COVANCE INC Form 10-Q July 23, 2004

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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, 2004

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: 1-12213** 

# **COVANCE INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware** (State of Incorporation) **22-3265977** (I.R.S. Employer Identification No.)

**210 Carnegie Center, Princeton, New Jersey** (Address of Principal Executive Offices) **08540** (Zip Code)

Registrant's telephone number, including area code: (609) 452-4440

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  $\circ$  NO o

Indicate by check mark whether the Registrant is an accelerated filer (as described in Rule 12b-2 of the Exchange Act). YES ý NO o

## APPLICABLE ONLY TO CORPORATE ISSUERS:

As of July 16, 2004, the Registrant had 62,632,757 shares of Common Stock outstanding.

## Covance Inc. Form 10-Q For the Quarterly Period Ended June 30, 2004

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## COVANCE INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS JUNE 30, 2004 AND DECEMBER 31, 2003

(Dollars in thousands)	June 30, 2004	December 31, 2003
	(UNAUDITED)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 152,610	\$171,600
Accounts receivable	160,210	156,799
Unbilled services	54,109	44,053
Inventory Deferred income taxes	39,317	39,926
	8,283	6,230
Prepaid expenses and other current assets	48,550	31,246
Total Current Access	462.070	440.054
Total Current Assets Property and equipment, pat	463,079	449,854
Property and equipment, net Goodwill, net	285,955	284,413
Other assets	56,876	56,876
Other assets	38,111	16,482
Total Assets	\$ 844,021	\$807,625
	\$ 644,021	\$807,025
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 22,787	\$ 20,129
Accrued payroll and benefits	49,197	50,433
Accrued expenses and other current liabilities	37,820	37,035
Unearned revenue	71,282	82,227
Income taxes payable	9,593	
Total Current Liabilities	190,679	189,824
Deferred income taxes	36,852	36,776
Other liabilities	19,356	17,044
Total Liabilities	246,887	243,644
Commitments and Contingent Liabilities		
Stockholders' Equity:		
Preferred Stock Par value \$1.00 per share; 10,000,000 shares		
authorized; no shares issued and outstanding at June 30, 2004		
and December 31, 2003, respectively	(0/	(())
Common Stock Par value \$0.01 per share; 140,000,000 shares	686	663
authorized; 68,599,775 and 66,345,070 shares issued, including		
those held in treasury, at June 30, 2004 and December 31,		

2003, respectively		
Paid-in capital	254,735	199,534
Retained earnings	440,709	395,245
Accumulated other comprehensive income		
Cumulative translation adjustment	24,530	21,960
Treasury stock at cost (6,011,842 and 3,820,531 shares at June		
30, 2004 and December 31, 2003, respectively)	(123,526)	(53,421)
Total Stockholders' Equity	597,134	563,981
Total Liabilities and Stockholders' Equity	\$ 844,021	\$807,625

The accompanying notes are an integral part of these consolidated financial statements.

## COVANCE INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF INCOME FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2004 AND 2003 (UNAUDITED)

	Three Months Ended June 30			Six Months Ended June 30																
	2004		2004		2004		2004		2003		2003		2003		2003		2004		2004 2003	
(Dollars in thousands, except per share data)																				
Net revenues	\$	250,995	\$	233,838	\$	495,238	\$	467,234												
Reimbursable out-of-pockets		7,622		8,507		14,879		18,160												
Total revenues		258,617	_	242,345		510,117		485,394												
Cost and expenses:																				
Cost of revenue		167,120		157,708		328,696		318,728												
Reimbursed out-of-pocket expenses		7,622		8,507		14,879		18,160												
Selling, general and administrative		38,393		36,522		77,247		70,142												
Depreciation and amortization		11,453		11,452		23,191		22,611												
Total		224,588		214,189		444,013		429,641												
Income from operations		34,029	_	28,156		66,104		55,753												
Other expense (income), net:																				
Interest expense		344		387		742		812												
Interest income		(544)		(235)		(1,486)		(628)												
Foreign exchange transaction loss (gain), net		218		(41)		418		21												
Other expense (income), net		18		111		(326)		205												
Income before taxes and equity investee																				
earnings		34,011		28,045		66,430		55,548												
Taxes on Income		10,885		9,861		21,401		19,623												
Equity investee earnings		169		70		435		247												
Net income	\$	23,295	\$	18,254	\$	45,464	\$	36,172												
Basic earnings per share	\$	0.37	\$	0.30	\$	0.73	\$	0.59												
Weighted average shares outstanding basic	6	2,512,302	6	1,445,088	6	2,553,616	6	1,515,200												
Diluted earnings per share	\$	0.36	\$	0.29	\$	0.70	\$	0.58												
Weighted average shares outstanding diluted	6	4,795,264	6	2,267,702	6	4,726,789	6	2,769,974												

The accompanying notes are an integral part of these consolidated financial statements.

## COVANCE INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003 (UNAUDITED)

	Six Months Ended June 30	
	2004	2003
(Dollars in thousands)		
Cash flows from operating activities:		
Net income	\$ 45,464	\$ 36,172
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	23,191	22,611
Stock issued under employee benefit and stock compensation plans	6,428	6,572
Deferred income tax (benefit) provision	(1,977)	4,106
Other	(237)	280
Changes in operating assets and liabilities:		10.000
Accounts receivable Unbilled services	(3,411)	10,386
Inventory	(10,056) 609	(10,710) 907
Accounts payable	2,658	(5,040)
Accrued liabilities	(451)	(23,579)
Unearned revenue	(10,945)	(23,343)
Income taxes payable	9,593	(-))
Other assets and liabilities, net	(7,488)	1,077
Net cash provided by operating activities	53,378	19,439
Cash flows from investing activities:		
Equity method investment	(20,741)	
Capital expenditures	(23,280)	(20,358)
Other, net	71	(46)
Net cash used in investing activities	(43,950)	(20,404)
Cash flows from financing activities:		
Stock issued under employee stock purchase and option plans	40,623	14,919
Purchase of treasury stock	(70,105)	(13,931)
Net cash (used in) provided by financing activities	(29,482)	988
Effect of exchange rate changes on cash	1,064	2,904
Net change in cash and cash equivalents	(18,990)	2,927

Cash and cash equivalents, beginning of period	171,600	75,913
Cash and cash equivalents, end of period	\$152,610	\$ 78,840

The accompanying notes are an integral part of these consolidated financial statements.

## COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. You should read these consolidated financial statements together with the historical consolidated financial statements of Covance Inc. and subsidiaries ("Covance") for the years ended December 31, 2003, 2002, and 2001 included in our Annual Report on Form 10-K for the year ended December 31, 2003.

#### 2. Summary of Significant Accounting Policies

#### **Principles of Consolidation**

These unaudited consolidated financial statements include the accounts of all entities controlled by Covance. All significant intercompany accounts and transactions are eliminated. The equity method of accounting is used for investments in affiliates in which Covance owns between 20 and 50 percent and does not have the ability to exercise control. See Note 4.

#### **Use of Estimates**

These unaudited consolidated financial statements have been prepared in conformity with GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

#### **Prepaid Expenses and Other Current Assets**

In connection with the management of multi-site clinical trials, Covance pays on behalf of its customers fees to investigators, volunteers and other out-of-pocket costs (such as travel, printing, meetings, couriers, etc.), for which we are reimbursed at cost, without mark-up or profit. Amounts receivable from customers in connection with billed and unbilled investigator fees, volunteer payments and other out-of-pocket pass-through costs are included in prepaid expenses and other current assets in the accompanying Consolidated Balance Sheets and totaled \$23.6 million and \$14.5 million at June 30, 2004 and December 31, 2003, respectively. See Note 2 "Reimbursable Out-of-Pocket Expenses".

