ACORDA THERAPEUTICS INC
Form 10-Q
August 05, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2008

OR

o **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 000-50513

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3831168**
(State of incorporation)	(I.R.S. Employer identification number)

15 Skyline Drive
Hawthorne, New York 10532
(914) 347-4300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 ý No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller Reporting Company o

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

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

Class	Outstanding at July 31, 2008
Common Stock, $0.001 par value per share	33,038,235 shares

ACORDA THERAPEUTICS, INC.

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PART I FINANCIAL INFORMATION

This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward- looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this report and in the "Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2007 that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements.

PART I

Item 1. Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Balance Sheets

	June 30, 2008 (unaudited)	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 34,252,619	$ 16,810,415
Restricted cash	293,469	288,194
Short-term investments	114,756,945	78,310,241
Trade accounts receivable, net	4,957,421	4,265,581
Prepaid expenses	2,514,496	2,341,585
Finished goods inventory held by the Company	4,260,544	5,849,929
Finished goods inventory held by others	2,214,067	1,874,405
Other current assets	952,048	1,293,496
Total current assets	164,201,609	111,033,846
Property and equipment, net of accumulated depreciation	1,826,142	1,651,739
Intangible assets, net of accumulated amortization	17,751,328	13,943,888
Other assets	619,299	676,993
Total assets	$ 184,398,378	$ 127,306,466
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,023,206	$ 6,675,894
Accrued expenses and other current liabilities	9,738,086	8,777,645
Deferred product revenue Zanaflex tablets	7,840,408	7,913,776
Deferred product revenue Zanaflex Capsules	16,855,878	13,923,781
Current portion of notes payable		187,645
Current portion of revenue interest liability	1,879,697	1,785,018
Total current liabilities	46,337,275	39,263,759
Put/call liability	412,500	462,500
Non current portion of revenue interest liability	18,432,522	17,444,324
Long-term convertible notes payable	6,804,059	6,703,235
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value. Authorized 80,000,000 shares at June 30, 2008 and December 31, 2007; issued and outstanding 32,813,251 and 28,574,678 shares as of June 30, 2008 and December 31, 2007, respectively	32,813	28,575
Additional paid-in capital	417,544,432	333,144,051
Accumulated deficit	(305,289,103)	(270,035,770)
Other comprehensive income	123,880	295,792
Total stockholders' equity	112,412,022	63,432,648
Total liabilities and stockholders' equity	$ 184,398,378	$ 127,306,466

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(unaudited)

	Three-month period ended June 30, 2008	Three-month period ended June 30, 2007	Six-month period ended June 30, 2008	Six-month period ended June 30, 2007
Gross sales Zanaflex	$ 13,098,842	$ 10,498,673	$ 25,775,351	$ 19,303,694
Less: discounts and allowances	(1,739,821)	(1,014,423)	(2,929,004)	(1,508,672)
Net sales	11,359,021	9,484,250	22,846,347	17,795,022
Grant revenue	26,693	10,192	52,925	16,187
Total net revenue	11,385,714	9,494,442	22,899,272	17,811,209
Less: cost of sales	(2,829,579)	(2,010,621)	(5,815,970)	(3,564,920)
Gross profit	8,556,135	7,483,821	17,083,302	14,246,289
Operating expenses:				
Research and development	8,058,113	4,007,479	17,650,435	7,251,432
Sales and marketing	11,732,527	7,118,313	21,929,161	14,087,735
General and administrative	5,837,831	4,475,797	10,901,033	8,829,929
Total operating expenses	25,628,471	15,601,589	50,480,629	30,169,096
Operating loss	(17,072,336)	(8,117,768)	(33,397,327)	(15,922,807)
Other income (expense):				
Interest and amortization of debt discount expense	(2,770,075)	(796,245)	(4,128,177)	(1,200,406)
Interest income	1,053,514	712,790	2,266,152	1,364,120
Other income	(33,561)	37,511	6,019	46,641
Total other income (expense)	(1,750,122)	(45,944)	(1,856,006)	210,355
Net loss	(18,822,458)	(8,163,712)	(35,253,333)	(15,712,452)
Net loss per share basic and diluted	$ (0.58)	$ (0.33)	$ (1.12)	$ (0.65)
Weighted average common shares outstanding used in computing net loss per share basic and diluted	32,557,460	24,450,036	31,450,705	24,073,945

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(unaudited)

