

BIO IMAGING TECHNOLOGIES INC

Form 10QSB

November 12, 2004

Table of Contents

United States

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

(Mark One)

Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2004

Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 1-11182

BIO-IMAGING TECHNOLOGIES, INC.

(Exact Name of Small Business Issuer as Specified in Its Charter)

Delaware

11-2872047

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10QSB

(State or Other Jurisdiction of

(I.R.S. Employer

Incorporation or Organization)

Identification No.)

826 Newtown-Yardley Road, Newtown, Pennsylvania 18940-1721

(Address of Principal Executive Offices)

(267) 757-3000

(Issuer's Telephone Number,

Including Area Code)

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

State the number of shares outstanding of each of the Issuer's classes of common stock, as of October 31, 2004:

<u>Class</u>	<u>Number of Shares</u>
Common Stock, \$0.00025 par value	10,835,217

Transitional Small Business Disclosure Format (check one): Yes: No:

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

	<u>Page</u>
PART I. <u>FINANCIAL INFORMATION.</u>	
Item 1. <u>Financial Statements</u>	1
<u>CONSOLIDATED BALANCE SHEETS as of September 30, 2004 and December 31, 2003 (unaudited)</u>	2
<u>CONSOLIDATED STATEMENTS OF INCOME For the Nine Months Ended September 30, 2004 and 2003 (unaudited)</u>	3
<u>CONSOLIDATED STATEMENTS OF INCOME For the Three Months Ended September 30, 2004 and 2003 (unaudited)</u>	4
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS For the Nine Months Ended September 30, 2004 and 2003 (unaudited)</u>	5
<u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Results of Operations</u>	16
<u>Business Segments</u>	22
<u>Liquidity and Capital Resources</u>	22
<u>Changes to Critical Accounting Policies and Estimates</u>	24
Item 3. <u>Controls and Procedures</u>	25
PART II. <u>OTHER INFORMATION.</u>	
Item 6. <u>Exhibits</u>	26
<u>SIGNATURES</u>	27

Table of Contents

PART I. FINANCIAL INFORMATION.

Item 1. Financial Statements.

References in this Form 10-QSB to Bio-Imaging, we, us, or our refer to Bio-Imaging Technologies, Inc., a Delaware corporation, and its subsidiaries.

Certain information and footnote disclosures required under generally accepted accounting principles in the United States of America have been condensed or omitted from the following consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission, although we believe that such financial disclosures are adequate so that the information presented is not misleading in any material respect. The following consolidated financial statements should be read in conjunction with the year-end consolidated financial statements and notes thereto included in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003.

The results of operations for the interim periods presented in this Form 10-QSB are not necessarily indicative of the results to be expected for the entire fiscal year.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

(unaudited)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,400,922	\$ 13,289,453
Accounts receivable, net	6,991,756	4,429,117
Prepaid expenses and other current assets	992,593	573,978
Deferred income taxes	1,028,837	1,613,498
Total current assets	21,414,108	19,906,046
Property and equipment, net	4,718,846	4,661,720
Other assets	1,113,030	1,338,848
Total assets	\$ 27,245,984	\$ 25,906,614
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,095,686	\$ 984,997
Accrued expenses and other current liabilities	1,157,387	1,602,806
Deferred revenue	3,273,750	3,070,359
Current maturities of capital lease obligations and convertible note	1,312,229	1,281,997
Total current liabilities	6,839,052	6,940,159
Long-term capital lease obligations	800,730	770,702
Deferred income taxes	661,019	661,018
Other liability	126,822	108,347
Total liabilities	8,427,623	8,480,226
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock - \$.00025 par value; authorized 3,000,000 shares, 0 issued and outstanding at September 30, 2004 and at December 31, 2003		
Common stock - \$.00025 par value; authorized 18,000,000 shares, issued and outstanding 10,826,967 shares at September 30, 2004 and 10,710,481 shares at December 31, 2003	2,707	2,678
Additional paid-in capital	21,024,254	20,873,968
Accumulated deficit	(2,208,600)	(3,450,258)
Stockholders' equity	18,818,361	17,426,388
Total liabilities and stockholders' equity	\$ 27,245,984	\$ 25,906,614

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME**

(unaudited)

	For the Nine Months Ended September 30,	
	2004	2003
Service revenues	\$ 18,987,530	\$ 15,922,710
Reimbursement revenues	2,558,697	2,289,141
Total revenues	21,546,227	18,211,851
Cost and expenses:		
Cost of revenues	13,916,942	12,246,484
General and administrative expenses	3,284,646	2,937,716
Sales and marketing expenses	2,262,938	1,501,868
Total cost and expenses	19,464,526	16,686,068
Income from operations	2,081,701	1,525,783
Interest income (expense) - net	6,289	(101,409)
Income before income tax provision	2,087,990	1,424,374
Income tax provision	846,332	296,412
Net income	\$ 1,241,658	\$ 1,127,962
Basic earnings per common share	\$ 0.12	\$ 0.13
Weighted average number of common shares	10,789,760	8,805,713
Diluted earnings per common share	\$ 0.10	\$ 0.11
Weighted average number of common shares and dilutive common equivalent shares	12,256,529	10,309,348