#### Inventory

Inventories, which consist principally of finished goods and supplies, are valued at the lower of cost (first-in, first-out method) or market.

#### Goodwill and Impairment of Goodwill

Goodwill represents investment costs in excess of the fair value of net tangible and identifiable net intangible assets acquired. In accordance with Financial Accounting Standards Board ("FASB") Statement No. 142, *Goodwill and Other Intangible Assets*, Covance performs an annual test for impairment of goodwill. The most recent annual test performed for 2003 did not identify any instances of impairment and there were no events through June 30, 2004 that warranted a reconsideration of our impairment test results.

### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 2. Summary of Significant Accounting Policies (Continued)

#### **Taxes on Income**

Covance uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of differences between the carrying amount of assets and liabilities and their respective tax bases using tax rates in effect for the year in which the temporary differences are expected to reverse. The effect on deferred taxes of a change in enacted tax rates is recognized in income in the period when the change is effective.

Covance has established, and periodically reviews and reevaluates, an estimated income tax reserve on its consolidated balance sheet to provide for the possibility of adverse outcomes in tax proceedings. When matters are settled or when facts indicate a material change in the probability or amount of the potential exposure, Covance adjusts the carrying value of the related reserve.

#### **Comprehensive Income**

Covance's total comprehensive income, which represents net income plus the change in the cumulative translation adjustment equity account for the periods presented, was \$26.2 million and \$25.0 million for the three months ended June 30, 2004 and 2003, respectively, and \$48.0 million and \$42.8 million for the six months ended June 30, 2004 and 2003, respectively.

#### Earnings Per Share ("EPS")

Basic EPS is computed by dividing net income available to common stockholders by the weighted average number of shares outstanding during the period. The computation of diluted EPS is similar to the computation of basic EPS, except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued; computed under the treasury stock method in accordance with the requirements of SFAS No. 128, *Earnings Per Share*. In computing diluted earnings per share for the three months ended June 30, 2004 and 2003, the denominator was increased by 2,282,962 shares and 822,614 shares, respectively, and for the six months ended June 30, 2004 and 2003, the denominator was increased by 2,173,173 shares and 1,254,774 shares, respectively, representing the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued for stock options outstanding at June 30, 2004 and 2003 with exercise prices less than the average market price of Covance's Common Stock during each respective period.

#### **Reimbursable Out-of-Pocket Expenses**

As discussed in Note 2 "Prepaid Expenses and Other Current Assets", Covance pays on behalf of its customers fees to investigators, volunteers and other out-of-pocket costs for which we are reimbursed at cost, without mark-up or profit. In connection with the requirements of Financial Accounting Standards Board Emerging Issues Task Force Rule No. 01-14 ("EITF 01-14"), *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred*, amounts paid to volunteers and other out-of-pocket costs are reflected in operating expenses, while the reimbursements received are reflected in revenues in the Consolidated Statements of Income. Covance will continue to exclude from revenue and expense in the Consolidated Statements of Income fees paid to investigators and the associated reimbursement since Covance acts as an agent on behalf of the pharmaceutical company sponsors with regard to investigator payments.

### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 2. Summary of Significant Accounting Policies (Continued)

#### **Stock-Based Compensation**

Covance has several stock-based compensation plans, which are described more fully in Note 10 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003. Effective January 1, 2003, Covance adopted FASB Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. Statement No. 148 amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide, among other things, prominent disclosure of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. Covance intends to continue to follow the disclosure-only provisions of FASB Statement No. 123 and, accordingly, will continue to account for these plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock price on the date of grant, no compensation expense is recognized.

While Covance does record compensation expense related to awards of stock, no compensation cost is recorded for option grants under Covance's stock option plans as all options granted under these plans are issued with an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income and earnings per share for the three and six months ended June 30, 2004 and 2003 had Covance applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to all of its stock-based employee compensation plans.

		Months June 30	Six Montl June	
	2004	2003	2004	2003
Net Income, as reported	\$23,295	\$18,254	\$45,464	\$36,172
Add: Stock award-based employee compensation included in reported net income, net of related tax effects	\$ 764	\$ 848	\$ 1,389	\$ 1,608
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net				
of related tax effects	\$ (3,563	) \$ (3,226)	\$ (6,446)	\$ (6,204)
Pro forma net income	\$20,496	\$15,876	\$40,407	\$31,576
Earnings per share: Basic as reported Basic pro forma	\$ 0.37 \$ 0.33		\$ 0.73 \$ 0.65	\$ 0.59 \$ 0.51
Diluted as reported Diluted pro forma	\$ 0.36 \$ 0.32		\$ 0.70 \$ 0.63	\$ 0.58 \$ 0.50

#### **Supplemental Cash Flow Information**

Cash paid for interest for each of the six month periods ended June 30, 2004 and 2003 totaled \$0.8 million. Cash paid for income taxes for the six month periods ended June 30, 2004 and 2003 totaled \$6.6 million and \$9.2 million, respectively.

#### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 3. Treasury Stock

In June 2004, the Covance Board of Directors authorized the repurchase of an additional 3.0 million shares under Covance's stock repurchase program. At June 30, 2004, there were 3.0 million shares remaining for purchase under this program, and another 0.3 million shares remaining under a previous 3.0 million share buyback program approved by the Covance Board of Directors in 2003. Covance also reacquires shares of its common stock in connection with certain employee benefit plans when employees tender shares upon choosing the reload option for stock option exercises and when employees tender shares to satisfy income tax withholdings associated with the vesting of stock awards. The following table sets forth the treasury stock activity during the six month periods ended June 30, 2004 and 2003.

	Six Months Ended June 30					
	20	04	2003			
	\$	# shares	\$	# shares		
Shares repurchased in connection with:						
Board approved buyback programs	\$66,883	2,095.0	\$13,515	640.3		
Employee benefit plans	3,222	96.3	416	9.4		
Total	\$70,105	2,191.3	\$13,931	649.7		

#### 4. Equity Method Investees

In March 2004, Covance acquired a 47% minority equity position in Noveprim Limited, an existing supplier of research products, for a total cost of \$20.7 million. The excess of the purchase price over the underlying equity in Noveprim's net assets is approximately \$13.8 million. This investment is reflected in Other Assets on the Consolidated Balance Sheet. During the three month period ended June 30, 2004, Covance recognized \$0.1 million, representing its share of Noveprim's earnings, less an elimination of profit on inventory purchased from Noveprim Limited and still on hand at Covance at June 30, 2004.

Covance has a minority equity position (approximately 22% at June 30, 2004) in Bio-Imaging Technologies, Inc. ("BITI"). BITI uses proprietary medical imaging technologies to process and analyze medical images, and also provides other services, including the data-basing and regulatory submission of medical images, quantitative data and text. During the three and six month periods ended June 30, 2004, Covance recognized \$0.1 million and \$0.4 million, respectively, representing its share of BITI's earnings. During the three and six month periods ended June 30, 2003, Covance recognized \$0.1 million and \$0.2 million, respectively, representing its share of BITI's earnings. The carrying value of Covance's investment in BITI as of June 30, 2004 was \$0.8 million while the fair market value was \$10.8 million.