	Six-month period ended June 30, 2008	Six-month period ended June 30, 2007
Cash flows from operating activities:		
Net loss	$(35,253,333)	$(15,712,452)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	2,685,900	
Share-based compensation expense	4,364,190	4,069,625
Amortization of net premiums and discounts on short-term investments	(1,498,141)	(817,808)
Amortization of revenue interest issuance cost	65,422	35,340
Depreciation and amortization expense	1,685,843	871,432
(Gain) Loss on put/call liability	(50,000)	12,500
(Gain) Loss on disposal of property and equipment		(23,750)
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(691,840)	751,710
Decrease in prepaid expenses and other current assets	168,537	134,871
Decrease in inventory held by the Company	1,589,385	271,463
Increase in inventory held by others	(339,662)	(46,250)
Increase in other assets	(7,728)	(5,715)
Increase in accounts payable, accrued expenses, other current liabilities	6,357,113	1,004,876
Decrease in deferred product revenue tablets	(73,368)	(716,156)
Increase (decrease) in deferred product revenue Capsules	2,932,097	(689,940)
Restricted cash	(5,275)	(6,810)
Net cash used in operating activities	(18,070,860)	(10,867,064)
Cash flows from investing activities:		
Purchases of property and equipment	(647,468)	(597,367)
Purchases of intangible assets	(5,000,000)	(5,000,000)
Purchases of short-term investments	(95,420,475)	(70,200,137)
Proceeds from maturities of short-term investments	60,300,000	37,550,000
Net cash used in investing activities	(40,767,942)	(38,247,504)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	77,354,529	63,571,338
Proceeds from sale of revenue interest		5,000,000
Repayments of revenue interest liability	(885,877)	(1,584,048)
Repayments of notes payable	(187,645)	(499,219)
Net cash provided by financing activities	76,281,007	66,488,071
Net increase in cash and cash equivalents	17,442,204	17,373,503
Cash and cash equivalents at beginning of period	16,810,415	18,100,908
Cash and cash equivalents at end of period	$ 34,252,619	$ 35,474,411
Supplemental disclosure:		
Cash paid for interest	2,060,151	1,095,778
Non-cash activities:		
Accrued Zanaflex milestone payment		5,000,000
Accrued Inventory		1,826,622

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

(unaudited)

(1) Organization and Business Activities

Acorda Therapeutics, Inc. ("Acorda" or the "Company") is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury and other disorders of the central nervous system (CNS).

The management of the Company is responsible for the accompanying unaudited interim consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, including normal recurring adjustments necessary for the fair presentation of the Company's financial position and results of operations and cash flows for the periods presented. Results of operations for interim periods are not necessarily indicative of the results to be expected for the entire year.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2007 included in the Company's Annual Report on Form 10-se in the number of treatments from approximately 1,189,000 in 2000 to approximately 1,301,000 in 2001. This growth in treatments is the result of the acquisition and development of various dialysis facilities and a 5.5% increase in same-center treatments for 2001 over 2000. In addition, average net revenue per dialysis treatment increased 9.3% from $248 in 2000 to $271 in 2001. The increase in revenue per treatment was generally due to a stronger payor mix in two businesses acquired in the fourth quarter of 2000, an improvement in the Company s overall payor mix, the effect of the 2.4% increase in the Medicare ESRD composite rate, increases in the utilization of certain drugs, and increases in acute hospital services.

Patient Care Costs. Patient care costs consist of costs directly related to the care of patients, including direct labor, drugs and other medical supplies, and operational costs of facilities. Patient care costs increased from $194.9 million for the six months ended June 30, 2000 to $232.1 million for the six months ended June 30, 2001 an increase of 19.1%. This increase was due principally to the increase in the number of treatments performed during

the period, which was reflected in corresponding increases in the use of labor, drugs and supplies. Patient care costs as a percentage of net revenue increased from 64.1% in 2000 to 64.8% in 2001. Patient care costs per treatment increased 8.5% from $164 in 2000 to $178 in 2001. These increases were due to Amgen s 3.9% increase in the price of EPO, generally higher patient care costs in two businesses acquired in the fourth quarter of 2000, increased labor costs to address wage pressures in many of the Company s markets, the cost of providing in-house laboratory services for a larger percentage of the Company s patients and other health care inflation.

General and Administrative Expenses. General and administrative expenses increased from $28.7 million for the six months ended June 30, 2000 to $30.8 million for the six months ended June 30, 2001, an increase of 7.3%. General and administrative expenses as a percentage of net revenue decreased from 9.4% in 2000 to 8.6% in 2001, primarily as the result of the increase in net revenue for 2001 and due to synergies realized in the successful integration of maturing mergers and acquisitions.

Provision for Doubtful Accounts. The provision for doubtful accounts increased from $8.3 million for the six months ended June 30, 2000 to $9.7 million for the six months ended June 30, 2001, an increase of $1.4 million, or 16.9%. The provision for doubtful accounts as a percentage of net revenue remained consistent at 2.7% in 2000 and 2001.

