation preference \$2,226,000)		
Series B Convertible;		
2,143,005 shares issued and outstanding (liquidation preference \$28,930,568)		2,000
Common stock, \$.001 par value; 20,000,000 shares authorized;		
4,399,065 shares issued and outstanding	5,000	3,000
Treasury Stock (16,150 shares at cost)	(51,000)	--
Additional paid-in capital	29,696,000	21,464,000
Deficit accumulated during the development stage	(26,789,000)	(12,656,000)
	-----	-----
Total stockholders' equity	5,089,000	8,813,000
	-----	-----
	\$ 6,028,000	\$ 11,655,000
	=====	=====

Consolidated Statements of Operations
(Unaudited)

	Nine Months Ended September 30,		Three Months Ended September 30,		May 18, 1993 (Inception) Through September 30, 1998
	1998	1997	1998	1997	1998
Interest income	\$ 353,000	\$ 594,000	\$ 127,000	\$ 288,000	\$ 1,271,000
Expenses:					
Write-off of acquired in-process research and development and supplies	8,230,000				14,093,000
Research and development	4,203,000	3,503,000	846,000	1,246,000	9,121,000
General and administrative	1,925,000	1,535,000	503,000	190,000	4,471,000
Interest					11,000
Total expenses	14,358,000	5,038,000	1,349,000	1,436,000	27,696,000
	\$(14,005,000)	(4,444,000)	(1,222,000)	(1,148,000)	(26,425,000)
Minority interest in net loss of subsidiary	24,000				26,000
Net loss	\$(13,981,000)	\$ (4,444,000)	\$ (1,222,000)	\$ (1,148,000)	\$(26,399,000)
Net loss per share - basic and diluted	\$ (3.85)	\$ (1.69)	\$ (0.28)	\$ (0.43)	
Weighted average number of common shares outstanding	3,635,000	2,630,000	4,356,000	2,625,000	

See notes to financial statements Page 4

Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,		May 18, 1993 (Inception) Through September 30, 1998
	1998	1997	
Cash flows from operating activities:			
Net loss	\$(13,981,000)	\$ (4,444,000)	\$(26,399,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-off of acquired in-process research and Development and supplies	8,230,000		14,093,000
Write-off of licenses		683,000	683,000
Depreciation and amortization	27,000	48,000	91,000
Changes in:			
Prepaid expenses	(10,000)	(20,000)	(169,000)
Accounts payable and accrued expenses	374,000	(30,000)	733,000
Other assets	(3,000)	217,000	(33,000)
Expenses paid on behalf of company			18,000
Employee stock compensation			42,000
Reduction of research and development supplies			(161,000)
Net cash used in operating activities	(5,363,000)	(3,546,000)	(11,102,000)
Cash flows from investing activities:			
Investment in Ansan Pharmaceuticals, Inc.		(1,300,000)	
Acquisition of furniture and equipment	(39,000)	(54,000)	(236,000)
Proceeds from disposal of furniture and equipment	25,000		25,000
Acquisition of licenses			(711,000)
Purchase of investments	(732,000)	(2,613,000)	(21,335,000)
Proceeds from sale or maturity of investments	2,763,000	4,044,000	18,814,000
Net cash payments on merger	(226,000)	(327,000)	(1,680,000)
Net cash provided by (used in) investing activities	1,791,000	(250,000)	(5,123,000)
Cash flows from financing activities:			
Proceeds on private placements of units, net of Expenses		(11,000)	18,925,000
Purchase of treasury stock	(51,000)		(51,000)
Collections on stock subscriptions and proceeds on exercise of stock options	27,000	7,000	52,000
Net cash (used in) provided by financing activities	(24,000)	(4,000)	18,926,000
Net (decrease) increase in cash and cash equivalents	(3,596,000)	3,800,000	2,701,000
Cash and cash equivalents - beginning of period	6,297,000	4,336,000	
Cash and cash equivalents - end of period	\$ 2,701,000	\$ 536,000	\$ 2,701,000
Noncash transactions:			
Accrued dividends on redeemable Series C preferred stock			