#### 5. Defined Benefit Plans

Covance sponsors various pension and other post-retirement benefit plans. During the first quarter of 2004, Covance adopted the interim disclosure provisions of SFAS No. 132 (revised 2003), *Employers' Disclosure About Pensions and Other Post-Retirement Benefits*. This statement requires the interim disclosures as shown below.

### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

## 5. Defined Benefit Plans (Continued)

#### **Defined Benefit Pension Plans**

Covance sponsors two defined benefit pension plans for the benefit of its employees at two United Kingdom subsidiaries and one defined benefit pension plan for the benefit of its employees at a German subsidiary, all of which are legacy plans of previously acquired companies. Benefit amounts for all three plans are based upon years of service and compensation. The German plan is unfunded while the UK plans are funded. Covance's funding policy has been to contribute annually a fixed percentage of the eligible employee's salary at least equal to the local statutory funding requirements. Pension plan assets are administered by the plans' trustees and are principally invested in equity and fixed income securities. The components of net periodic pension expense for these plans for the three and six month periods ended June 30, 2004 and 2003 are as follows:

	United K Plan		German Plan Three Months Ended June 30		
	Three M Ended J				
	2004	2003	2004	2003	
Components of Net Periodic Pension Cost:					
Service cost	\$ 1,167	\$1,050	\$ 72	\$ 63	
Interest cost	1,217	943	60	52	
Expected return on plan assets	(1,089)	(806)			
Amortization of net actuarial loss	281	296	1	2	
Participant contributions	(507)	(463)			
Net periodic pension cost	\$ 1,069	\$1,020	\$ 133	\$ 117	
Assumptions Used to Determine Nat Derivatio Dension Costs					
Assumptions Used to Determine Net Periodic Pension Cost: Discount rate	6.00%	6.00%	5.75%	5.75%	
Expected rate of return on assets	6.00%			n/a	
Salary increases	3.50%				
	United K Plan		Germa	n Plan	
	Six Mo Ended J		Six M Ended J		
	2004	2003	2004	2003	
Components of Net Periodic Pension Cost:					
Service cost	\$ 2,339	\$ 2,100	\$ 145	\$ 126	
Interest cost	2,439	1,886	121	104	
Expected return on plan assets	(2,183)	(1,612)			
Amortization of net actuarial loss	563	592	3	3	
Participant contributions	(1,017)	(926)			

Net periodic pension cost	\$ 2,141	\$ 2,040	\$ 269	\$ 239
Assumptions Used to Determine Net Periodic Pension Cost:				
Discount rate	6.00%	6.00%	5.75%	5.75%
Expected rate of return on assets	6.00%	6.00%	n/a	n/a
Salary increases	3.50%	3.50%	3.00%	3.00%

### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 5. Defined Benefit Plans (Continued)

#### Supplemental Executive Retirement Plan

In addition to these foreign defined benefit pension plans, Covance also has a non-qualified Supplemental Executive Retirement Plan ("SERP"). The SERP, which is not funded, is intended to provide retirement benefits for certain executive officers of Covance. Benefit amounts are based upon years of service and compensation of the participating employees. The components of net periodic pension cost for the three and six month periods ended June 30, 2004 and 2003 are as follows:

	Three Months Ended June 30		Six Month June	
	2004	2003	2004	2003
Components of Net Periodic Pension Cost:				
Service cost	\$ 237	\$ 141	\$ 474	\$ 282
Interest cost	131	98	262	196
Amortization of prior service cost	19		38	
Amortization of net actuarial loss	5	2	10	4
	—			
Net periodic pension cost	\$ 392	\$ 241	\$ 784	\$ 482
Assumptions Used to Determine Net Periodic				
Pension Cost:				
Discount rate	6.25%	6.75%	6.25%	6.75%
Salary increases	4.00%	4.50%	4.00%	4.50%

#### Post-Employment Retiree Health and Welfare Plan

Covance also sponsors a post-employment retiree health and welfare plan for the benefit of eligible employees at certain U.S. subsidiaries who retire after satisfying service and age requirements. This plan is funded on a pay-as-you-go basis and the cost of providing these benefits is shared with the retirees. The components of net periodic post-retirement benefits cost for the three and six month periods ended June 30, 2004 and 2003 are as follows:

	Three Months Ended June 30		Ended Six Months I	
	2004	2003	2004	2003
Components of Net Periodic Post-retirement Benefits Cost:				
Service cost	\$ 60	\$ 56	\$ 120	\$ 112
Interest cost	98	96	196	192
Amortization of prior service cost (benefit)	(98)	(99)	(196)	(198)
Amortization of net actuarial loss	50	45	100	90

Net periodic post-retirement benefits cost	\$ 110	\$ 98	\$ 220	\$ 196
Assumptions Used:				
Discount rate	6.25%	6.75%	6.25%	6.75%
Health care cost trend rate	9.00% (a)	$9.90\%_{(a)}$	$9.00\%_{(a)}$	$9.90\%_{(a)}$

(a)

decreasing to ultimate trend of 5.00% in 2009

#### COVANCE INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued) (UNAUDITED) June 30, 2004 and 2003 (dollars in thousands, unless otherwise indicated)

#### 6. Segment Information

Covance has two reportable segments: early development and late-stage development. Early development services, which includes Covance's preclinical and Phase I clinical service capabilities, involve evaluating a new compound for safety and early effectiveness as well as evaluating the absorption, distribution, metabolism and excretion of the compound in the human body. It is at this stage that a pharmaceutical company, based on available data, will generally decide whether to continue further development of a drug. Late-stage development services, which include Covance's central laboratory, clinical development, periapproval, central ECG diagnostic services, and healthcare economic and reimbursement services, are geared toward demonstrating the clinical effectiveness of a compound in treating certain diseases or conditions, obtaining regulatory approval and maximizing the drug's commercial potential.

The accounting policies of the reportable segments are the same as those described in Note 2. Segment net revenues, operating income and total assets for the three and six months ended June 30, 2004 and 2003 are as follows:

	Early Development	Late-Stage Development	Other Reconciling Items	Total
Three months ended June 30, 2004				
Total revenues from external				
customers	\$ 120,688	\$ 130,307	\$ 7,622 <sub>(a)</sub>	\$258,617
Operating income	\$ 27,915	\$ 19,508	\$(13,394) <sub>(b)</sub>	\$ 34,029
Total assets	\$ 426,125	\$ 341,815	\$ 76,081 (c)	\$844,021
Three months ended June 30, 2003				
Total revenues from external				
customers	\$ 98,693	\$ 135,145	\$ 8,507 (a)	\$242,345
Operating income	\$ 19,199	\$ 20,949	\$(11,992) <sub>(b)</sub>	\$ 28,156
Total assets	\$ 342,651	\$ 320,045	\$ 24,630 (c)	\$687,326
Six months ended June 30, 2004				
Total revenues from external				
customers	\$ 236,002	\$ 259,236	\$ 14,879 <sub>(a)</sub>	\$510,117
Operating income	\$ 54,831	\$ 37,960	\$(26,687) (b)	\$ 66,104
Total assets	\$ 426,125	\$ 341,815	\$ 76,081 (c)	\$844,021
Six months ended June 30, 2003				
Total revenues from external				
customers	\$ 198,688	\$ 268,546	\$ 18,160 <sub>(a)</sub>	\$485,394
Operating income	\$ 38,288	\$ 40,090	\$(22,625) <sub>(b)</sub>	\$ 55,753
Total assets	\$ 342,651	\$ 320,045	\$ 24,630 (c)	\$687,326

<sup>(</sup>a)

Represents revenues associated with reimbursable out-of-pocket expenses

Represents corporate expenses (primarily information technology, marketing, communications, human resources, finance and legal)

Represents corporate assets

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

You should read the following discussion together with the unaudited Covance consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.