See Notes to Consolidated Financial Statements

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME**

(unaudited)

	For the Three Months Ended September 30,	
	2004	2003
Service revenues	\$ 6,547,281	\$ 5,462,240
Reimbursement revenues	1,019,743	875,709
Total revenues	7,567,024	6,337,949
Cost and expenses:		
Cost of revenues	5,020,102	4,170,449
General and administrative expenses	1,067,226	1,026,504
Sales and marketing expenses	759,456	520,669
Total cost and expenses	6,846,784	5,717,622
Income from operations	720,240	620,327
Interest expense - net	2,664	31,036
Income before income tax provision	717,576	589,291
Income tax provision	287,784	62,417
Net income	\$ 429,792	\$ 526,874
Basic earnings per common share	\$ 0.04	\$ 0.06
Weighted average number of common shares	10,824,041	9,132,327
Diluted earnings per common share	\$ 0.04	\$ 0.05
Weighted average number of common shares and dilutive common equivalent shares	12,154,820	10,782,284

See Notes to Consolidated Financial Statements

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CASH FLOWS**

(unaudited)

	For the Nine Months Ended September 30,	
	2004	2003
Cash flows from operating activities:		
Net income	\$ 1,241,658	\$ 1,127,962
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,300,001	769,115
Provision for deferred income taxes	671,759	251,000
Bad debt provision	12,588	
Stock based compensation expense	10,278	23,975
Changes in operating assets and liabilities:		
Increase in accounts receivable	(2,575,227)	(1,026,937)
Increase in prepaid expenses and other current assets	(418,615)	(80,980)
Decrease in other assets	52,903	34,725
Increase in accounts payable	110,689	179,682
(Decrease) increase in accrued expenses and other current liabilities	(455,697)	508,147
Increase in deferred revenue	203,391	676,520
Decrease in other liabilities	(26,838)	
Net cash provided by operating activities	126,890	2,463,209
Cash flows from investing activities:		
Purchases of property and equipment	(1,184,212)	(1,278,420)
Net cash used in investing activities	(1,184,212)	(1,278,420)
Cash flows from financing activities:		
Payments under equipment lease obligations	(486,841)	(471,790)
Payments under promissory note	(125,001)	(125,000)
Proceeds from sales leaseback	672,102	
Proceeds from exercise of stock options	108,531	252,234
Net proceeds from private placement		9,874,251
Net cash provided by financing activities	168,791	9,529,695
Net (decrease) increase in cash and cash equivalents	(888,531)	10,714,484
Cash and cash equivalents at beginning of period	13,289,453	2,563,266
Cash and cash equivalents at end of period	\$ 12,400,922	\$ 13,277,750
Supplemental schedule of noncash investing and financing activities:		
Equipment purchased under capital lease obligations	\$ 672,102	\$ 247,695



See Notes to Consolidated Financial Statements

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1 - Basis of Presentation:

The financial statements included in this Form 10-QSB have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-KSB for the year ended December 31, 2003.

In the opinion of management, the accompanying consolidated financial statements contain all adjustments, consisting solely of those which are of a normal recurring nature, necessary for the fair presentation of the results for the interim periods.

Interim results are not necessarily indicative of results for the full fiscal year.

Note 2 Stock-Based Compensation:

At September 30, 2004, we have one stock-based employee compensation plan. We account for this plan under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and Related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under this plan as of September 30, 2004 had an exercise price equal to or greater than the fair 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 if we had applied the fair value recognition provisions of FASB Statement No. 123, Accounting for Stock-Based Compensation, as amended by FASB Statement No. 148 Accounting for Stock-Based Compensation Transition and Disclosure, to account for stock-based employee compensation.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2004	2003	2004	2003
Net income, as reported	\$ 1,241,658	\$ 1,127,962	\$ 429,792	\$ 526,874
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	6,167	18,940	2,056	3,049
Deduct: Total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(329,496)	(628,885)	(109,832)	(205,063)
Pro forma net income	\$ 918,329	\$ 518,017	\$ 322,016	\$ 324,860
Earnings per share:				
Basic-as reported	\$ 0.12	\$ 0.13	\$ 0.04	\$ 0.06
Basic-pro forma	\$ 0.09	\$ 0.06	\$ 0.03	\$ 0.04
Diluted-as reported	\$ 0.10	\$ 0.11	\$ 0.04	\$ 0.05
Diluted-pro forma	\$ 0.08	\$ 0.05	\$ 0.03	\$ 0.03

We have an employment agreement with an executive officer that provided for the granting of 30,000 restricted shares of Common Stock to the executive officer on January 31, 2005. We accrued \$10,278 and \$23,975 of stock based compensation expense during the nine months ended September 30, 2004 and 2003, respectively. We accrued \$3,426 of stock based compensation expense during each of the three months ended September 30, 2004 and 2003.

