

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q

(MARK ONE)

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

For the quarterly period ended September 30, 1996

OR

TRANSACTION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER 1-10113

HALSEY DRUG CO., INC.

(Exact name of registrant as specified in its charter)

New York

11-0853640

(State or other Jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

1827 Pacific Street  
Brooklyn, New York

11233

(Address of Principal executive officer) (Zip Code)

(718) 467-7500

(Registrants telephone number, including area code)

Not Applicable

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

Indicate by check mark whether the registrant (1) has filed all reports required  
to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934  
during the preceding 12 months (or for such shorter period that the registrant  
was required to file such reports), and (2) has been subject to such filing  
requirements for the past 50 days.

YES X NO  
--- ---

As of November 12, 1996, the registrant had 11,191,403 shares of Common  
Stock, \$.01 par value, outstanding.

HALSEY DRUG CO., & SUBSIDIARIES

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HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)  
(UNAUDITED)  
September 30, 1996      DECEMBER 31,  
1995

-----  
LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Bank overdraft	\$ 780	\$ 213
Due to banks	3,195	3,395
Current maturities of long-term debt	200	200
Convertible subordinated debentures	5,645	7,347
Department of Justice settlement	2,129	2,000
Accounts payable	2,814	2,546
Accrued expenses and other liabilities	2,654	1,867
Advances from minority stockholders	206	206
Income taxes payable	33	33

Total current liabilities	17,656	17,807
---------------------------	--------	--------

LONG-TERM DEBT

	2,674	2,595
--	-------	-------

CONTINGENCIES

STOCKHOLDERS' EQUITY (DEFICIT)

Common stock - \$.01 par value; authorized 20,000,000 shares; issued and outstanding 11,141,403 shares at September 30, 1996 and 8,973,459 shares at December 31, 1995	116	90
Additional paid-in capital	19,958	14,459
Accumulated deficit	(23,322)	(14,989)
	(3,248)	(440)

Less: Treasury stock - at cost (474,603 shares)  
at September 30, 1996 and 500,000 shares at  
December 31, 1995

(1,044)	(1,100)
---------	---------

Total stockholders' equity

(4,292)	(1,540)
---------	---------

\$ 16,038	\$ 18,862
=====	=====

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

Amounts in thousands except per share data	For the nine months ended September 30,		For the three months ended September 30,	
	1996	1995	1996	1995
Net Sales	\$ 10,580	\$ 16,104	\$ 2,937	\$ 4,347
Cost of goods sold	12,094	12,868	4,354	4,049
Gross(loss) profit	(1,514)	3,236	(1,417)	298
Research & Development	820	489	191	182
Selling, general and administrative expenses	4,678	4,487	1,534	1,506
Loss from operations	(7,012)	(1,740)	(3,142)	(1,390)
Gain on the sale of assets		2,288		
Other income	5	7	1	1
Interest expense	1,326	862	443	422
(Loss) before income taxes	(8,333)	(307)	(3,584)	(1,811)
Provision for income taxes		296		
NET(LOSS)	(\$ 8,333)	(\$ 603)	(\$ 3,584)	(\$ 1,811)
Net(loss)per common share	(\$ 0.89)	(\$ 0.08)	(\$ 0.37)	(\$ 0.23)
Weighted average number of outstanding shares	9,390,613	7,819,214	9,650,652	7,717,882

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

Amounts in thousands	NINE MONTHS ENDED	
	September 1996	September 30 1995
	----	----
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$(8,333)	\$ (603)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,722	1,547
Gain on sale of assets		(2,288)
Accrued Department of Justice interest	129	56
Deferred income taxes		296
Changes in assets and liabilities		
Accounts receivable	534	563
Inventories	1,738	(909)
Prepaid insurance and other current assets	126	55
Accounts payable	268	(919)
Accrued expenses	787	328
Income taxes payable		(183)
	-----	-----
Total adjustments	5,304	(1,454)
	-----	-----
Net cash used in operating activities	(3,029)	(2,057)
	-----	-----
Cash flows from investing activities		
Capital expenditures	(405)	(403)
Increase in other assets	(594)	(320)
Proceeds from sale of assets		2,000
	-----	-----
Net cash (used in)provided by investing activities	(999)	1,277
	-----	-----
Cash flows from financing activities		
Decrease in notes payable	(4,111)	(1,563)
Proceeds from issuance of convertible debentures	2,145	3,707
Issuance of common stock from conversion of debentures	3,613	
Exercise of warrants	1,514	
Exercise of stock-options	136	
Issuance of common stock	318	
Acquisition of treasury stock		(1,100)
Payment to Department of Justice		(100)
Bank overdraft	567	89
Advances from former minority stockholder		(212)
	-----	-----
Net cash provided by financing activities	4,182	821
	-----	-----
NET INCREASE IN CASH AND CASH EQUIVALENTS	154	41
Cash and cash equivalents at beginning of period	353	28
	-----	-----
Cash and cash equivalents at end of period	\$ 507	\$ 69
	=====	=====