#### Overview

Covance is a leading drug development services company providing a wide range of early stage and late-stage product development services on a worldwide basis primarily to the pharmaceutical, biotechnology and medical device industries. Covance also provides services such as laboratory testing to the chemical, agrochemical and food industries. The foregoing services comprise two reportable segments for financial reporting purposes: early development services, which includes preclinical and Phase I clinical; and late-stage development services, which includes central laboratory, clinical development, periapproval, central ECG diagnostic services, and healthcare economic and reimbursement services. Although each segment has separate services within it, they can be combined in joint service offerings and we believe clients increasingly are interested in opportunities for such combined services. Covance believes it is one of the largest drug development services designed to provide data to clients as rapidly as possible and reduce product development services. Covance offers its clients high quality services designed to provide data to clients as rapidly as possible and reduce product development time. We believe this enables Covance's customers to introduce their products into the marketplace faster and as a result, maximize the period of market exclusivity and monetary return on their research and development investments. Additionally, Covance's comprehensive services and broad experience provide its customers with a variable cost alternative to fixed cost internal development capabilities.

#### **Critical Accounting Policies**

Covance's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principals, which require management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from these estimates. The following discussion highlights what we believe to be the critical accounting policies and judgments made in the preparation of these consolidated financial statements.

*Revenue Recognition.* Covance recognizes revenue either as services are performed or products are delivered, depending upon the nature of the work contracted. Historically, a majority of Covance's net revenues have been earned under contracts which range in duration from a few months to two years, but can extend in duration up to five years or longer. Service contracts generally take the form of fee-for-service or fixed-price arrangements. In the case of fee-for-service contracts, revenue is recognized as services are performed, based upon, for example, hours worked or samples tested. For long-term fixed-price service contracts, revenue is recognized as services are performed, with performance generally assessed using output measures, such as units-of-work performed to date as compared to the total units-of-work contracted. Changes in the scope of work generally result in a renegotiation of contract pricing terms. Renegotiated amounts are not included in net revenues until earned and realization is assured. Estimates of costs to complete are made to provide, where appropriate, for losses expected on contracts. Costs are not deferred in anticipation of contracts being awarded, but instead are expensed as incurred. In some cases, for multi-year contracts, a portion of the contract fee is paid at the time the trial is initiated. These advances are deferred and recognized as revenue as services are performed, as discussed above. Additional payments may be made based upon the achievement of performance-based milestones over the contract duration. Most contracts are terminable by the client either immediately or upon notice. These contracts typically require payment to Covance of expenses to wind down the study, fees earned to date and, in some cases, a termination fee or a payment to Covance of some portion of the fees or profits that could have been earned by Covance under the contract if it had not been terminated early. Termination fees are included in net revenues when realization is assured.

**Bad Debts.** Covance endeavors to assess and monitor the creditworthiness of its customers to which it grants credit terms in the ordinary course of business. Covance maintains a provision for doubtful accounts to provide for the possibility that amounts due Covance may not be collected. This bad debt provision is monitored on a monthly basis and adjusted as circumstances warrant. Since the recorded bad debt provision is based upon management's judgment, actual bad debt write-offs may be greater or less than the amount recorded. Historically bad debt write-offs have not been material.

*Taxes on Income.* Since Covance conducts operations on a global basis, its effective tax rate has and will continue to depend upon the geographic distribution of its pre-tax earnings among locations with varying tax rates. Covance's profits are further impacted by changes in the tax rates of the various jurisdictions. In particular, as the geographic mix of Covance's pre-tax earnings among various tax jurisdictions changes, Covance's effective tax rate may vary from period to period. Covance has established, and periodically reevaluates, an estimated income tax reserve on its consolidated balance sheet to provide for the possibility of adverse outcomes in income tax proceedings. While Covance believes that it has identified all reasonably identifiable exposures and that the reserve it has established for identifiable exposures is appropriate under the circumstances, it is possible that additional exposures exist and that exposures will be settled at amounts different than the amounts reserved. It is possible that changes in estimates in the future could cause Covance to either materially increase or reduce the carrying amount of its income tax reserve. In addition, Covance's policy is to provide income taxes on earnings of foreign subsidiaries to the extent those earnings are taxable or are expected to be remitted. Taxes have not been provided on accumulated foreign unremitted earnings totaling \$127.0 million as of December 31, 2003 because Covance currently intends to leave these earnings invested in those countries. If Covance were to repatriate these earnings, or a portion of these earnings, Covance might incur a significant income tax liability.

*Stock Based Compensation.* Covance grants stock options to its employees at an exercise price equal to the fair value of the shares at the date of grant and accounts for these stock option grants in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock on the date of grant, no compensation expense is recognized in the income statement.

*Impairment of Assets.* Covance reviews its long-lived assets for impairment, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based upon Covance's judgment of its ability to recover the asset from the expected future undiscounted cash flows of the related operations. Actual future cash flows may be greater or less than estimated.

Covance performs an annual test for impairment of goodwill. This test is performed by comparing, at the reporting unit level, the carrying value of goodwill to its fair value. Covance assesses fair value based upon its best estimate of the present value of the future cash flows that it expects to be generated by the reporting unit. The test performed for 2003 did not identify any instances of impairment. However, changes in expectations as to the present value of the reporting unit's future cash flows might impact subsequent years' assessments of impairment.

*Defined Benefit Pension Plans.* Covance sponsors defined benefit pension plans for the benefit of its employees at three foreign subsidiaries. The measurement of the related pension benefit obligation and the expense recorded in each year is based upon actuarial computations which require judgment as to (a) the appropriate discount rate to use in computing the present value of the benefit obligation, (b) the expected return on plan assets and (c) the expected future rate of salary increases. Actual results will likely differ, in some periods materially, from the assumptions used in the actuarial valuation.

## **Foreign Currency Risks**

Since Covance operates on a global basis, it is exposed to various foreign currency risks. Two specific risks arise from the nature of the contracts Covance executes with its customers since from time to time contracts are denominated in a currency different than the particular Covance subsidiary's local currency. These risks are generally applicable only to a portion of the contracts executed by Covance's foreign subsidiaries providing clinical services. The first risk occurs as revenue recognized for services rendered is denominated in a currency different from the currency in which the subsidiary's expenses are incurred. As a result, the subsidiary's net revenues and resultant earnings can be affected by fluctuations in exchange rates. Historically, fluctuations in exchange rates from those in effect at the time contracts were executed have not had a material effect upon Covance's consolidated financial results. See "Risk Factors".

The second risk results from the passage of time between the invoicing of customers under these contracts and the ultimate collection of customer payments against such invoices. Because the contract is denominated in a currency other than the subsidiary's local currency, Covance recognizes a receivable at the time of invoicing for the local currency equivalent of the foreign currency invoice amount. Changes in exchange rates from the time the invoice is prepared and payment from the customer is received will result in Covance receiving either more or less in local currency than the local currency equivalent of the invoice amount at the time the invoice was prepared and the receivable established. This difference is recognized by Covance as a foreign currency transaction gain or loss, as applicable, and is reported in other expense (income) in Covance's Consolidated Statements of Income.