Note 3 - Earnings Per Share:

Basic earnings per common share for the nine months and three months ended September 30, 2004 and 2003 was calculated based upon net income divided by the weighted average number of shares of our common stock, \$0.00025 par value, outstanding during the period. Diluted earnings per share for the nine months and three months ended September 30, 2004 and

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

2003 was calculated based upon net income divided by the weighted average number of shares of our common stock outstanding during the period, adjusted for dilutive securities using the treasury method.

-8-

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

The computation of basic earnings per common share and diluted earnings per common share was as follows:

	Nine Months Ended		Three Months Ended	
	September 30,		September 30,	
	2004	2003	2004	2003
Net income basic	\$ 1,241,658	\$ 1,127,962	\$ 429,792	\$ 526,874
Interest expense on convertible note	24,897	31,381	11,516	14,111
Net income diluted	\$ 1,266,555	\$ 1,159,343	\$ 441,308	\$ 540,985
Denominator basic:				
Weighted average number of common shares	10,789,760	8,805,713	10,824,041	9,132,327
Basic earnings per common	\$ 0.12	\$ 0.13	\$ 0.04	\$ 0.06
Denominator diluted:				
Weighted average number of common shares	10,789,760	8,805,713	10,824,041	9,132,327
Common share equivalents of outstanding stock options and restricted stock	1,318,086	1,368,579	1,181,969	1,514,637
Common share equivalents related to the convertible promissory note	148,683	135,056	148,810	135,320
Weighted average number of common shares common shares and dilutive common equivalent shares	12,256,529	10,309,348	12,154,820	10,782,284
Diluted earnings per common share	\$ 0.10	\$ 0.11	\$ 0.04	\$ 0.05

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

As of September 30, 2004, options to purchase 206,100 shares of our common stock have been excluded from the calculation of diluted earnings per common share as they were all antidilutive. As of September 30, 2003, there were no stock options that are excluded from the calculation of diluted earnings per common share as they are all dilutive.

Note 4 - Debt:

On May 15, 2004, we renewed and amended our agreement with Wachovia Bank, National Association. The renewed and amended agreement is for an unsecured committed line of credit of \$5,000,000. Interest is payable at the LIBOR Market Index Rate plus 2.0%. The agreement requires us, among other things, to maintain certain financial covenants. The committed line of credit matures June 30, 2005 and may be renewed on an annual basis. At September 30, 2004, we had no borrowings under the committed line of credit and are compliant with the financial covenants.

On October 1, 2001, we acquired effective control of the Intelligent Imaging business unit of Quintiles, Inc., a North Carolina corporation, referred to as Quintiles, and a wholly-owned subsidiary of Quintiles Transnational Corporation. The acquisition of Intelligent Imaging closed on October 25, 2001. In connection with the acquisition of Intelligent Imaging, as of February 1, 2002, we are obligated to pay quarterly payments of principal of \$41,667 under a note, referred to as the Quintiles Note, plus accrued interest thereon, and one payment of principal of \$500,000 on November 1, 2004, unless the Quintiles Note is previously converted into shares of our common stock. The Quintiles Note bears interest at the rate in effect on the business day immediately prior to the date on which payments are due under the Quintiles Note equal to the three-month LIBOR (London Interbank Offering Rate) as published from time to time in The Wall Street Journal plus 3%, compounded annually based on a 365-day year. We have recorded the balance of the Quintiles Note of \$541,663 as a current liability as of September 30, 2004.

The number of shares of our common stock into which the Quintiles Note may be converted is calculated by dividing the outstanding principal balance of the Quintiles Note, plus all accrued and unpaid interest thereon, by the greater of: (i) 75% of the average closing price of our common stock over the ten consecutive trading days ending prior to the date of conversion; or (ii) \$0.906 per share. At September 30, 2004, the Quintiles Note would have been convertible into 148,683 shares of our common stock. This was calculated by dividing the unpaid principal balance (\$541,663 as of September 30, 2004) plus accrued interest (\$4,606 as of September 30, 2004), totaling \$546,269, by \$3.65 (75% of the average closing price of our common stock over the ten consecutive trading days ending on September 30, 2004). Under the formula contained in the Quintiles Note, at the minimum price per share of \$0.906, the maximum number of shares of our common stock to be issued to Quintiles, based upon the outstanding principal amount and accrued interest at September 30, 2004, would be 602,946 shares.

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

On November 1, 2004, we made the final payment on the Quintiles Note. This payment was comprised of the remaining principal balance of \$541,663 and interest of \$7,045.

On June 23, 2004, we entered into a \$339,567 sale-leaseback transaction whereby we sold and leased back computer equipment and furniture. The resulting lease is being accounted for as a capital lease. There was no gain or loss recorded on the sale. The lease term is 3 years with an interest rate of 5.35%.

On September 29, 2004, we entered into a \$332,536 sale-leaseback transaction whereby we sold and leased back computer equipment and furniture. The resulting lease is being accounted for as a capital lease. There was a gain recorded on the sale in the amount of \$20,964 which is being deferred over the life of the lease. The lease term is for 3 years with an interest rate of 5.87%.