Depreciation and Amortization. Depreciation and amortization increased from $15.6 million for the six months ended June 30, 2000 to $18.1 million for the six months ended June 30, 2001, an increase of $2.5 million, or 16.0%. This net increase was due to the start-up of dialysis facilities, the normal replacement costs of dialysis facilities and equipment, the purchase of information systems, and the amortization of the goodwill and other intangible assets associated with the acquisitions accounted for as purchases.

Income from Operations. Income from operations increased from $52.7 million for the six months ended June 30, 2000 to $67.5 million for the six months ended June 30, 2001, an increase of $14.8 million, or 28.1%. Income from operations as a percentage of net revenue increased

from 17.3% in the 2000 period to 18.8% in the 2001 period as a result of the factors discussed above.

Interest Expense, Net. Interest expense decreased from $2.9 million for the six months ended June 30, 2000 to $2.3 million for the six months ended June 30, 2001. The decrease was the result of lower average borrowings during 2001, offset by a charge of $700,000 resulting from the anticipated settlements of Federal, state and local tax audits.

Minority Interest. Minority interest represents the proportionate equity interest of other partners in the Company s consolidated entities that are not wholly-owned, whose financial results are included in the Company s consolidated results. Minority interest as a percentage of net revenue increased to 1.9% in 2001 from 1.5% in 2000. This increase was the result of continued operational improvements in Renal Care Group s joint ventures, primarily those in Ohio and Oregon, as well as an increase in the number of facilities operated as joint ventures.

Provision for Income Taxes. Income tax expense increased from $18.6 million for the six months ended June 30, 2000 to $22.3 million for the six months ended June 30, 2001, an increase of $3.7 million or 19.9%. The increase is a result of pre-tax earnings increasing by 28.7%. The effective tax rate of the Company decreased from 40.9% for the six months ended June 30, 2000 to 38.2% for the six months ended June 30, 2001. This decrease is the result of significant non-deductible merger costs recorded in the 2000 period.

Net Income. Net income increased from $26.8 million for the six months ended June 30, 2000 to $36.1 million for the six months ended June 30, 2001, an increase of $9.3 million or 34.7%. The increase is a result of the items discussed above.

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Liquidity and Capital Resources

Renal Care Group requires capital primarily to acquire and develop dialysis centers, to purchase property and equipment for existing centers, and to finance working capital needs. At June 30, 2001, the Company s working capital was $125.2 million, cash and cash equivalents were $32.2 million, and the Company s current ratio was approximately 2.2 to 1.

Net cash provided by operating activities was $52.9 million for the six months ended June 30, 2001. Cash provided by operating activities consists of net income before depreciation and amortization expense, adjusted for changes in components of working capital, primarily accounts receivable. Net cash used in investing activities was $35.0 million for the six months ended June 30, 2001. Cash used in investing activities consisted primarily of $26.2 million of purchases of property and equipment and $6.2 million of cash paid for acquisitions, net of cash acquired. Net cash used in financing activities was $15.6 million for the six months ended June 30, 2001. Cash used in financing activities primarily reflects $34.2 million in net payments under Renal Care Group s line of credit partially offset by $18.6 million in net proceeds from the issuance of common stock.

On June 23, 1999, the Company executed a Second Amendment to its First Amended and Restated Loan Agreement with a group of banks. The Second Amendment provided for an increase in the credit facility from $125.0 million to $185.0 million through August 2000 at which point the lender commitments were reduced to $157.3 million. Lender commitments were further reduced to $129.5 million in August 2001. Borrowings under the credit facility may be used for acquisitions, capital expenditures, working capital and general corporate purposes. No more than $25.0 million of the credit facility may be used for working capital purposes. Within the working capital sublimit, Renal Care Group may borrow up to $5.0 million in swing line loans.

The Company has negotiated loan pricing based on a LIBO rate margin pursuant to leverage tiers. These leverage tiers extend from 0.75 to 2.25 times and are priced at a LIBO rate margin of 0.60% to 1.35%. Commitment fees are also priced pursuant to leverage ratio tiers. Commitment fees range from 0.20% to 0.30% pursuant to leverage ratios ranging between 0.75 and 2.25. Under the loan agreement, commitments range in amounts and dates from the closing date through August 2003. Renal Care Group obtained lender commitments of $185.0 million that were reduced to $129.5 million in August 2001. Lender commitments remain at $129.5 million through August 2002, and will then be reduced to $101.8 million through August 2003. All loans under the loan agreement are due and payable on August 4, 2003. As of June 30, 2001, there was $20.0 million outstanding under this agreement. These variable rate debt instruments of the Company carry a degree of interest rate risk. Specifically variable rate debt may result in higher costs to the Company if interest rates rise.