Finally, Covance's consolidated financial statements are denominated in U.S. dollars. Accordingly, changes in exchange rates between the applicable foreign currency and the U.S. dollar will affect the translation of each foreign subsidiary's financial results into U.S. dollars for purposes of reporting Covance's consolidated financial results. The process by which each foreign subsidiary's financial results are translated into U.S. dollars is as follows: income statement accounts are translated at average exchange rates for the period; balance sheet asset and liability accounts are translated at end of period exchange rates; and equity accounts are translated at historical exchange rates. Translation of the balance sheet in this manner affects the stockholders' equity account, referred to as the cumulative translation adjustment account. This account exists only in the foreign subsidiary's U.S. dollar balance sheet and is necessary to keep the foreign balance sheet stated in U.S. dollars in balance.

#### **Operating Expenses and Reimbursable Out-of-Pockets**

Covance segregates its recurring operating expenses among four categories: cost of revenue; reimbursed out-of-pocket expenses; selling, general and administrative expenses; and depreciation and amortization. Cost of revenue includes direct labor and related benefits, other direct costs, shipping and handling fees, and an allocation of facility charges and information technology costs, and excludes depreciation and amortization. Cost of revenue, as a percentage of net revenues, tends and is expected to fluctuate from one period to another, as a result of changes in labor utilization and the mix of service offerings involving hundreds of studies conducted during any period of time. Selling, general and administrative expenses consist primarily of administrative payroll and related benefit charges, advertising and promotional expenses, administrative travel and an allocation of facility charges and information technology costs, and excludes depreciation.

In connection with the management of multi-site clinical trials, Covance pays on behalf of its customers fees to investigators, volunteers and other out-of-pocket costs (such as for travel, printing, meetings, couriers, etc.), for which it is reimbursed at cost, without mark-up or profit. Investigator fees are not reflected in total revenues or expenses where Covance acts in the capacity of an agent on behalf of the pharmaceutical company sponsor, passing through these costs without risk or reward to Covance. All other out-of-pocket costs are included in total revenues and expenses.

#### **Quarterly Results**

Covance's quarterly operating results are subject to variation, and are expected to continue to be subject to variation, as a result of factors such as (1) delays in initiating or completing significant drug development trials, (2) termination or reduction in size of drug development trials, (3) acquisitions and divestitures, and (4) exchange rate fluctuations. Delays and terminations of trials are often the result of actions taken by Covance's customers or regulatory authorities and are not typically controllable by Covance. Since a large amount of Covance's operating costs are relatively fixed while revenue is subject to fluctuation, moderate variations in the commencement, progress or completion of drug development trials may cause significant variations in quarterly results.

#### **Results of Operations**

*Three Months Ended June 30, 2004 Compared with Three Months Ended June 30, 2003.* Net revenues increased 7.3% to \$251.0 million for the three months ended June 30, 2004 from \$233.8 million for the corresponding 2003 period. Excluding the impact of foreign exchange rate variances between both periods net revenues increased 4.9% as compared to the corresponding 2003 period. Net revenues from Covance's early development segment grew 22.3%, or 18.4% excluding the impact of foreign exchange rate variances between both periods to xicology, chemistry and North American Phase I services. Net revenues from Covance's late-stage development segment decreased 3.6%, or 5.0% excluding the impact of foreign exchange rate variances between both periods. Growth in our late-stage development segment continued to be negatively impacted by reduced testing volumes in our central laboratory service offering due to low order volume in the first half of 2003.

Cost of revenue increased 6.0% to \$167.1 million or 66.6% of net revenues for the three months ended June 30, 2004 as compared to \$157.7 million or 67.4% of net revenues for the corresponding 2003 period. Gross margins improved 80 basis points to 33.4% for the three months ended June 30, 2004 from 32.6% for the corresponding 2003 period on process improvements and cost controls, especially across most of our early development service offerings.

Overall, selling, general and administrative expenses increased 5.1% to \$38.4 million for the three months ended June 30, 2004 from \$36.5 million for the corresponding 2003 period. As a percentage of net revenues, selling, general and administrative expenses decreased 30 basis points to 15.3% for the three month period ended June 30, 2004 from 15.6% for the corresponding 2003 period.

Depreciation and amortization was \$11.5 million for each of the three month periods ended June 30, 2004 and 2003, or 4.6% and 4.9% of net revenues for the corresponding 2004 and 2003 periods, respectively.

Income from operations increased 20.9% to \$34.0 million or 13.6% of net revenues for the three months ended June 30, 2004 from \$28.2 million or 12.0% of net revenues for the corresponding 2003 period. Income from operations from Covance's early development segment increased \$8.7 million or 45.4% to \$27.9 million or 23.1% of net revenues for the three months ended June 30, 2004 from \$19.2 million or 19.5% of net revenues for the corresponding 2003 period, primarily driven by strong performance in our global toxicology, chemistry and North American Phase I services. Income from operations from Covance's late-stage development segment decreased \$1.4 million or 6.9% to \$19.5 million or 15.0% of net revenues for the three months ended June 30, 2004 from \$20.9 million or 15.5% of net revenues for the corresponding 2003 period, primarily driven by strong performance in our global toxicology, chemistry and North American Phase I services. Income from operations from Covance's late-stage development segment decreased \$1.4 million or 6.9% to \$19.5 million or 15.0% of net revenues for the three months ended June 30, 2004 from \$20.9 million or 15.5% of net revenues for the corresponding 2003 period. Late-stage development operating income continued to be negatively impacted by reduced testing volumes in our central laboratory service offering resulting from low order volume in the first half of 2003. Corporate expenses increased \$1.4 million to \$13.4 million or 5.3% of net revenues for the three months ended June 30, 2004 from \$12.0 million or 5.1% of net revenues for the three months ended June 30, 2004 from \$12.0 million or 5.1% of net revenues for the three months ended June 30, 2003. The increase is primarily attributable to increased centralized information technology costs.

Covance's effective tax rate for the three months ended June 30, 2004 was 32.0% compared to 35.2% for the corresponding 2003 period. The year over year 320 basis point reduction in Covance's effective tax rate is attributable to a number of factors, including the mix of our pre-tax earnings across various tax jurisdictions, recently enacted research and development tax credits in the United Kingdom, and other planning measures.

Covance has a minority equity position (approximately 22% at June 30, 2004) in Bio-Imaging Technologies, Inc. ("BITI"). BITI uses proprietary medical imaging technologies to process and analyze medical images, and also provides other services, including the data-basing and regulatory submission of medical images, quantitative data and text. During each of the three month periods ended June 30, 2004 and 2003, Covance recognized \$0.1 million, representing its share of BITI's earnings.

In March 2004, Covance acquired a 47% minority equity position in Noveprim Limited, an existing supplier of research products. Covance began recognizing earnings from this investment in the second quarter of 2004. For the three month period ended June 30, 2004, Covance recognized \$0.1 million, representing its share of Noveprim's earnings, less an elimination of profit on inventory purchased from Noveprim Limited and still on hand at Covance at June 30, 2004.

Net income of \$23.3 million for the three months ended June 30, 2004 increased \$5.0 million or 27.6% as compared to \$18.3 million for the corresponding 2003 period.

*Six Months Ended June 30, 2004 Compared with Six Months Ended June 30, 2003.* Net revenues increased 6.0% to \$495.2 million for the six months ended June 30, 2004 from \$467.2 million for the corresponding 2003 period. Excluding the impact of foreign exchange rate variances between both periods, net revenues increased 2.9% as compared to the corresponding 2003 period. Net revenues from Covance's early development segment grew 18.8%, or 14.2% excluding the impact of foreign exchange rate variances between both periods, primarily on strong performance in our global toxicology, chemistry and North American Phase I services. Net revenues from Covance's late-stage development segment decreased 3.5%, or 5.4% excluding the impact of foreign exchange rate variances between both periods. Growth in our late-stage development segment was negatively impacted by reduced testing volumes in our central laboratory service offering due to low order volume in the first half of 2003.