Note 5 Business Segments

FASB Statement No. 131, Disclosures about Segments of an Enterprise and Related Information, requires companies to provide certain information about their operating segments. In November 2003, we acquired the intellectual property of CapMed Corporation. Accordingly, we now have two reportable segments: pharmaceutical contract services and the CapMed division. Our pharmaceutical contract service segment provides services that support the product development process of the pharmaceutical, biotechnology and medical device industries. Our CapMed segment offers a software application that enables users to manage and store personal health information, including their medical images, on the privacy of their desktop computer, while linking directly to sponsor-directed resources such as drug information, patient education, or disease guidelines. The operating segments are managed separately because each offers different services and applications to different markets. Our management evaluates the performance of each segment based upon operating earnings or losses before interest and income taxes.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

Summarized financial information concerning our reportable segments is shown in the following table:

	Pharmaceutical Contract Services	CapMed Division	Consolidated Total
	<u> </u>	<u> </u>	<u> </u>
For the nine months ended September 30, 2004			
Total revenues	\$ 21,524,271	\$ 21,956	\$ 21,546,227
Total cost and expenses	\$ 18,723,800	\$ 740,726	\$ 19,464,526
Income (loss) from operations	\$ 2,800,471	\$ (718,770)	\$ 2,081,701
For the nine months ended September 30, 2003			
Total revenues	\$ 18,211,851		\$ 18,211,851
Total cost and expenses	\$ 16,686,068		\$ 16,686,068
Income from operations	\$ 1,525,783		\$ 1,525,783
For the three months ended September 30, 2004			
Total revenues	\$ 7,551,682	\$ 15,342	\$ 7,567,024
Total cost and expenses	\$ 6,528,108	\$ 318,676	\$ 6,846,784
Income (loss) from operations	\$ 1,023,574	\$ (303,334)	\$ 720,240
For the three months ended September 30, 2003			
Total revenues	\$ 6,337,949		\$ 6,337,949
Total cost and expenses	\$ 5,717,622		\$ 5,717,622
Income from operations	\$ 620,327		\$ 620,327
Segment assets at September 30, 2004	\$ 26,330,726	\$ 915,258	\$ 27,245,984
Segment assets at September 30, 2003	\$ 23,734,091		\$ 23,734,091

Our foreign customers accounted for approximately 0% and 11% of service revenues for the three months ended September 30, 2004 and 2003, respectively. For the nine months ended September 30, 2004 and 2003, our foreign customers accounted for approximately 9% and 18% of service revenues, respectively.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

Note 6 Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable does not bear interest. We maintain allowances for doubtful accounts on a specific identification method for estimated losses resulting from the inability of our customers to make required payments. We do not have any off-balance-sheet credit exposure related to our customers.

	September 30, 2004	December 31, 2003
Trade	6,672,498	4,350,523
Employee		
Other	319,258	78,594
Total Receivables	6,991,756	4,429,117
<u>Allowance Rollforward:</u>		
Balance at December 31, 2002	65,000	
Additions		
Write offs (net of recoveries)	(38,179)	
Balance at December 31, 2003	26,821	
Balance at December 31, 2003	26,821	
Additions	1,563	
Write offs (net of recoveries)	(12,574)	
Balance at September 30, 2004	15,810	

Table of Contents

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

Overview

We are a healthcare contract service organization, providing services that support the product development process of the pharmaceutical, biotechnology and medical device industries. We specialize in assisting our clients in the design and management of the medical-imaging component of clinical trials for all imaging modalities, including computerized tomography, magnetic resonance imaging, x-rays, dual energy x-ray absorptiometry, positron emission tomography, single photon emission computerized tomography and ultrasound. We provide services that include the processing and analysis of medical images and the data-basing and regulatory submission of medical images, quantitative data and text. We also offer a service called Bio-Imaging ET&CSM, which focuses on education, training and certification for medical imaging equipment, facilities and staff.

Our sales cycle, referring to the period from the presentation by us to a potential client to the engagement of us by such client, has historically been approximately 12 months. In addition, the contracts under which we perform services typically cover a period of 12 to 60 months and the volume and type of services performed by us generally vary during the course of a project. We cannot assure you that our project revenues will remain at levels sufficient to maintain profitability. Service revenues were generated from 78 clients encompassing 191 distinct projects for the nine months ended September 30, 2004. This compares to 68 clients encompassing 167 distinct projects for the nine months ended September 30, 2003.

Our contracted/committed backlog, referred to as backlog, is the amount of service revenue that remains to be earned and recognized on both signed and verbally agreed to contracts. Our backlog was approximately \$46.5 million as of September 30, 2004. This compares to approximately \$40.2 million as of September 30, 2003, an increase of 15.7%. Contracts included in backlog are subject to termination by our clients at any time. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date. The duration of the projects included in our backlog range from less than 3 months to 7 years. We believe that our backlog assists our management as an indicator of our long-term business. However, we do not believe that backlog is a reliable predictor of near-term results because service revenues may be incurred in a given period on contracts that were not included in the previous reporting period's backlog and/or contract cancellations may occur in a given period on contracts that were included in the previous reporting period's backlog.