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

The Company

Discovery Laboratories, Inc. (the "Company"), formerly known as Ansan Pharmaceuticals, Inc. ("Ansan"), was incorporated in Delaware on November 6, 1992 and following formation was a wholly owned subsidiary of Titan Pharmaceuticals, Inc. ("Titan"). The Company was formed to license and develop pharmaceutical products to treat a variety of human diseases. In August 1995, Ansan issued its securities in an initial public offering and ceased to be a wholly-owned subsidiary of Titan. In November 1997, Ansan merged (the "1997 Merger") with Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), and was the surviving corporate entity. Subsequent to the 1997 Merger, Ansan changed its name to Discovery Laboratories, Inc. Pursuant to the 1997 Merger, each outstanding share of Old Discovery's common stock was converted into 1.167471 shares of the Company's common stock and each share of Old Discovery's Series A Convertible Preferred Stock was converted into one share of the Company's Series B Convertible Preferred Stock (the "Exchange Ratios"). The Company also assumed all outstanding options and warrants to purchase Old Discovery's common stock and Series A Convertible Preferred Stock, which options and warrants became exercisable for the Company's common stock and Series B Convertible Preferred Stock, respectively, based on the Exchange Ratios. In connection with the 1997 Merger, the Company and Titan entered into arrangements providing for the relinquishment by the Company of rights to certain drug compounds and the transfer of such rights to Titan in exchange for (i) a 2% net royalty payable by Titan to the Company from net sales of such drug compounds and (ii) the cancellation of all common stock of the Company owned by Titan. On consummation of the 1997 Merger, 13,000 shares of preferred stock of the Company held by Old Discovery were cancelled.

The 1997 Merger was accounted for as a reverse acquisition with Old Discovery as the acquirer for financial reporting purposes since Old Discovery's stockholders owned approximately 92% of the merged entity on a fully diluted basis. The consolidated financial statements include the historical accounts of Old Discovery and Acute Therapeutics, Inc. ("ATI") (which was a majority-owned subsidiary of the Company until June 16, 1998, when the Company acquired the then outstanding minority interest in ATI) and the accounts of the Company from November 25, 1997 (the date of acquisition). The assets and liabilities acquired pursuant to the 1997 Merger are recorded at their fair values on the date of the 1997 Merger. The difference between the fair value of the net assets acquired and the value of the common stock issued plus 1997 Merger-related costs has been attributed to in-process research and development and has been recorded as an expense upon acquisition.

On June 16, 1998, the shareholders of the Company, at the Company's 1997 Annual Meeting of Stockholders, approved the merger of a wholly-owned subsidiary of the Company with ATI (the "1998 Merger"). Pursuant to the 1998 Merger, each outstanding share of ATI's common stock was exchanged for 3.90 shares of the Company's common stock (the "1998 Exchange Ratio") and each share of ATI's Series B preferred stock was converted into one share of the Company's Series C preferred stock. All outstanding options for the purchase of ATI Common Stock were assumed by the Company and are presently exercisable for shares of the Company's common stock on the basis of the 1998 Exchange Ratio. Pursuant to employment agreements entered into with the Company in connection with the 1998 Merger, the ATI management team was granted, in the aggregate, options to purchase (i) 338,500 shares of the Company's common stock, subject to vesting, (ii) 175,000 shares of the Company common stock at such time as the market capitalization of the Company exceeds \$75 million and (iii) 160,000 shares of the Company's common stock upon consummation of a corporate partnering deal having a total value of at least \$20 million. In addition, pursuant to a management agreement entered into between the Company and ATI at the time the merger agreement relating to the 1998 Merger was executed, the former members of the ATI management team were granted options to purchase 126,500 shares of the Company's common stock.

The historical consolidated financial position of the Company includes the accounts of ATI. The value of the common stock of the Company issued to ATI's common stockholders plus the assumption of the outstanding ATI options and merger related costs has been attributed to in-process research and development and has been recorded as an expense upon acquisition.

The cost of the 1998 Merger is as follows:

Common stock issued to ATI stockholders (1,033,500 shares at fair value)	\$ 5,038,000
Fair value of common stock issuable on exercise of options to purchase ATI common stock (net of exercise proceeds)	2,966,000
Transaction costs	\$ 226,000

	\$ 8,230,000
	=====

The following pro forma statement of operations gives effect to the 1998 Merger as if it had occurred at the beginning of the respective periods. A non-recurring charge of \$8,230,000 for in-process research and development has not been considered in the pro forma results:

	Nine Months Ended September 30, 1998	1997
	----	----
Net loss	\$ (5,775,000)	\$ (4,444,000)
Net loss per common share-basic and diluted	\$ (1.35)	\$ (1.21)
Weighted average number of common shares outstanding	4,267,000	3,657,000
	-----	-----

The pro forma results are not indicative of the results that would have actually been achieved had the merger taken place as of January 1, 1998 or January 1, 1997 or of the results which may occur in the future.