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 1996

Amounts in thousands except per share data  
(UNAUDITED)

	Common Stock		Additional	Accumulated
	\$.01 par Shares	Amount	Paid-in Capital	Deficit
Balance at December 31, 1995	8,973,459	\$ 90	\$14,459	(\$14,989)
Net loss for the nine months ended September 30, 1996				(8,333)
Issuance of common stock-conversion of debentures	2,040,000	21	3,592	
Issuance of shares as settlement	49,166		228	
Issuance of warrants of convertible debentures			355	
Exercise of stock warrants	524,400	5	1,154	
Issuance of shares as settlement of liability	10,384		34	
Exercise of stock options	43,994		136	
Balance at September 30, 1996	11,641,403	\$ 116	\$19,958	(\$23,322)

	Treasury Stock At Cost		
	Shares	Amount	Total
Balance at December 31, 1995	(500,000)	(\$ 1,100)	(\$1,540)
Net loss for the nine months ended September 30, 1996			(8,333)
Issuance of common stock-conversion of debentures			3,613
Issuance of shares as settlement	25,397	56	284
Issuance of warrants of convertible debentures			355
Exercise of stock warrants			1,159
Issuance of shares as settlement of liability			34
Exercise of stock options			136
Balance at September 30, 1996	(474,603)	(\$1,044)	(\$4,292)

The accompanying notes are an integral part of these statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Halsey Drug Co., Inc. and subsidiaries (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. 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, which consist of normal recurring adjustments, considered necessary for the three month and nine month periods ended September 30, 1996 have been made, but the financial results for the nine month and three month periods ended September 30, 1996 are not necessarily indicative of the results that may be expected for the full year ended December 31, 1996. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 1995 included in the Company's Annual Report on Form 10-K/A.

Note 2 - INVENTORIES

(Amounts in thousands)

Inventories consists of the following:

	September 30, 1996	December 31, 1995
	-----	-----
Finished Goods	\$1,630	\$2,491
Work in Process	1,805	1,398
Raw Materials	2,543	3,827
	-----	-----
	\$5,978	\$7,716
	=====	=====

NOTE 3 - DEBT

Borrowings under lines of credit and long-term debt consist of the following at September 30, 1996 and December 31, 1995.

(Amounts in thousands)

	September 30, 1996	December 31, 1995
	-----	-----
Convertible subordinated promissory note	\$ 1,474	\$ 1,395
Subordinated promissory note	1,400	1,400
	-----	-----
	2,874	2,795
Less current maturities	200	200
	-----	-----
	\$ 2,674	\$ 2,595
	=====	=====



#### NOTE 4 -SUBSEQUENT EVENTS

On October 23, 1996, the Company withdrew four of its ANDAs, including its ANDA (the "Capsule ANDA") for acetaminophen/oxycodone capsules, and halted sales of the affected products. Net sales pursuant to the withdrawn Capsule ANDA were approximately \$2.15 million and \$8.00 million for the six months and the year ended June 30, 1996 and December 31, 1995, respectively, and accounted for approximately 28% and 40% of the Company's total net sales during such six and twelve month periods. The Company instituted the withdrawal in anticipation of its release from the FDA's Application Integrity Policy list and its restrictions (collectively, the "AIP"). The FDA had placed the Company on the AIP in connection with its investigation of the Company's operations which culminated in the 1993 consent decree. Under the AIP, the FDA suspended all of the parent company's (i.e., Halsey Drug Co.'s) applications for new drug approvals, including ANDAs and supplements to ANDAs. At the FDA's suggestion, the Company retained outside consultants to perform validity assessments of its drug applications. Thereafter, the FDA recommended that several applications, including the Capsule ANDA, be withdrawn. As a basis for its decision, the FDA cited questionable and incomplete data submitted in connection with the applications. The FDA indicated that withdrawal of the four ANDAs was necessary for the release of the Company from the AIP.