We believe that demand for our services and technologies will continue to grow as the use of digital technologies for data acquisition and management increases in the radiology and drug development communities. We also believe that there is a growing recognition within the bio-pharmaceutical industry of the advantages in using an independent centralized core laboratory for analysis of medical-imaging data and compliance with the regulatory demands for

Table of Contents

the submission of such data. In addition, the Food and Drug Administration is gaining experience with electronic submissions and is continuing to develop sophisticated guidelines for computerized submission of clinical trial data, including medical images. Furthermore, the increased use of digital medical images in clinical trials, especially for important drug classes such as anti-inflammatory, neurologic and oncologic therapeutics and diagnostic image agents, generate large amounts of image data from a large number of imaging sources. These studies require processing, analysis, data management and submission services best handled by vendors with scalable logistical capabilities and extensive experience working with research facilities worldwide. Due to several factors, including, without limitation, competition from commercial competitors and academic research centers, we cannot assure you that demand for our services and technologies will grow, sustain growth, or that additional revenue generating opportunities will be realized by us.

In November 2003, we acquired the intellectual property of CapMed Corporation, located in Wilmington, Delaware, including the Personal Health Record software, referred to as PHR, and the patent-pending Personal HealthKey technology. The PHR is a software application that enables users to manage and store personal health information, including their medical images, on the privacy of their desktop computer, while linking directly to sponsor-directed resources such as drug information, patient education, or disease guidelines. The Personal HealthKey plugs into a computer's USB port, allowing doctors and patients easy access to the patient's medical record without the need for additional hardware or software, and it is password protected. In connection with the acquisition, CapMed received aggregate consideration of \$550,000, consisting of \$211,828 in cash paid directly to CapMed's creditors and \$338,171 of our common stock, which amounted to a total of 51,724 shares, of which 40,361 were issued to CapMed and 11,363 were issued to an escrow agent pursuant to the terms of the acquisition.

We intend to expand our CapMed division through partnerships and marketing efforts devoted to the PHR and Personal HealthKey products. We believe that continued emphasis on improving patient care and reducing cost will contribute to the growth of the personal electronic medical records market.

Certain matters discussed in this Form 10-QSB are forward-looking statements intended to qualify for the safe harbors from liability established by the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as believes, expects, may, will, should, or anticipates or the negative thereof or other variations thereof, comparable terminology, or by discussions of strategy that involve risks and uncertainties. In particular, our statements regarding the successful integration and consummation of proposed acquisitions, the demand for our services and technologies, growing recognition for the use of independent centralized core laboratories, trends toward the outsourcing of imaging services in clinical trials, realized return from our marketing efforts and increased use of digital medical images in clinical trials and our statements regarding the growth of the personal electronic medical records are examples of such forward-looking statements. The forward-looking

Table of Contents

statements include risks and uncertainties, including, but not limited to, the timing of revenues due to the variability in size, scope and duration of projects, estimates made by management with respect to our critical accounting policies, regulatory delays, clinical study results which lead to reductions or cancellations of projects, and other factors, including general economic conditions and regulatory developments, not within our control. The factors discussed in this Form 10-QSB and expressed from time to time in our filings with the Securities and Exchange Commission, as well as the risk factors set forth in our most recent Form 10-KSB, could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this filing and we undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Results of OperationsNine Months Ended September 30, 2004 and 2003

	Nine Months		Nine Months		\$ Change	% Change
	Ended		Ended			
	September 30, 2004	% of Total Revenue	September 30, 2003	% of Total Revenue		
Service revenues	\$ 18,987,530	88.1%	\$ 15,922,710	87.4%	\$ 3,064,820	19.2%
Reimbursement Revenues	2,558,697	11.9%	2,289,141	12.6%	269,556	11.8%
Total revenues	21,546,227	100.0%	18,211,851	100.0%	3,334,376	18.3%
Cost of revenues	13,916,942	64.6%	12,246,484	67.2%	1,670,458	13.6%
General and administrative expenses	3,284,646	15.2%	2,937,716	16.1%	346,930	11.8%
Sales and marketing Expenses	2,262,938	10.5%	1,501,868	8.2%	761,070	50.7%
Total cost and Expenses	19,464,526	90.3%	16,686,068	91.6%	2,778,458	16.7%
Interest income (expense)-net	6,289	0.0%	(101,409)	(0.6)%	107,698	106.2%
Income before income tax provision	2,087,990	9.7%	1,424,374	7.8%	663,616	46.6%
Income tax provision	846,332	3.9%	296,412	1.6%	549,920	185.5%
Net income	\$ 1,241,658	5.8%	\$ 1,127,962	6.2%	\$ 113,696	10.1%

Service revenues for the nine months ended September 30, 2004 and 2003 were

Table of Contents

\$18,987,530 and \$15,922,710, respectively, an increase of \$3,064,820 or 19.2%. The increase in service revenues was due to an increase in the number of projects resulting from the overall market growth for medical-imaging related services for clinical trials and what we believe to be our increasing market share.