Each of Renal Care Group s subsidiaries has guaranteed all of Renal Care Group s obligations under the loan agreement. Further, Renal Care Group s obligations under the loan agreement, and the obligations of each of its subsidiaries under its guaranty, are secured by a pledge of the equity interests held by Renal Care Group in each of the subsidiaries. Financial covenants are customary based on the amount and duration of this commitment.

A significant component of Renal Care Group s growth strategy is the acquisition and development of dialysis facilities. There can be no assurance that Renal Care Group will be able to identify suitable acquisition candidates or to close acquisition transactions with them on acceptable terms. Management of Renal Care Group believes that existing cash and funds from operations, together with funds available under the line of credit, will be sufficient to meet Renal Care Group s acquisition, expansion, capital expenditure and working capital needs for the foreseeable future. However, in order to finance certain large strategic acquisition opportunities, Renal Care Group may from time to time incur additional short and long-term bank indebtedness and may issue equity or debt securities. The availability and terms of any future financing will depend on market and other conditions. There can

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be no assurance that any additional financing, if required, will be available on terms acceptable to Renal Care Group.

Renal Care Group plans to make capital expenditures of between $45.0 million to $50.0 million in 2001, primarily for equipment replacement, expansion of existing dialysis facilities and construction of de novo facilities. The Company has made capital expenditures of $26.2 million through June 30, 2001. The Company expects that remaining capital expenditures in 2001 will be funded with cash provided by operating activities and the Company s existing credit facility. Management believes that capital resources available to Renal Care Group will be sufficient to meet the needs of its business, both on a short- and long-term basis.

Newly Issued Accounting Standards

On June 29, 2001, the Financial Accounting Standards Board approved the issuance of Statements of Financial Accounting Standards No. 141, *Business Combinations* (SFAS No. 141), and No. 142, *Goodwill and Other Intangible Assets* (SFAS No. 142). SFAS No. 141 eliminates the pooling-of-interests method of accounting for all business combinations except those initiated prior to July 1, 2001. Additionally, this statement changes the criteria to recognize intangible assets apart from goodwill. SFAS No. 142 supersedes APB Opinion No. 17, *Intangible Assets,* that previously required goodwill and intangible assets be amortized over a life not to exceed 40 years. Under SFAS No. 142, goodwill and other intangible assets with indefinite lives will no longer be amortized but must be reviewed at least annually for impairment. Separable intangible assets that have finite lives will continue to be amortized over their useful lives, for which SFAS No. 142 does not impose a limit. The provisions of SFAS No. 142 apply currently to goodwill and intangible assets acquired after June 30, 2001 and upon adoption of the statement with respect to goodwill and intangibles acquired prior to July 1, 2001. During 2002, the Company will perform the first of the required impairment tests of goodwill and indefinite lived intangible assets as of January 1, 2002 and has not yet determined what the effect of these tests will be on the earnings and financial position of the Company. Management is also currently assessing the impact from the application of the nonamortization provisions of SFAS No. 142.

RISK FACTORS

You should carefully consider the risks described below before investing in Renal Care Group. The risks and uncertainties described below ***are not*** *the only ones facing Renal Care Group. Other risks and uncertainties that we have not predicted or assessed may also adversely affect our company.*

If any of the following risks occur, our earnings, financial condition or business could be materially harmed, and the trading price of our common stock could decline, resulting in the loss of all or part of your investment.

If Medicare or Medicaid Changes its Programs for Dialysis, Our Revenue and Earnings Could Decrease

If the government changes the Medicare, Medicaid or similar government programs or the rates paid by those programs for our services, then our revenue and earnings may decline. We estimate that approximately 57% of our net revenue for 1999, 53% of our net revenue for 2000 and 50% of our net revenue for the six months ended June 30, 2001 consisted of reimbursements from Medicare, including the administration of EPO to treat anemia. We also estimate that approximately 4% of our net revenue for 1999, 5% of our net revenue for 2000 and 7% of our net revenue for the six months ended June 30, 2001 consisted of reimbursements from Medicaid or comparable state programs. Any of the following actions in connection with government programs could cause our revenue and earnings to decline:

a reduction of the amount paid to us under government programs;

an increase in the costs associated with performing our services that are subject to inflation, such as labor and supply costs, without a corresponding increase in reimbursement rates;

the inclusion of some or all ancillary services, for which we are now reimbursed separately, in the flat composite rate for a standard dialysis treatment; or

changes in laws, or the interpretations of laws, which could cause us to modify our operations.