Basis of Presentation

The accompanying financial statements include the accounts of the Company and ATI. All intercompany balances and transactions have been eliminated.

The accompanying unaudited, consolidated, condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information in accordance with the instructions to Form 10-QSB. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the nine-month period ended September 30, 1998 are not necessarily indicative of the results that may be expected for the year ended December 31, 1998. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's 1997 Annual Report on Form 10-KSB.

The Company's activities since incorporation have primarily consisted of conducting research and development, performing business and financial planning and raising capital. Accordingly, the Company is considered to be in the development stage, and expects to incur increasing losses and require additional financial resources to achieve commercialization of its products.

The Company also depends on third parties to conduct research on the Company's behalf through various research agreements. All of the Company's current products under development are subject to license agreements that will require the payment of future royalties.

Net Loss Per Share

Net loss per share is computed based on the weighted average number of common shares outstanding for the periods and common shares issuable for little or no cash consideration. Common shares issuable upon the exercise of options and warrants and the conversion of convertible securities are not included in the calculation of the net loss per share as their effect would be antidilutive.

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

When used in this report, the words "estimate", "project", "intend", "forecast", "anticipate" and similar expressions are intended to identify forward-looking statements. In addition, certain other statements set forth in this report, including, without limitation, statements concerning the Company's research and development programs, the possibility of submitting regulatory filings for the Company's products under development, the seeking of joint development or licensing arrangements with pharmaceutical companies or others, the research and development of particular compounds and technologies for particular indications and the period of time for which the Company's existing resources will enable the Company to fund its operations and the possibility of contracting with other parties additional licenses to develop, manufacture and market commercially viable products, are forward-looking and based upon the Company's current belief as to the outcome, occurrence and timing of future events or current expectations and plans. All such statements involve significant risks and uncertainties. Many important factors affect the Company's ability to achieve the stated outcomes and to successfully develop and commercialize its product candidates, including, among other things, the ability to obtain substantial additional funds, obtain and maintain all necessary patents or licenses, to demonstrate the safety and efficacy of product candidates at each state of development, to meet applicable regulatory standards and receive required regulatory approvals, to meet obligations and required milestones under its license agreements, to be capable of producing drug candidates in commercial quantities at reasonable costs, to compete successfully against other products and to market products in a profitable manner. Although the Company believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there also can be no assurance that these statements included in the report will prove to be accurate. In light of the significant uncertainties inherent in these statements included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved; in fact, actual results could differ materially from those contemplated by such forward-looking statements. The Company does not undertake any obligation to publicly release any revisions to these forward-looking statements or to reflect the occurrence of unanticipated events.

The following discussion principally reflects the historical results of Old Discovery as the 1997 Merger was accounted for as a reverse acquisition with Old Discovery as the acquirer for financial reporting purposes.

Plan of Operations

Since its inception, the Company has concentrated its efforts and resources in the development and commercialization of pharmaceutical products and technologies. The Company has been unprofitable since its founding and has incurred a cumulative net loss of approximately \$26,399,000 as of September 30, 1998. The Company expects to incur significantly increasing operating losses over the next several years, primarily due to the expansion of its research and development programs, including clinical trials for some or all of its existing products and technologies and other products and technologies that it may acquire or develop. The Company's ability to achieve profitability depends upon, among other things, its ability to discover and develop products, obtain regulatory approval for its proposed products, and enter into agreements for product development, manufacturing and commercialization. None of the Company's products currently generates revenues and the Company does not expect to achieve revenues for the foreseeable future. Moreover, there can be no assurance that the Company will ever achieve significant revenues or profitable operations from the sale of any of its products or technologies.