Service revenues were generated from 78 clients encompassing 191 distinct projects for the nine months ended September 30, 2004. This compares to 68 clients encompassing 167 distinct projects for the nine months ended September 30, 2003. There were no clients that accounted for more than 10% of our service revenues for the nine months ended September 30, 2004, while for the comparable period last year, one client, NPS Pharmaceuticals, encompassing four projects represented 12.7% of our service revenues. No other client accounted for more than 10% of service revenues in each of the nine-month periods ended September 30, 2004 and 2003. Service revenues generated from our client base, while still concentrated as measured by the number of clients, has continued to become more dispersed over time. We believe more diversification is evident when revenue concentration is measured by the number of individual projects. We believe that measuring revenue concentration by project diversification may be more indicative of revenue concentration risk since we are often working on several separately-based and funded projects with a single client, with each project often being wholly independent from the others. Our primary scope of work in both periods included medical-imaging core laboratory services and image-based information management services.

Reimbursement revenues consist of reimbursements received from the customer for pass-through costs. Reimbursement revenues fluctuate significantly over the course of any given project and quarter to quarter variations are a reflection of this project timing. Therefore, our management believes that reimbursement revenues are not a significant indicator of our overall performance trends.

Cost of revenues for the nine months ended September 30, 2004 and 2003 was \$13,916,942 and \$12,246,484, respectively, an increase of \$1,670,458 or 13.6%. The increase in cost of revenues is substantially all due to the variable costs associated with the increase in staffing levels required for project related tasks due to the increase in revenues for the nine months ended September 30, 2004. Cost of revenues for the nine months ended September 30, 2004 and nine months ended September 30, 2003 were comprised of professional salaries and benefits, allocated overhead and pass-through costs. We expect that our cost of revenues will continue to increase in fiscal 2004 as revenue increases.

The decrease in the cost of revenues as a percentage of total revenues to 64.6% for the nine months ended September 30, 2004 from 67.2% for the nine months ended September 30, 2003 is primarily due to our increase in total revenues with a lesser increase in costs associated with project related tasks. The cost of revenues as a percentage of total revenues also fluctuates due to work-flow variations in the utilization of staff and the mix of services provided by us in any given period.

Table of Contents

General and administrative expenses for the nine months ended September 30, 2004 and 2003 were \$3,284,646 and \$2,937,716, respectively, an increase of \$346,930 or 11.8%. The increase is primarily due to an increase in personnel needed to support the growth in our service revenues and also includes approximately \$297,000 of expenses associated with the CapMed division. General and administrative expenses in each of the nine months ended September 30, 2004 and 2003 consisted primarily of professional salaries and benefits, depreciation and amortization, professional and consulting services, office rent and corporate insurance. We expect that our general and administrative expenses will continue to increase to support our operations in fiscal 2004 as revenue increases.

The decrease in general and administrative expenses as a percentage of total revenues to 15.2% for the nine months ended September 30, 2004 from 16.1% for the nine months ended September 30, 2003 is primarily due to a lesser increase in personnel needed to support the growth in our service revenues as compared to the increase in our total revenues.

Sales and marketing expenses for the nine months ended September 30, 2004 and 2003 were \$2,262,938 and \$1,501,868, respectively, an increase of \$761,070 or 50.7%. The increase is primarily due to expenses associated with the CapMed division of approximately \$444,000 and an increase in expenses associated with tradeshow attendance of approximately \$60,000, increased in marketing expenses of approximately \$24,000 and an increase in personnel and commission expense of approximately \$232,000. Sales and marketing expenses in each of the nine months ended September 30, 2004 and September 30, 2003 were comprised of direct sales and marketing costs, professional salaries and benefits and allocated overhead. We expect that sales and marketing expenses will increase in fiscal 2004 as we continue to expand our market presence in the United States and Europe.

The increase in sales and marketing expenses as a percentage of total revenues to 10.5% for the nine months ended September 30, 2004 from 8.2% for the nine months ended September 30, 2003 is primarily due to increased expenses associated with our CapMed division.

Net interest income for the nine months ended September 30, 2004 was \$6,289 and net interest expense for the nine months ended September 30, 2003 was \$101,409, an increase of \$107,698 or 106.2%. This increase is primarily due to interest income earned on a higher average cash balance for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003. Net interest income and expense for the nine months ended September 30, 2004 and 2003 is comprised of interest income earned on our cash balance and interest expense incurred on equipment lease obligations and the Quintiles Note.

Income before income taxes was \$2,087,990 for the nine months ended September 30, 2004 and \$1,424,374 for the nine months ended September 30, 2003, an increase of \$663,616 or 46.6%. The increase was attributable to the increased revenues associated with an increase in services performed on projects for which we were contracted offset, in part, by the costs associated with increased staffing levels necessary to perform the newly contracted services.

Table of Contents

The increase in income before income taxes as a percentage of total revenues to 9.7% for the nine months ended September 30, 2004 from 7.8% for the nine months ended September 30, 2003 is primarily due to increased revenues associated with an increase in services performed on projects for which we were contracted with a lesser increase in costs of revenue as a percentage of total revenues for the nine months ended September 30, 2004.

Income tax provision for the nine months ended September 30, 2004 and 2003 was \$846,332 and \$296,412, respectively, an increase of \$549,920 or 185.5%. The increase is primarily due to the increase in our estimated effective tax rate for 2004 to 41% as compared to 21% for the nine months ending September 30, 2003.