Specifically, Congress and the Centers for Medicare & Medicaid Services, or CMS (formerly known as the Health Care Financing Administration), have proposed reviewing and potentially recalculating the average wholesale prices of certain drugs, including some drugs that we bill for outside of the flat composite rate. CMS has indicated that it believes the average wholesale prices on which it currently bases reimbursement are too high and that Medicare reimbursement for these drugs is, therefore, too high. Because we are unable to predict accurately whether reimbursement will be changed and, if so, by how much, we are unable to quantify what the net effect of changes in reimbursement for these drugs would have on our revenue and earnings.

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If Reimbursement for EPO Decreases, Then We Could Be Less Profitable

If government or private payors decrease reimbursement rates for EPO, for which we are currently reimbursed separately outside of the flat composite rate, our revenue and earnings will decline. EPO is a bio-engineered hormone that is used to treat anemia. Revenues from the administration of EPO were approximately 26% of our net revenue for 1999 and 2000 and for the six months ended June 30, 2001. Most of our payments for EPO come from government programs. For the six months ended June 30, 2001, Medicare and Medicaid reimbursement represented approximately 57% of the total revenue we derived from EPO. A reduction in the reimbursement rate for EPO could materially and aversely affect our revenue and earnings.

If Amgen Raises the Price for EPO or if EPO Becomes in Short Supply, Then We Could Be Less Profitable

EPO is produced by a single manufacturer, Amgen Inc., and there are no substitute products marketed to dialysis providers in the United States. In May 2001, Amgen announced a 3.9% increase in the price of EPO. This price increase will not affect our earnings in 2001 because our contract with Amgen has pricing protection through 2001. This price increase will, however, adversely affect our earnings in 2002 by up to $0.05 per share. In addition, Amgen implemented a 3.9% increase in the price of EPO in February 2000. This price increase adversely affected our earnings in 2000. If Amgen imposes additional EPO price increases or if Amgen or other factors interrupt the supply of EPO, then our revenue and earnings will decline. Amgen is also developing a new product that may replace EPO or reduce its use. The Food and Drug Administration has not yet approved this new drug. We cannot predict when, or whether, Amgen will seek to introduce this product into the dialysis market or how it will impact our revenue or earnings if it is introduced.

If Payments by Private Insurers, Hospitals or Managed Care Organizations Decrease, Then Our Revenue and Earnings Could Decrease

If private insurers, hospitals or managed care organizations reduce their rates or we experience a significant shift in our revenue mix toward additional Medicare or Medicaid reimbursement, then our revenue and earnings will decline. We estimate that approximately 39% of our net revenue for 1999, 42% of our net revenue for 2000 and 43% of our net revenue for the six months ended June 30, 2001, were derived from sources other than Medicare and Medicaid. In general, payments we receive from private insurers and hospitals for our services are at rates significantly higher than the Medicare or Medicaid rates. Additionally, payments we receive from managed care organizations are typically at rates higher than Medicare and Medicaid rates but lower than those paid by private insurers. As a result, any of the following events could have a material adverse effect on our revenue and earnings:

any number of economic or demographic factors could cause private insurers, hospitals or managed care companies to reduce the rates they pay us;

a portion of our business that is currently reimbursed by private insurers or hospitals may become reimbursed by managed care organizations, which currently have lower rates for our services; or

the scope of coverage by Medicare or Medicaid under the flat composite rate could expand and, as a result, reduce the extent of our services being reimbursed at the higher private-insurance rates.

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If We are Unable to Make Acquisitions in the Future, Our Rate of Growth Will Slow

Much of our historical growth has come from acquisitions. Although we intend to continue to pursue growth through the acquisition of dialysis centers, we may be unable to continue to identify and complete suitable acquisitions at prices we are willing to pay or we may be unable to obtain the necessary financing. Further, due to the increased size of our Company since its formation, the amount that acquired businesses contribute to our revenue and profits will likely be smaller on a percentage basis. Also, as a result of consolidation in the dialysis industry, the four largest providers of outpatient dialysis services own approximately 60% of the total outpatient dialysis facilities in the United States. We compete with these other companies to identify and complete suitable acquisitions. We expect this competition to intensify in light of the smaller pool of available acquisition candidates and other market forces. As a result, we believe it will be more difficult for us to acquire suitable companies on favorable terms. Further, the businesses we acquire may not perform well enough to justify our investment. If we are unable to make additional acquisitions on suitable terms, we may not meet our growth expectations.

If We Fail to Integrate Acquired Companies, We Will Be Less Profitable

We have grown significantly by acquisitions of other dialysis providers since our formation in February 1996. We have completed some of our acquisitions as recently as July 2001. We intend to pursue acquisitions of more dialysis businesses in the future. We are unable to predict the number and size of any future acquisitions. We face significant challenges in integrating an acquired company s management and other personnel, clinical operations, and financial and operating systems with ours, often without the benefit of continued services from key personnel of the acquired company. We may be unable to integrate the businesses we acquire successfully or to achieve anticipated benefits from an acquisition in a timely manner, which could lead to substantial costs and delays or other operational, technical or financial problems, including diverting management s attention from our existing business. Any of these results could damage our profitability and our prospects for future growth.