It is the Company's understanding that it will be removed from the AIP in the very near future. Accordingly, the Company has submitted a new ANDA with respect to the Capsules, which the Company anticipates will be reviewed on an expedited basis. However, there can be no assurance that the new Capsule ANDA will be approved or that the Company will in fact be removed from the AIP. The Company will not be able to market the capsules unless and until the FDA approves the new Capsule ANDA. Failure to obtain FDA approval for the new Capsule ANDA, or a significant delay in obtaining such approval, would materially adversely affect the Company's business operations and financial condition.

HALSEY DRUG CO., INC. AND SUBSIDIARIES  
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND  
RESULTS OF OPERATIONS

	Percentage of net sales Nine months ended September 30			Percentage of net sales Three Months ended September 30		
	1996 %	1995 %	Percentage Change Year-to-Year Increase (Decrease) 1996 as Compared to 1995	1996 %	1995 %	Percentage Change Year-to-Year Increase (Decrease) 1996 as Compared to 1995
Net Sales	100.0	100.0	(34.3)	100.0	100.0	(32.4)
Cost of Goods	114.3	79.9	(6.3)	148.2	93.1	7.5
Gross Profit(Loss)	(14.3)	20.09	(146.8)	(48.2)	6.9	(575.5)
Research & Development	7.8	3.0	67.7	6.5	4.2	4.9
Selling, general and administrative expenses	44.2	27.9	4.3	52.3	34.6	1.8
Loss from operations	(66.3)	(10.8)	(303.0)	(107.0)	(32.0)	(125.9)
Gain on the sale of assets		14.2	(100.0)			
Other income						
Interest expense	12.4	5.4	53.8	15.1	9.7	5.0
Loss before income taxes	(78.8)	(1.9)	(2614.3)	(122.0)	(41.7)	(97.9)
Provision for income taxes		1.8	(100.0)			
Net Loss	(78.8)	(3.7)	(1281.9)	(122.0)	(41.7)	(97.9)

NET SALES

The Company's net sales for the nine months ended September 30, 1996 of \$10,580,000 represents a decrease of \$5,524,000 (34.3%) as compared to net sales for the nine months ended September 30, 1995 of \$16,104,000. The decrease in 1996 is attributable to the reduction in shipments of tablet and capsule products due to the sale at the end of the first quarter of 1995 by the Company of its abbreviated new drug application for 5mg Oxycondone HCL/325mg Acetaminophen tablets (the "Tablet ANDA") to an affiliate of Mallinckrodt Chemical, Inc. ("Mallinckrodt") which is partially offset by manufacturing revenue that the Company is receiving as part of its agreement with Mallinckrodt. In addition, increased competition during the current year resulted of price reductions which contributed to the decrease.

COST OF GOODS SOLD

For the nine months ended September 30, 1996, cost of goods sold of \$12,094,000 represents a decrease of approximately \$774,000 as compared to \$12,868,000 for the nine months ended September 30, 1995. The decrease for 1996 is attributable to the reduction in shipments of tablet products due to the sale at the end of the first quarter of 1995 by the Company of the Tablets ANDA combined with significant reductions in manufacturing costs of personnel and other expenses. In addition during the current year, the Company effected price reductions as a result of increased market competition which directly impacted gross margin. The Company's gross margin (loss) as a percentage of sales for the nine months ended September 30, 1996 was (14.3%) as compared to 20.9% for the nine months ended September 30, 1995.

RESEARCH AND DEVELOPMENT EXPENSES

For the nine months ended September 30, 1996, research and development expenses of \$820,000 increased by \$331,000 as compared to research and development expenses in 1995 of \$ 489,000. The Company has engaged in a research and development plan which includes the reintroduction of products suspended from shipment and the submission of several new products to the Food and Drug Administration (the "FDA") for its review as soon the Company is removed from the FDA's Application Integrity program (the "AIP"), of which there can be no assurance.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of sales for the nine months ended September 30, 1996 and 1995 were 44.2% and 27.9%, respectively. These expenses increased by approximately \$191,000 as compared to 1995. This increase in expenses is attributable to increased legal expenses, professional fees and rent.