Cost of revenue increased 3.1% to \$328.7 million or 66.4% of net revenues for the six months ended June 30, 2004 as compared to \$318.7 million or 68.2% of net revenues for the corresponding 2003 period. Gross margins improved 180 basis points to 33.6% for the six months ended June 30, 2004 from 31.8% for the corresponding 2003 period primarily, on process improvements and cost controls, especially across most of our early development service offerings.

Overall, selling, general and administrative expenses increased 10.1% to \$77.2 million for the six months ended June 30, 2004 from \$70.1 million for the corresponding 2003 period. As a percentage of net revenues, selling, general and administrative expenses increased 60 basis points to 15.6% for the six months ended June 30, 2004 from 15.0% for the corresponding 2003 period.

Depreciation and amortization increased 2.6% to \$23.2 million or 4.7% of net revenues for the six months ended June 30, 2004 from \$22.6 million or 4.8% of net revenues for the corresponding 2003 period.

Income from operations increased 18.6% to \$66.1 million or 13.3% of net revenues for the six months ended June 30, 2004 from \$55.8 million or 11.9% of net revenues for the corresponding 2003 period. Income from operations from Covance's early development segment increased \$16.5 million or 43.2% to \$54.8 million or 23.2% of net revenues for the six months ended June 30, 2004 from \$38.3 million or 19.3% of net revenues for the corresponding 2003 period, primarily driven by strong performance in our global toxicology, chemistry and North American Phase I services. Income from operations from Covance's late-stage development segment decreased \$2.1 million or 5.3% to \$38.0 million or 14.6% of net revenues for the six months ended June 30, 2004 from \$40.1 million or 14.9% of net revenues for the corresponding 2003 period, primarily due to reduced testing volumes in our central laboratory service offering resulting from low order volume in the first half of 2003. Corporate expenses increased \$4.1 million to \$26.7 million or 5.4% of net revenues for the six months ended June 30, 2004 from \$2003. Corporate expenses for the six months ended June 30, 2003. The increase is primarily attributable to increased centralized information technology and human resources costs and increased spending in sales and marketing, finance, legal and resource management.

Other income, net increased \$0.5 million to \$0.3 million for the six months ended June 30, 2004 from net expense of \$0.2 million for the corresponding 2003 period. This increase is the result of a \$0.9 million increase in net interest income due primarily to higher invested cash balances, partially offset by a \$0.4 million increase in foreign exchange losses due to the weakening of the U.S. dollar during the six months ended June 30, 2004.

Covance's effective tax rate for the six months ended June 30, 2004 was 32.2% compared to 35.3% for the corresponding 2003 period. The 310 basis point reduction in Covance's effective tax rate year over year is attributable to a number of factors, including the mix of our pre-tax earnings across various tax jurisdictions, recently enacted research and development tax credits in the United Kingdom, and other initiatives.

Covance has a minority equity position (approximately 22% at June 30, 2004) in Bio-Imaging Technologies, Inc. ("BITI"). BITI uses proprietary medical imaging technologies to process and analyze medical images, and also provides other services, including the data-basing and regulatory submission of medical images, quantitative data and text. During the six month period ended June 30, 2004, Covance recognized \$0.4 million, representing its share of BITI's earnings, as compared to \$0.2 million for the corresponding 2003 period.

In March 2004, Covance acquired a 47% minority equity position in Noveprim Limited, an existing supplier of research products. Covance began recognizing earnings from this investment in the second quarter of 2004. For the three month period ended June 30, 2004, Covance recognized \$0.1 million, representing its share of Noveprim's earnings, less an elimination of profit on inventory purchased from Noveprim Limited and still on hand at Covance at June 30, 2004.

Net income of \$45.5 million for the six months ended June 30, 2004 increased \$9.3 million or 25.7% as compared to \$36.2 million for the corresponding 2003 period.

## Liquidity and Capital Resources

Covance's expected primary cash needs on both a short and long-term basis are for capital expenditures, expansion of services, possible future acquisitions, geographic expansion, working capital and other general corporate purposes, including possible share repurchases. On June 30, 2004, Covance entered into a new \$75.0 million revolving credit facility which expires in June 2009. Covance believes cash from operations and available borrowings under its new credit facility will provide sufficient liquidity for the foreseeable future. At June 30, 2004, there were no outstanding borrowings and no outstanding letters of credit under the new credit facility. Interest on all outstanding borrowings under the new credit facility is based upon the London Interbank Offered Rate ("LIBOR") plus a 75 basis point margin. Costs associated with the new credit facility consisted primarily of bank and legal fees totaling \$0.4 million which will be amortized over the five year facility term. The new credit facility contains various financial and other covenants. The new credit facility is collateralized by guarantees of

certain of Covance's domestic subsidiaries and a pledge of 65 percent of the capital stock of certain of Covance's foreign subsidiaries. A commitment fee of 15 basis points on the undrawn balance of the new credit facility will be payable in arrears on the first day of each July, October, January and April, beginning in October 2004.

During the six months ended June 30, 2004, Covance's operations provided net cash of \$53.4 million, an increase of \$33.9 million from the corresponding 2003 period. The change in net operating assets used \$19.5 million in cash during the six months ended June 30, 2004, primarily due to a reduction in unearned revenue and an increase in unbilled services, while this net change used \$50.3 million in cash during the six months ended June 30, 2003, primarily due to a reduction in accrued liabilities (primarily from the payment of 2002 bonuses in the first quarter of 2003) and unearned revenue. Covance's ratio of current assets to current liabilities was 2.43 at June 30, 2004 and 2.37 at December 31, 2003.

Investing activities for the six months ended June 30, 2004 used \$44.0 million, compared to using \$20.4 million for the corresponding 2003 period. Capital spending for the first six months of 2004 totaled \$23.3 million, and was primarily for the outfitting of new facilities, purchase of new equipment, upgrade of existing equipment and computer equipment and software for newly hired employees. Investment activities for the six months ended June 30, 2004 also include a 47% equity investment in Noveprim Limited, an existing supplier of research products, totaling \$20.7 million. Capital spending for the corresponding 2003 period totaled \$20.4 million, and was primarily for the expansion and enhancement of our Harrogate, England facility, outfitting of new facilities, purchase of new equipment, upgrade of existing equipment and computer equipment and software for newly hired employees.

Financing activities for the six months ended June 30, 2004 used \$29.5 million and consisted primarily of the purchase of 2,095,000 shares of Covance common stock for an aggregate cost of \$70.1 million, primarily in connection with a 3.0 million share buyback program authorized by Covance's Board of Directors in February 2003, partially offset by \$40.6 million received from stock option exercises and employee contributions to Covance's noncompensatory employee stock purchase plan. Financing activities for the six months ended June 30, 2003 provided \$1.0 million, and consisted primarily of \$14.9 million received from stock option exercises and employee contributions to Covance's noncompensatory employee stock purchase plan, partially offset by the purchase of 649,700 shares of Covance common stock for an aggregate cost of \$13.9 million, primarily in connection with a 3.0 million share buyback program authorized by Covance's Board of Directors in February 2003.