If We Complete Future Acquisitions, We May Dilute Existing Stockholders by Issuing More of Our Common Stock or We May Incur Additional Expenses Related to Debt and Goodwill, Which Could Reduce Our Earnings

We may issue equity securities in future acquisitions that could be dilutive to our shareholders. We also may incur additional debt and amortization expense related to goodwill and other intangible assets in future acquisitions. We have used the pooling-of-interests accounting method for many of our acquisitions, and as a result we have not recorded goodwill (the excess of acquisition cost over identifiable tangible assets) in these acquisitions. In those instances where we have used the purchase accounting method in acquisitions, we have recorded goodwill and other intangible assets, which are then amortized yearly against our earnings at a blended average life of 35 years. We had approximately $230.1 million of goodwill and other intangibles, net, as of June 30, 2001. The Financial Accounting Standards Board announced the finalization of rules that eliminate the pooling-of-interests method. The elimination of the pooling-of-interests method will likely result in the recording of goodwill for all acquisitions subsequent to June 30, 2001. Under the rule and policy changes goodwill and other intangible assets with indefinite lives will not be amortized to expense; however, we will be required to review all such assets at regular intervals and to charge an appropriate amount to expense when impairment is identified. Interest expense on additional debt incurred to fund our acquisitions may significantly reduce profitability.

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If Acquired Businesses Have Unknown Liabilities, Then We Could Be Exposed to Liabilities That Could Harm Our Business and Profitability

Businesses we acquire may have unknown or contingent liabilities, including liabilities for failure to comply with health care laws. Although we generally attempt to identify practices that may give rise to unknown or contingent liabilities and conform them to our standards after the acquisition, private plaintiffs or governmental agencies may still assert claims. Even though we generally seek to obtain indemnification from prospective sellers, unknown and contingent liabilities may not be covered by indemnification or may exceed contractual limits or the financial capacity of the indemnifying party.

If Our Referring Physicians Stop Referring To Our Centers or Were Prohibited From Referring for Regulatory Reasons, Our Revenue and Earnings Would Decline

Our dialysis centers depend on referrals from local nephrologists. Typically, one or a few physicians patients make up all or a significant portion of the patient base at each of our dialysis centers, and the loss of the patient base of one or more referring physicians could have a

material adverse effect on the operations of that center. The loss of the patient base of a significant number of referring physicians could cause our revenue and earnings to decline. In many instances, the primary referral sources for our centers are physicians who are also stockholders and serve as medical directors of our centers. If stock ownership or the medical director relationship were deemed to violate applicable federal or state law, including fraud and abuse laws and laws prohibiting self-referrals, the physicians owning our stock or acting as medical directors could be forced to stop referring patients to our centers. Further, we may not be able to renew or renegotiate our medical director agreements successfully, which could result in a loss of patients since dialysis patients are typically treated at a center where their physician serves as a medical director.

If Our Business Is Alleged or Found To Violate Heath Care or Other Applicable Laws, Our Revenue and Earnings Could Decrease

We are subject to extensive federal, state and local regulation regarding the following:

fraud and abuse prohibitions under health care reimbursement laws;

prohibitions and limitations on patient referrals;

billing and reimbursement, including false claims prohibitions under health care reimbursement laws;

collection, use, storage and disclosure of patient health information;

facility licensure;

health and safety requirements;

environmental compliance; and

medical and toxic waste disposal.

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Much of this regulation, particularly in the areas of fraud and abuse and patient referral, is complex and open to differing interpretations. Due to the broad application of the statutory provisions and the absence in many instances of regulations or court decisions addressing the specific arrangements by which we conduct our business, including our arrangements with medical directors, physician shareholders and physician joint venture partners, governmental agencies could challenge some of our practices under these laws.

New regulations governing electronic transactions and the collection, use, storage and disclosure of health information impose significant administrative and financial obligations on our business. If, after the required compliance date, we are found to have violated these restrictions, we could be subject to:

criminal or civil penalties;

claims by persons who believe their health information has been improperly used or disclosed; and

administrative penalties by payors.

Government investigations of health care providers, including dialysis providers, have continued to increase. We have been the subject of investigations in the past, and the government may investigate our business in the future. For example, the OIG has indicated that it is focusing on a number of areas related to ESRD in its 2001 work plan. In addition, one of our competitors, DaVita, Inc., recently announced that it is the subject of an investigation by the U.S. Attorney for the Eastern District of Pennsylvania, and another competitor, Gambro Healthcare, Inc., recently announced that it is the subject of an investigation by the U.S. Attorney s Office in St. Louis, Missouri. If any of our operations are found to violate these laws, we may be subject to severe sanctions or be required to alter or discontinue the challenged conduct or both. If we are required to alter our practices, we may not be able to do so successfully. If any of these events occur, our revenue and earnings could decline.