The Company is currently engaged in the development and commercialization of investigational drugs for critical care that have previously been tested in humans or animals. The Company anticipates that during the next 12 months it will conduct substantial research and development of its products under development. A pivotal Phase

2/3 clinical trial of Surfaxin(TM) for the treatment of acute respiratory distress syndrome/acute lung injury ("ARDS/ALI") was commenced on July 14, 1998. Of the 48 clinical sites identified by the Company for participation in the ARDS/ALI trial, 30 facilities have completed all internal review board and other approvals. The Company anticipates that the remaining facilities will have completed such approvals, and that all participating facilities will have been supplied with drug product by mid-December 1998. To date, ten patients have been enrolled in the ARDS/ALI trial.

A Phase 2A clinical trial of Surfaxin(TM) for the treatment of meconium aspiration syndrome ("MAS") was commenced on May 27, 1997. The MAS trial was terminated in October 1998 upon the expiration of the life of the Surfaxin(TM) drug product used in the trial. The Company intends to analyze the results on the Phase 2A MAS trial and believes that such will yield sufficient data to support a Phase 2B clinical trial of Surfaxin(TM) for the treatment of MAS.

A Phase 1/2 clinical trial of SuperVent(TM) for the treatment of cystic fibrosis ("CF") was commenced on March 17, 1997. Part A of such clinical trial was completed on March 31, 1998. The Company is in the process of revising the design of its clinical investigation of SuperVent(TM) for the treatment of CF and anticipates that a Phase 2 clinical trial will be commenced during the first quarter of 1999.

On December 5, 1997 a Phase 1 clinical study of DSC103 (formerly known as ST-630) as a once-daily, orally administered drug for the treatment of postmenopausal osteoporosis in the United States was initiated. Part B of such trial was commenced on April 2, 1998 and was successfully completed on June 29, 1998. It is the Company's present intention to seek to develop DSC103 through a corporate partnering arrangement rather than directly.

In May 1996, the Company entered into a license agreement with Boehringer Ingelheim GmbH pursuant to which the Company previously pursued a development program for an injectable formulation of Apafant for the treatment of acute pancreatitis. During the third quarter of 1998, the Company determined to discontinue all development and sublicensing efforts with respect to Apafant.

The Company is currently planning a Phase 3 clinical trial of Surfaxin(TM) for the treatment of infant (idiopathic) respiratory distress syndrome during 1999. Such trial, and any other clinical trials of the Company's products in development that have not yet commenced, will require the receipt of approvals by the United States Food and Drug Administration (the "FDA"). There can be no assurance as to the receipt or the timing of such approvals.

In addition to its clinical research activities, the Company dedicates substantial efforts to the development of manufacturing processes for its Surfaxin(TM) product. During 1998, Dr. Harry Brittain, the Company's Vice President, Pharmaceutical and Chemical Development, developed a method for reducing the viscosity of the original product formulation which renders the product more efficacious and easier to deliver. The Company has the capability to manufacture Surfaxin(TM) in large quantities for the adult market.

During October 1998, the FDA granted the Company fast track approval status for the ARDS/ALI and MAS indications. Fast track status facilitates the development and expedites the review of new drugs intended for treatment of life-threatening conditions for which there is presently no medical option. The FDA Office of Orphan Products Development (the "OOPD") has designated Surfaxin(TM) as an orphan drug for the treatment of MAS and ARDS/ALI. During October 1998, the OOPD awarded Discovery a renewable Orphan Products Development Grant, ranging from \$194,390 for the first year to \$583,170 over three years, to finance the Company's MAS trial.

Liquidity

The Company anticipates that its current resources will permit it to meet its business objectives until approximately the second quarter of 1999. The Company's working capital requirements will depend upon numerous factors, including, without limitation, progress of the Company's research and development programs, preclinical and clinical testing, timing and cost of obtaining regulatory approvals, levels of resources that the Company devotes to the development of manufacturing and marketing capabilities, technological advances, status of competitors and the ability of the Company to establish collaborative arrangements with other organizations.

As such there can be no assurance that the Company will not be required to raise additional capital prior to the second quarter of 1999 (or that it would be successful in doing so) or, in general, that the Company will be able to achieve its business objectives.

Year 2000 Compliance

With the new millenium approaching, many institutions around the world are reviewing and modifying their computer systems to ensure that they are Year 2000 compliant. The issue, in general terms, is that many existing computer systems and microprocessors with data functions use only two digits to identify a year in the date field with the assumption that the first two digits are always "19". Consequently, on January 1, 2000, computers that are not Year 2000 compliant may read the year as 1900. Systems that calculate, compare or sort using the incorrect date may malfunction.