In June 2004, Covance's Board of Directors authorized the repurchase of up to 3.0 million additional shares of Covance common stock. At June 30, 2004, there are also 264,700 shares remaining for repurchase under the 2003 Board approved repurchase program.

### Inflation

While most of Covance's net revenues are earned under contracts, the long-term contracts (those in excess of one year) generally include an inflation or cost of living adjustment for the portion of the services to be performed beyond one year from the contract date. As a result, Covance believes that the effects of inflation generally do not have a material adverse effect on its operations or financial condition.

Forward Looking Statements. Statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as in certain other parts of this Quarterly Report on Form 10-Q that look forward in time, are forward looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward looking statements include statements concerning plans, objectives, goals, strategies, future events or performance, expectations, predictions, and assumptions and other statements which are other than statements of historical facts. All such forward looking statements are based on the current expectations of management and are subject to, and are qualified by, risks and uncertainties that could cause actual results to differ materially from those expressed or implied by those statements. These risks and uncertainties include, without limitation, competitive factors, outsourcing trends in the pharmaceutical industry, levels of industry research and development spending, the Company's ability to continue to attract and retain qualified personnel, the fixed price nature of contracts or the loss of large contracts, risks associated with acquisitions and investments, the Company's ability to increase order volume in clinical development services and central laboratory and commercialization services, and other factors described in Covance's filings with the Securities and Exchange Commission, including, its Annual Report on Form 10-K.

## **Risk Factors**

This section discusses various risk factors that are attendant with our business and the provision of our services. If the events outlined below were to occur individually or in the aggregate, our business, results of operations, financial condition, and cash flows could be materially adversely affected.

# Changes in government regulation or in practices relating to the pharmaceutical industry could decrease the need for the services we provide.

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies navigate the regulatory drug approval process. Changes in regulation, such as a relaxation in regulatory requirements or the introduction of simplified drug approval procedures or an increase in regulatory requirements that we have difficulty satisfying, could eliminate or substantially reduce the need for our services. Also, if government efforts to contain drug costs and pharmaceutical and biotechnology company profits from new drugs, our customers may spend less, or reduce their growth in spending, on research and development. If health insurers were to change their practices with respect to reimbursements for pharmaceutical products, our customers may spend less, or reduce their growth in spending on research and development.

#### Failure to comply with existing regulations could result in a loss of revenue or earnings or in increased costs.

Any failure on our part to comply with applicable regulations could result in the termination of on-going research or the disqualification of data for submission to regulatory authorities. For example, if we were to fail to verify that patient participants were fully informed and have fully consented to a particular clinical trial, the data collected from that trial could be disqualified. If this were to happen, we could be contractually required to repeat the trial at no further cost to our customer, but at substantial cost to us.

# We may bear financial losses because most of our contracts are of a fixed price nature and may be delayed or terminated or reduced in scope for reasons beyond our control.

Many of our contracts provide for services on a fixed price or fee-for-service with a cap basis and they may be terminated or reduced in scope either immediately or upon notice. Cancellations may occur for a variety of reasons, including:

the failure of products to satisfy safety requirements;

unexpected or undesired results of the products;

insufficient patient enrollment;

insufficient investigator recruitment;

the client's decision to terminate the development of a product or to end a particular study; and

our failure to perform properly our duties under the contract.

The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts frequently entitle us to receive the costs of winding down the terminated projects, as well as all fees earned by us up to the time of termination. Some contracts also entitle us to a termination fee.

#### We may bear financial risk if we under price our contracts or overrun cost estimates.

Since our contracts are often structured as fixed price or fee-for-service with a cap, we bear the financial risk if we initially under price our contracts or otherwise overrun our cost estimates. Such under pricing or significant cost overruns could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

#### We may not be able to successfully develop and market new services.

We may seek to develop and market new services that complement or expand our existing business or expand our service offerings through acquisition. If we are unable to develop new services and/or create demand for those newly developed services, or expand our service offerings through acquisition, our future business, results of operations, financial condition, and cash flows could be adversely affected.

#### Our quarterly operating results may vary.

Our operating results may vary significantly from quarter to quarter and are influenced by such factors over which we have little control such as:

exchange rate fluctuations;

the commencement, completion or cancellation of large contracts;

the progress of ongoing contracts;

the timing of and charges associated with completed acquisitions or other events; and

changes in the mix of our services.

We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. While fluctuations in our quarterly operating results could negatively or positively affect the market price of our common stock, these fluctuations may not be related to our future overall operating performance.

#### We depend on the pharmaceutical and biotechnology industries.

Our revenues depend greatly on the expenditures made by the pharmaceutical and biotechnology industries in research and development. Accordingly, economic factors and industry trends that affect our clients in these industries also affect our business. If companies in these industries were to reduce the number of research and development projects they outsource, our business could be materially adversely affected.

#### We operate in a highly competitive industry.

Competitors in the contract research organization industry range from small, limited-service providers to full service global contract research organizations. Our main competition consists of in-house departments of pharmaceutical companies, full-service contract research organizations, and universities and teaching hospitals, although to a lesser degree. We compete on a variety of factors, including:

reputation for on-time quality performance; expertise and experience in specific areas; scope of service offerings; strengths in various geographic markets; price; technological expertise and efficient drug development processes; ability to acquire, process, analyze and report data in an accurate manner; ability to manage large-scale clinical trials both domestically and internationally; expertise and experience in health economics and outcomes services; and

size.

For instance, our clinical development services have from time to time experienced periods of increased price competition which had a material adverse effect on Covance's late-stage development profitability and consolidated net revenues and net income. Covance took actions in 2000 to mitigate the effects of this price competition; however, if market conditions were to deteriorate, additional actions might be required in the future.

There is competition among the larger contract research organizations for both clients and potential acquisition candidates. Additionally, small, limited-service entities considering entering the contract research organization industry will find few barriers to entry, thus further

increasing possible competition. These competitive pressures may affect the attractiveness of our services and could adversely affect our financial results.

#### We may expand our business through acquisitions.

We review many acquisition candidates and, in addition to acquisitions which we have already made, we are continually evaluating new acquisition opportunities. Factors which may affect our ability to grow successfully through acquisitions include:

difficulties and expenses in connection with integrating the acquired company and achieving the expected benefits;

diversion of management's attention from current operations;

the possibility that we may be adversely affected by risk factors facing the acquired companies;

acquisitions could be dilutive to earnings, or in the event of acquisitions made through the issuance of our common stock to the shareholders of the acquired company, dilutive to the percentage of ownership of our existing stockholders;

potential losses resulting from undiscovered liabilities of acquired companies not covered by the indemnification we may obtain from the seller;

risks of not being able to overcome differences in foreign business practices, language and other cultural barriers in connection with the acquisition of foreign companies; and

loss of key employees of the acquired company.

#### We may be affected by potential health care reform.

In recent years the United States Congress and state legislatures have considered various types of health care reform in order to control growing health care costs. We are unable to predict what legislative proposals will be adopted in the future, if any. Similar reform movements have occurred in Europe and Asia.

Implementation of health care reform legislation that contain costs could limit the profits that can be made from the development of new drugs. This could adversely affect research and development expenditures by pharmaceutical and biotechnology companies which could in turn decrease the business opportunities available to us both in the United States and abroad. In addition, new laws or regulations may create a risk of liability, increase our costs or limit our service offerings.

#### We rely on third parties for important services.

We depend on third parties to provide us with services critical to our business. For instance, we have entered into an agreement with IBM to manage our information technology infrastructure including our computer and telephone network, e-mail system, help desks, computer support and data centers worldwide. The failure of any of these third parties to adequately provide the needed services could have a material adverse effect on our business.