Changes In the Health Care Delivery, Financing or Reimbursement Systems Could Adversely Affect Our Business

The health care industry in the United States remains in a period of rapid change and uncertainty. Health care organizations, public or private, may dramatically change the way they operate and pay for services. Our business is designed to function within the current health care financing and reimbursement system. During the past several years, the health care industry has been subject to increasing levels of government regulation of, among other things, reimbursement rates and capital expenditures. In addition, proposals to reform the health care system have been

considered by Congress. These proposals, if enacted, may further increase government regulation of or other involvement in health care, lower reimbursement rates and otherwise change the operating environment for health care companies. We cannot predict the likelihood of those events or what impact they may have on our business.

The Dialysis Business Is Highly Competitive. If We Do Not Compete Effectively in Our Markets, We Could Lose Market Share and Our Rate of Growth Could Slow

The dialysis industry is rapidly consolidating. There is a small number of large dialysis companies that compete for the acquisition of outpatient dialysis centers and the development of relationships with referring physicians. Several of our competitors are part of larger companies that also manufacture dialysis equipment, which allows them to realize lower equipment costs. Several of our competitors, including these equipment manufacturers, are much larger than we are and have substantially greater financial resources and more

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established operations and infrastructure than us. We also experience competition from nephrologists who open their own dialysis centers. There can be no assurance that we will be able to compete effectively with any of our competitors.

If We Lose Any of Our Executive Officers, or Are Unable To Attract and Retain Qualified Management Personnel and Medical Directors, Our Ability To Run Our Business Could Be Adversely Affected, and Our Revenue and Earnings Could Decline

We are dependent upon the services of our executive officers Sam A. Brooks, Jr., our Chairman, Chief Executive Officer and President, and Raymond Hakim, M.D., Ph.D., R. Dirk Allison and Gary Brukardt, each an Executive Vice President. Mr. Brooks, Dr. Hakim and Mr. Brukardt have each been with Renal Care Group since its formation. The services of Mr. Brooks and these three Executive Vice Presidents would be very difficult to replace. We do not carry key-man life insurance on any of our officers. Further, our growth will depend in part upon our ability to attract and retain skilled employees, for whom competition is intense. We also believe that our future success will depend on our ability to attract and retain qualified physicians to serve as medical directors of our dialysis centers. We have entered into medical director agreements with the physicians serving as medical directors of our dialysis centers, most of which contain noncompetition covenants of varying durations.

If We Are Liable for Damages in Litigation, Our Insurance May Not be Sufficient to Cover Such Potential Damages

On August 30, 2000, nineteen patients were hospitalized and one patient died shortly after becoming ill while receiving treatment at one of our dialysis centers in Youngstown, Ohio. One of the nineteen hospitalized patients also died some time later. Eight lawsuits had been filed against us as of June 30, 2001, and other suits could be brought in the future. While management believes Renal Care Group s insurance should be adequate to cover these events, if we are found liable for damages in litigation stemming from these illnesses, our present insurance coverage may not be sufficient to cover such damages.

If Our Board of Directors Does Not Approve an Acquisition or Change in Control of Renal Care Group, Our Shareholders May Not Realize the Full Value of Their Stock

Our certificate of incorporation and bylaws contain a number of provisions that may delay, deter or inhibit a future acquisition or change in control of Renal Care Group that is not first approved by our board of directors. This could occur even if our shareholders receive an attractive offer for their shares or if a substantial number or even a majority of our shareholders believe the takeover may be in their best interest. These provisions are intended to encourage any person interested in acquiring Renal Care Group to negotiate with and obtain approval from our board of directors prior to pursuing the transaction. Provisions that could delay, deter or inhibit a future acquisition or change in control of Renal Care Group include the following:

a staggered board of directors that would require two annual meetings to replace a majority of the board of directors;

restrictions on calling special meetings at which an acquisition or change in control might be brought to a vote of the shareholders;

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blank check preferred stock that may be issued by our board of directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquiror; and

a poison pill that would substantially dilute the interest sought by an acquiror.

These provisions could also discourage bids for our common stock at a premium and cause the market price of our common stock to decline.