GAIN ON SALE OF ASSETS

On March 21, 1995, the Company sold the tablets ANDA and certain equipment used in the production of the Tablets for up to \$5.4 million to Mallinckrodt. The Company received \$500,000 of the proceeds in July 1994. Mallinckrodt also paid the Company \$2,000,000 on March 21,1995 and the remainder will be payable as follows: (i) \$1,000,000 upon the Company receiving general clearance from the FDA for unrestricted operations at its Brooklyn facility and written notice from the FDA that it is in compliance with certain provisions of the consent decree dated September 29, 1993 and (ii) \$1,900,000 at the earlier of (a) Mallinckrodt receiving certain authorizations from the FDA or (b) September 21, 1997 (the "Deferred Payments"). Mallinckrodt also agreed to defer \$1,200,000 of the Company's trade debt due to an affiliate of Mallinckrodt. For the nine months ended September 30, 1995, the Company recorded a gain of \$2,288,000 for the sale of the ANDA and related equipment net of expenses related to the sale. If prior to the time it is possible for Mallinckrodt to commence production under the Tablets ANDA or any new Tablets ANDA at its own facility, and the Company ceases or is forced to cease or substantially curtail production under the Tablet ANDA, as a consequence of (i) any action or communication by the FDA or any other regulatory or governmental authority or (ii) any financial or other

business difficulty, then Mallinckrodt has the right to cancel payment of any yet unpaid portion of the Deferred Payment(\$1.9 million) and shall further have the right to a full refund of any portion of the Deferred Payment already made to the Company.

The Company has revised the gain recorded on the sale of assets to Mallinckrodt and will not recognize the Deferred Payment until the earlier of (a) Mallinckrodt receiving certain authorizations from the FDA or (b) March 31, 1998. The effect of the adjustments on the accompanying financial statements is as follows(In thousands, except for per share amounts):

As of September 30, 1995:

In thousands except for per share amounts	As Previously reported	As restated
	-----	-----
Net earnings(loss)	\$ 1,297	(\$ 603)
Net earnings per common share	.16	.15
Long-term receivable	1,900	--
Accumulated deficit	(\$9,589)	(\$11,489)

#### INTEREST EXPENSE

Interest expense for 1996 increased by \$464,000 as compared to 1995 as a result of the private placements of convertible subordinated debentures consummated in July 1995, November 1995 and August 1996 combined with the note from Mallinckrodt.

#### PROVISION FOR INCOME TAXES

In 1995, the Company had a tax provision of \$296,000 as a result of available net operating loss carryforwards. In 1996, the Company has no tax benefit since the available loss carryback to prior years was utilized by the net operating loss for 1993 carryback to the prior years.

#### NET (LOSS) EARNINGS

For the nine months ended September 30, 1996, the Company had a net loss of \$8,333,000 as compared to a net loss of \$603,000 for the nine months ended September 30, 1995. The increase in net loss is attributable to the gain on the sale of assets of \$ 4,188,000, net of the tax provision of \$ 296,000, or \$3,892,000. This increase is attributable to price reductions and discounts during the current year in an effort to meet increased competition combined with unabsorbed manufacturing costs and increases in expenses and legal fees incurred for certain subsidiary operations without any revenue being generated at the current time.

THREE MONTHS ENDED SEPTEMBER 30, 1996 Vs THREE MONTHS ENDED SEPTEMBER 30, 1995

#### NET SALES

The Company's net sales for the three months ended September 30, 1996 of \$2,937,000 represents a decrease of \$1,410,000 (32.4%) as compared to net sales for the three months ended September 30, 1995 of \$4,347,000. The decrease in 1996 is attributable to reductions in prices and increases in discounts due to intensely increased market competition.

#### COST OF GOODS SOLD

For the three months ended September 30, 1996, cost of goods sold of \$4,354,000 representing an increase of approximately \$305,000 as compared to the three months ended September 30, 1995. The increase for 1996 is attributable to increases in unabsorbed manufacturing costs which include costs of certain subsidiary operations which are not generating revenues at the current time as originally anticipated.

#### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of sales for the three months ended September 30, 1996 and 1995 were 52.3% and 34.6%, respectively. These expenses increased by approximately \$28,000 or 1.8% as compared to 1995. This increase in expenses is attributable to increased legal expenses, professional fees and rent.