Three Months Ended September 30, 2004 and 2003

	Three Months		Three Months		\$ Change	% Change
	Ended	% of Total	Ended	% of Total		
	September 30,	Revenue	September 30,	Revenue		
	2004		2003			
Service revenues	\$ 6,547,281	86.5%	\$ 5,462,240	86.2%	\$ 1,085,041	19.9%
Reimbursement Revenues	1,019,743	13.5%	875,709	13.8%	144,034	16.4%
Total revenues	7,567,024	100.0%	6,337,949	100.0%	1,229,075	19.4%
Cost of revenues	5,020,102	66.3%	4,170,449	65.8%	849,653	20.4%
General and administrative expenses	1,067,226	14.1%	1,026,504	16.2%	40,722	4.0%
Sales and marketing Expenses	759,456	10.0%	520,669	8.2%	238,787	45.9%
Total cost and Expenses	6,846,784	90.5%	5,717,622	90.2%	1,129,162	19.7%
Interest expense - net	2,664	0.0%	31,036	0.5%	(28,372)	(91.4)%
Income before income tax provision	717,576	9.5%	589,291	9.3%	128,285	21.8%
Income tax provision	287,784	3.8%	62,417	1.0%	225,367	361.1%
Net income	\$ 429,792	5.7%	\$ 526,874	8.3%	(97,082)	(18.4)%

Service revenues for the three months ended September 30, 2004 and 2003 were \$6,547,281 and \$5,462,240, respectively, an increase of \$1,085,041 or 19.9%. The increase in service revenues was due to an increase in the number of projects resulting from the overall market growth for medical-imaging related services for clinical trials and what we believe to be our increasing market share.

Table of Contents

Service revenues were generated from 75 clients encompassing 179 distinct projects for the three months ended September 30, 2004. This compares to 62 clients encompassing 143 distinct projects for the three months ended September 30, 2003. One client, Novartis, encompassing 14 projects represented 13.9% of our service revenues for the three months ended September 30, 2004, while for the comparable period last year, one client, NPS Pharmaceuticals, encompassing four projects represented 12.0% of our service revenues. No other client accounted for more than 10% of service revenues in each of the three-month periods ended September 30, 2004 and 2003. Service revenues generated from our client base, while still concentrated as measured by the number of clients, has continued to become more dispersed over time and we believe more diversification is evident when revenue concentration is measured by the number of individual projects. We believe that measuring revenue concentration by project diversification may be more indicative of revenue concentration risk since we are often working on several separately-based and funded projects with a single client, with each project often being wholly independent from the others. Our primary scope of work in both periods included medical-imaging core laboratory services and image-based information management services.

Reimbursement revenues consist of reimbursements received from the customer for pass-through costs. Reimbursement revenues fluctuate significantly over the course of any given project and quarter to quarter variations are a reflection of this project timing. Therefore, our management believes that reimbursement revenues are not a significant indicator of our overall performance trends.

Cost of revenues for the three months ended September 30, 2004 and 2003 was \$5,020,102 and \$4,170,449 respectively, an increase of \$849,653 or 20.4%. The increase in cost of revenues is substantially all due to the variable costs associated with the increase in staffing levels required for project related tasks due to the increase in revenues for the three months ended September 30, 2004. Cost of revenues for the three months ended September 30, 2004 and three months ended September 30, 2003 were comprised of professional salaries and benefits, allocated overhead and pass-through costs. We expect that our cost of revenues will continue to increase in fiscal 2004 as revenue increases.

The increase in the cost of revenues as a percentage of total revenues to 66.3% for the three months ended September 30, 2004 from 65.8% for the three months ended September 30, 2003 is primarily due to our increase in total revenues with a lesser increase in costs associated with project related tasks. The cost of revenues as a percentage of total revenues also fluctuates due to work-flow variations in the utilization of staff and the mix of services provided by us in any given period.

General and administrative expenses for the three months ended September 30, 2004 and 2003 were \$1,067,226 and \$1,026,504, respectively, an increase of \$40,722 or 4.0%. The increase is primarily due to an increase in personnel to support the growth in our service revenues

Table of Contents

and also includes approximately \$127,000 of expenses associated with the CapMed division. General and administrative expenses in each of the three months ended September 30, 2004 and 2003 consisted primarily of professional salaries and benefits, depreciation and amortization, professional and consulting services, office rent and corporate insurance. We expect that our general and administrative expenses will continue to increase to support our operations in fiscal 2004 as revenue increases.

The decrease in general and administrative expenses as a percentage of total revenues to 14.1% for the three months ended September 30, 2004 from 16.2% for the three months ended September 30, 2003 is primarily due to a lesser increase in personnel to support the growth in our service revenues as compared to the increase in our total revenues.

Sales and marketing expenses for the three months ended September 30, 2004 and 2003 were \$759,456 and \$520,669, respectively, an increase of \$238,787 or 45.9%. The increase is primarily due to approximately \$192,000 of expenses associated with the CapMed division. Sales and marketing expenses in each of the three months ended September 30, 2004 and September 30, 2003 were comprised of direct sales and marketing costs, professional salaries and benefits and allocated overhead. We expect that sales and marketing expenses will increase in fiscal 2004 as we continue to expand our market presence in the United States and Europe.