Our Stock Price Is Volatile and as a Result, the Value of Your Investment May Go Down for Reasons Unrelated To the Performance of Our Business

Our common stock is traded on the Nasdaq National Market. The market price of our common stock has been volatile, ranging from a low of $23.43 per share to a high of $32.89 per share during the three months ended June 30, 2001. The market price for our common stock could fluctuate substantially based on a variety of factors, including the following:

future announcements concerning us, our competitors or the health care market;

the threat of litigation;

changes in government regulations; and

changes in earnings estimates by analysts.

Furthermore, stock prices for many companies fluctuate widely for reasons that may be unrelated to their operating results. These fluctuations, coupled with changes in demand or reimbursement levels for our services and general economic, political and market conditions, could cause the market price of our common stock to decline.

Forward Looking Statements

Some of the information in this quarterly report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words like may, will, expect, anticipate, believe, intend, estimate continue or similar words. You should read statements that contain these words carefully for the following reasons:

the statements discuss our future expectations;

the statements contain projections of our future earnings or of our financial condition; and

the statements state other forward-looking information.

We believe it is important to communicate our expectations to our investors. There may be events in the future, however, that we are not able to predict accurately or over which we have no control. The risk factors listed above, as well as any cautionary language in or incorporated by reference into this quarterly report on Form 10-Q, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. The SEC allows us to incorporate by reference the

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information we file with them, which means we can disclose important information to you by referring you to those documents. Before you invest in our common stock, you should be aware that the occurrence of any of the events described in the above risk factors, elsewhere in or incorporated by reference into this quarterly report on Form 10-Q and other events that we have not predicted or assessed could have a material adverse effect on our earnings, financial condition and business. If the events described above or other unpredicted events occur, then the trading price of our common stock could decline and you may lose all or part of your investment.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

On August 30, 2000, nineteen patients were hospitalized and one patient died shortly after becoming ill while receiving treatment at one of the Company s dialysis centers in Youngstown, Ohio. One of the nineteen hospitalized patients also died some time later.

In March 2001, the Company was sued in Mahoning County, Ohio by one of the affected patients for injuries related to the August 30, 2000 illnesses. Additional suits have been filed, and as of June 30, 2001, a total of eight suits were pending. The suits allege negligence, medical malpractice and product liability. Additional defendants are named in each of the suits. Additional defendants include the water system vendors who installed and maintained the water system in the dialysis centers. Renal Care Group has denied the allegations and has filed cross-claims against the water system vendors. Renal Care Group intends to pursue these cross-claims vigorously.

These suits are styled:	Renee Chesney, et al. v. Physicians Dialysis Centers, Inc., et al. Clifford Hickson v. Physicians Dialysis Centers, Inc., et al. Joanne Hight, et al. v. Physicians Dialysis Centers, Inc., et al. Andrew Kraynack, et al. v. Physicians Dialysis Centers, Inc., et al. Kay F. Lingo v. Physicians Dialysis Centers, Inc., et al. Charles J. Lowry, Sr. v. Physicians Dialysis Centers, Inc., et al. Lawrence Payne v. Physicians Dialysis Centers, Inc., et al. William E. Repasky, et al. v. Physicians Dialysis Centers, Inc., et al.

Additional suits arising out of these illnesses may be filed in the future. Management believes that Renal Care Group s insurance should be adequate to cover these illnesses and does not anticipate a material adverse effect on the Company s consolidated financial position or results of operation.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

On June 6, 2001, the Annual Meeting of Stockholders of Renal Care Group, Inc. was held in Nashville, Tennessee for the following purposes and with the following results:

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1. To elect Joseph C. Hutts, Harry R. Jacobson, M.D. and Thomas A. Lowery as Class II Directors, each to serve for a term of three (3) years and until his successor is elected:

	FOR	ABSTAIN
Election of Joseph C. Hutts	40,111,843	1,507,580
Election of Harry R. Jacobson, M.D. 40,256,990 1,362,433		
Election of Thomas A. Lowrey, M.D. 39,229,307 2,390,116		

Directors whose terms continued following the meeting but who were not subject to election at the meeting are: Sam A. Brooks, Jr., John D. Bower, M.D., Kenneth E. Johnson, M.D., William V. Lapham, Stephen D. McMurray, M.D., and W. Tom Meredith, M.D.

2. To approve an amendment to the Renal Care Group, Inc. 1999 Long-Term Incentive Plan (the Long-Term Incentive Plan) to increase the number of shares available for issuance thereunder:

FOR	AGAINST	ABSTAIN
23,087,669	18,334,385	197,369

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits:

None.

(b) Reports on Form 8-K:

Form 8-K filed May 16, 2001.

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SIGNATURE

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.

RENAL CARE GROUP, INC.

August 14, 2001 BY: /s/ R. Dirk Allison

R. Dirk Allison
Executive Vice President,
Chief Financial Officer, and Principal
Financial Officer and Principal
Accounting Officer