#### INTEREST EXPENSE

Interest expense for 1996 increased by \$464,000 as compared to 1995 as a result of the private placements of convertible subordinated debentures consummated in July 1995, November 1995 and August 1996.

#### NET (LOSS)

For the three months ended September 30, 1996, the Company had a net loss of \$3,584,000 as compared to a net loss of \$1,811,000 for the three months ended September 30, 1995. This increase is attributable to price reductions and discounts during the current year in an effort to meet increased competition combined with unabsorbed manufacturing costs and increases in expenses and legal fees incurred for certain subsidiary operations without any revenue being generated at the current time.

## LIQUIDITY AND CAPITAL RESOURCES

At September 30, 1996, the Company had cash and cash equivalents of \$507,000 as compared to \$353,000 at December 31, 1995. The Company had a working capital deficiency at September 30, 1996 of \$9,486,000 and \$7,393,000 at December 31, 1995. In August of 1996, the Company signed an agreement with its banks which granted waivers for the outstanding defaults and extended the bank agreement termination date to December 31, 1996.

As a result of the decline in shipments of solid dosage products from the Company's Brooklyn plant following the entry of the consent decree, and as a result of the lack of available borrowing under the Company's credit agreement, the Company's liquidity position has been materially adversely affected since September 30, 1993 and the Company's capital resources have been severely limited. The Company has actively sought to reduce its operating costs at the Brooklyn plant, where it has made significant reductions in personnel. In addition, the Company's liquidity position has been affected since the second half of 1994 by the discontinuance of shipments of liquid products from its California subsidiary as a result of a review completed by the Company of this liquid operation. In an effort to reduce the loss from lower revenues at this subsidiary, the Company has reduced its operating costs at the California subsidiary through significant reductions of personnel and other expenses however, the Company is still incurring operating costs which are not being offset by revenues at this time.

The Company has insufficient resources to meet both its current obligations at September 30, 1996 and its long-term obligations. As previously indicated, the Company has continued to actively pursue financing as indicated by the completion of a third private placement of convertible debentures with warrants during the third quarter of 1996. However, there can be no assurance that the Company will be able to obtain any such additional financing on commercially acceptable terms to replace its existing bank debt.

The consummation of a private offering during the third quarter of 1996 resulted in net proceeds of approximately \$ 2,160,000. The Company was required to use \$391,000 of such net proceeds to repay a portion of its bank debt, accrued interest and legal fees as discussed in Note 3. The Company used the balance of the net proceeds of the Offering for: working capital; registration of the Underlying Shares under the Securities Act; purchase of equipment; and for research and development expenses.

PART II OTHER INFORMATION

Item 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) Exhibits:
  - Financial Data Schedule
  
- (b) Reports on Form 8-K
  - Current report on Form 8-k dated as of August 22, 1996:
  - Item 1 - Changes in Control of Registrant
  - Item 6 - Resignation of Registrant's Directors
  - Item 7 - Financial Statements and Exhibits

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this report under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: changes in general economic and business conditions; loss of market share through competition; introduction of competing services by other companies; changes in industry capacity; pressure on prices from competition or from purchasers of the Company's products; regulatory changes in the generic pharmaceutical manufacturing industry; regulatory obstacles to the introduction of new services that are important to the Company's growth; availability of qualified personnel; the loss of any significant customers; and other factors both reference and not referenced in this report. When used in this report, the words "estimate", "project", "anticipate", "expect", "intend", "believe", and similar expressions are intended to identify forward-looking statements.



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.

HALSEY DRUG CO., INC.

Date: November 14, 1996

By: /s/ Rosendo Ferran

-----  
Rosendo Ferran  
President and Chief  
Executive Officer

Date: November 14, 1996

By: /s/ Robert J. Melage

-----  
Robert J. Melage  
Corporate Controller

End of Document

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL CONDITION AT SEPTEMBER 30, 1996 (UNAUDITED) AND THE CONDENSED CONSOLIDATED STATEMENT OF INCOME FOR THE THREE MONTHS ENDED SEPTEMBER 30, 1996 (UNAUDITED) AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

3-MOS

	DEC-31-1996	
	SEP-30-1996	507
		0
	1,338	
	183	
	5,978	
	8,170	18,890
	12,372	
	16,038	
17,656		0
0		0
		116
	19,958	
16,038		10,580
	0	
		12,094
	0	
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		0
	(8,333)	
	(0.89)	
	0	