#### Our revenues and earnings are exposed to exchange rate fluctuations.

We derive a large portion of our net revenues from international operations. In the six month period ended June 30, 2004, we derived approximately 35% of our net revenues from outside the United States. Our financial statements are denominated in U.S. dollars. As a result, factors associated with international operations, including changes in foreign currency exchange rates, could significantly affect our results of operations, financial condition, and cash flows.

#### The loss of our key personnel could adversely affect our business.

Our success depends to a significant extent upon the efforts of our senior management team and other key personnel. The loss of the services of such personnel could adversely affect our business. Also, because of the nature of our business, our success is dependent upon our ability to attract and retain technologically qualified personnel. There is substantial competition for qualified personnel, and an inability to recruit or retain qualified personnel may impact our ability to grow our business and compete effectively in our industry.

#### Contract research services create a risk of liability.

In contracting to work on drug development trials, we face a range of potential liabilities. For example:

errors or omissions that create harm during a trial to study volunteers or after a trial to consumers of the drug after regulatory approval of the drug;

general risks associated with our Phase I facilities, including negative consequences from the administration of drugs to clinical trial participants or the professional malpractice of Phase I medical care providers;

errors or omissions from tests conducted for the agrochemical and food industries;

risks that animals in breeding facilities may be infected with diseases that may be harmful and even lethal to themselves and humans despite preventive measures contained in our company policies for the quarantine and handling of imported animals; and

errors and omissions during a trial that may undermine the usefulness of a trial or data from the trial.

We also contract with physicians, also referred to as investigators, to conduct the clinical trials to test new drugs on human volunteers. These tests can create a risk of liability for personal injury or death to volunteers, resulting from negative reactions to the drugs administered or from professional malpractice by third party investigators, particularly to volunteers with life-threatening illnesses. We believe that our risks in this area are generally reduced by the following:

contract provisions entitling us to be indemnified or entitling us to a limitation of liability;

insurance maintained by our clients, investigators, and by us; and

various regulatory requirements we must follow in connection with our business.

Contractual indemnifications generally do not protect us against liability arising from certain of our own actions, such as negligence or misconduct. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim which is not covered by a contractual indemnification provision or in the event that a party who must indemnify us does not fulfill its indemnification obligations or which is beyond the level of our insurance coverage. There can be no assurance that we will be able to maintain such insurance coverage on terms acceptable to us.

## Reliance on air transportation.

Our central laboratories and, to a lesser extent, our other businesses, are heavily reliant on air travel for transport of clinical trial kits and other material and people, and a significant disruption to the air travel system could have a material adverse effect on our business.

#### Actions of animal rights extremists may affect our business.

Our early development services utilize animals (predominantly rodents) in preclinical testing of the safety and efficacy of drugs and also breed and sell animals for biomedical research. Such activities are required for the development of new medicines and medical devices under regulatory regimes in the United States, Europe, Japan and other countries. Acts of vandalism and other acts by animal rights extremists who object to the use of animals in drug development could have a material adverse effect on our business.

# Our animal populations may suffer diseases that can damage our inventory, harm our reputation and result in decreased sales of research products.

It is important that our research products be free of diseases, including infectious diseases. The presence of diseases can distort or compromise the quality of research results, can cause loss of animals in our inventory or other losses. Such results could harm our reputation or have a material adverse effect on our financial condition, results of operations, and cash flows.

## Item 3. Quantitative and Qualitative Disclosure About Market Risk

For the six months ended June 30, 2004, approximately 35% of our net revenues were derived from our operations outside the United States. We do not engage in derivative or hedging activities related to our potential foreign exchange exposures. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Estimates Foreign Currency Risks" for a more detailed discussion of our foreign currency risks and exposures.

## **Item 4. Controls and Procedures**

Evaluation of disclosure controls and procedures. The Company's Principal Executive Officer and Principal Financial Officer have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, the Principal Executive Officer and the Principal Financial Officer have concluded that the Company's current disclosure controls and procedures are effective. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect those controls.

## Part II. Other Information

#### Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

Repurchases of equity securities as reported on a settlement date basis during the quarter ended June 30, 2004 were as follows:

## **Issuer Purchases of Equity Securities**<sup>(a)(b)</sup>:

Period	Total # of Shares Purchased	Average Price Paid Per Share	Total # of Shares Purchased as Part of Currently Authorized Programs	Maximum # of Shares that May Yet Be Purchased Currently Under Authorized Programs
April 1, 2004 April 30, 2004	84,000	\$34.4671	1,905,300	1,094,700 (a)
May 1, 2004 May 31, 2004	830,000	\$34.6847	2,735,300	264,700 <sub>(a)</sub>
June 1, 2004 June 30, 2004			2,735,300	3,264,700 <sub>(b)</sub>

(a)

On February 27, 2003, the Company announced that its Board of Directors had approved the repurchase of up to three million shares of common stock.

(b)

On June 28, 2004, the Company announced that its Board of Directors had approved the repurchase of up to an additional three million shares of common stock.

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

The Annual Meeting of Stockholders of Covance was held on April 29, 2004, pursuant to notice.

Two directors were reelected to the Board of Directors with the following votes cast: Robert M. Baylis received 34,850,129 votes for and 21,016,311 votes were withheld; Irwin Lerner received 33,773,714 votes for and 22,092,726 votes were withheld. The following directors' terms of office as a director continued after the meeting: Robert Barchi, Sandra L. Helton, Christopher A. Kuebler, J. Randall McDonald, Kathleen G. Murray and William C. Ughetta.

In addition, a shareholder proposal seeking to require the annual election of all members of the Board of Directors received 40,388,789 votes for, 10,542,742 votes against, 271,282 votes abstained and 4,663,627 broker non-votes.

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

(a)

Exhibits

10.1Letter Agreement between Covance Inc. and Wendel Barr dated as of February 25, 2004.*Filed herewith.* 

10.2

Letter Agreement between Covance Laboratories Limited and Anthony Cork dated as of February 25, 2004. *Filed herewith.* 

- 10.3 Credit Agreement among Covance Inc., PNC Bank, National Association, as agent, and the banks named therein dated as of June 30, 2004. *Filed herewith*.
- 31.1 Certification Christopher A. Kuebler*Filed herewith*.
- 31.2 Certification William E. Klitgaard*Filed herewith*.
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 Christopher A. Kuebler*Filed herewith.*
- 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 William E. Klitgaard*Filed herewith.*

(b)

## Reports on Form 8-K

During the three month period ended June 30, 2004, one report on Form 8-K was filed. The report dated April 22, 2004, was filed reporting the issuance of a press release on April 21, 2004 announcing Covance's financial results for the quarter ended March 31, 2004.

## 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.

## COVANCE INC.

Dated: July 23, 2004

By: /s/ CHRISTOPHER A. KUEBLER

Christopher A. Kuebler Chairman of the Board and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHRISTOPHER A. KUEBLER	Chairman of the Board and Chief Executive Officer	July 23, 2004
Christopher A. Kuebler	(Principal Executive Officer)	
/s/ WILLIAM E. KLITGAARD	Corporate Senior Vice President and Chief Financial Officer	July 23, 2004
William E. Klitgaard	(Principal Financial Officer)	
/s/ MICHAEL GIANNETTO	Corporate Vice President and Controller (Principal Accounting Officer)	July 23, 2004
Michael Giannetto		

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