The Company is working to resolve the potential impact of the Year 2000 on the ability of its computerized information systems to accurately process date-sensitive information. The systems include database , networking and accounting software licensed by the Company. The Company does not use equipment with embedded chip technology that is date sensitive. Although the Company has not yet completed its assessment of its internal operations, the Company has been advised by the vendors of its office and networking software that the Company will receive vendor certifications confirming that these systems are Year 2000 compliant. The Company has previously been advised that its accounting software package is Year 2000 compliant. If such software does not in fact prove to be Year 2000 compliant, the Company would experience temporary administrative disruptions but such disruptions would not threaten or materially interfere with the Company's drug development activities.

The Company intends to make inquiries of suppliers and other third parties with whom it has significant business relationships in order to determine whether such third parties have undertaken measures to ensure that their information technology systems will be Year 2000 compliant insofar as the Company is concerned. These third parties include contract manufacturing facilities utilized by the Company to produce Surfaxin(TM) and SuperVent(TM), contract laboratories at which stability testing of raw drug product is performed, facilities at which the Company's clinical trials are being undertaken and the Company's transfer agent. The Company intends to transfer manufacturing and stability testing activities away from any contract manufacturing facilities or contract laboratories that have not confirmed Year 2000 compliant status by May of 1999. If the contract manufacturing or contract laboratory facilities utilized by the Company fail to achieve Year 2000 compliance, it is unlikely that the Company would be materially affected since in most instances recordkeeping or backup recordkeeping is maintained in hard copy. It is possible, however, that data transmitted electronically to the FDA under such circumstances would be inconsistent with submitted documentation, which in turn could result in the Company receiving a citation from the FDA. The potential consequences of a Year 2000 compliance failure on the part of a hospital or other facility participating in the Company's clinical trials range from the possible need to eliminate data points generated by specific facilities to delay in completion and evaluation of such trials, and could also result in a need for further dialogue with the FDA regarding clinical trial integrity if a significant problem were to emerge.

The Company's Year 2000 project is expected to be substantially completed by June 30, 1999. The Company believes that completing the program within the time-frame it set for itself will avoid any adverse impact on its operating systems. Assuming that the Company is not required to incur transfer costs as a result of any failure of its vendors to achieve Year 2000 compliance in a timely fashion, the Company anticipates that the cost of implementing its Year 2000 program will be limited to out-of-pocket costs related to making inquiries of, and receiving and reviewing confirmations from, third parties. The Company currently estimates that such costs will not exceed \$10,000.

The Company has purchased back-up electrical generators to ensure that temperature sensitive materials that are critical to the Company's drug development efforts will not be harmed by any power outages at its Doylestown, Pennsylvania facility. Although not purchased with a view toward Year 2000-related risks, these generators are available to address any interruptions in electrical service related to Year 2000 compliance problems experienced by local utilities. The Company intends to develop contingency plans to address any other Year 2000 compliance risks that are uncovered by its continuing evaluation efforts.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 2. Change in Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

During August 1998, the Company's Board of Directors approved the adoption of a shareholder rights plan. Adoption of the shareholder rights plan is contingent upon approval of the plan by holders of a 66.67% of the Company's Series B Convertible Preferred Stock. During September 1998, the Company solicited the written consent of the holders of such preferred stock to the adoption of the rights plan. The Company has not yet obtained the requisite consents for the implementation of the rights plan.

Item 5. Other Information.

None

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

27.1 Financial Data Schedule

(b) Reports on Form 8-K:

A report on Form 8-K relating to the approval by the Company's Board of Directors of the adoption of a shareholder rights plan was filed by the Company on August 21, 1998.

Signatures

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 13, 1998

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
Chief Executive Officer

Date: November 13, 1998

/s/ Evan Myrianthopoulos

Evan Myrianthopoulos
Vice President, Finance
(Principal Financial and
Accounting Officer)

9-MOS

	DEC-31-1998	
	JAN-01-1998	
	SEP-30-1998	
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		2,926,000
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	5,827,000	
		168,000
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	6,028,000	
939,000		
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	(1,222,000)	
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	0	
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		0
		0
	(1,222,000)	
		0.28
		0.28

EPS Basic and Diluted is \$0.28. The Company calculates Earnings Per Share pursuant to FASB 128.