The increase in sales and marketing expenses as a percentage of total revenues to 10.0% for the three months ended September 30, 2004 from 8.2% for the three months ended September 30, 2003 is primarily due to increased expenses associated with our CapMed division.

Net interest expense for the three months ended September 30, 2004 and 2003 was \$2,664 and \$31,036, respectively, a decrease of \$28,372 or 91.4%. This decrease is primarily due to interest income earned on a higher average cash balance for the three months ended September 30, 2004 as compared to the three months ended September 30, 2003. Net interest income and expense for the three months ended September 30, 2004 and 2003 is comprised of interest income earned on our cash balance and interest expense incurred on equipment lease obligations and the Quintiles Note.

Income before income taxes was \$717,576 for the three months ended September 30, 2004 and \$589,291 for the three months ended September 30, 2003, an increase of \$128,285 or 21.8%. The increase was attributable to the increased revenues associated with an increase in services performed on projects for which we were contracted offset, in part, by the costs associated with increased staffing levels necessary to perform the newly contracted services.

Income before income taxes as a percentage of total revenues remained relatively flat at 9.5% for the three months ended September 30, 2004 as compared to 9.3% for the three months ended September 30, 2003.

Income tax provision for the three months ended September 30, 2004 and 2003 was

Table of Contents

\$287,784 and \$62,417, respectively, an increase of \$225,367 or 361.1%. The increase is primarily due to the increase in our estimated effective tax rate for 2004 to 41% as compared to 11% for the three months ended September 30, 2003.

Business Segments

We have set forth certain financial information with respect to our two business segments, pharmaceutical contract services and the CapMed division, in Note 5 Business Segments to our Consolidated Financial Statements in this Form 10-QSB. The quarter ended September 30, 2004 is the 3rd full quarter of operations of our CapMed business segment as we acquired the intellectual property of CapMed Corporation in November 2003. During the nine months ended September 30, 2004, we had CapMed segment sales of \$21,956 and total costs and expenses of \$740,726, consisting of approximately \$444,000 of sales and marketing expenses and approximately \$297,000 of general and administrative expenses. During the three months ended September 30, 2004, we had CapMed segment sales of \$15,342 and total costs and expenses of \$318,676, consisting of approximately \$191,000 of sales and marketing expenses and approximately \$128,000 of general and administrative expenses.

Liquidity and Capital Resources

	Nine Months Ended September 30, 2004	Nine Months Ended September 30, 2003
Net cash provided by operating activities	\$ 126,890	\$ 2,463,209
Net cash used in investing activities	\$ (1,184,212)	\$ (1,278,420)
Net cash provided by financing activities	\$ 168,791	\$ 9,529,695

At September 30, 2004, we had cash and cash equivalents of \$12,400,922. Working capital at September 30, 2004 was \$14,575,056.

Net cash provided by operating activities for the nine months ended September 30, 2004 was \$126,890 as compared to net cash provided by operating activities of \$2,463,209 for the nine months ended September 30, 2003. This decrease is primarily due to the increase in accounts receivable of \$2,575,227 at September 30, 2004 from December 31, 2003 due to increased revenues, offset by the higher depreciation and amortization expense of \$1,300,001 and the provision for deferred income taxes of \$671,759.

Net cash used in investing activities represents our investment in capital and leasehold improvements. We currently anticipate that capital expenditures for the remainder of the fiscal year ending December 31, 2004 will be approximately \$500,000. These expenditures represent additional upgrades in our networking, data storage and core laboratory capabilities for both our United States and European operations.

Net cash provided by financing activities is primarily attributable to the proceeds of \$672,102 from our sales leaseback transaction offset by payments under equipment lease obligations and the Quintiles Note.

Table of Contents

The following table lists our cash contractual obligations as of September 30, 2004:

Contractual obligations	Payments Due By Period			
	Total	Less than 1 year	1-3 years	4-5 years After 5 years
Long-term debt obligations				
Capital lease obligations	\$ 1,571,296	\$ 770,566	\$ 800,730	
Facility rent operating leases	\$ 5,058,612	\$ 973,233	\$ 2,770,310	\$ 1,315,069
Purchase obligations				
Employment agreements	\$ 150,000	\$ 150,000		
Quintiles Note	\$ 541,663	\$ 541,663		
Total contractual cash obligations	\$ 7,321,571	\$ 2,435,462	\$ 3,571,040	\$ 1,315,069

On May 15, 2004, we renewed and amended our agreement with Wachovia Bank, National Association. The renewed and amended agreement is for an unsecured committed line of credit of \$5,000,000. Interest is payable at the LIBOR Market Index Rate plus 2.0%. The agreement requires us, among other things, to maintain certain financial covenants. The committed line of credit matures June 30, 2005 and may be renewed on an annual basis. At September 30, 2004, we had no borrowings under the committed line of credit and are compliant with the financial covenants.

In connection with our acquisition of Intelligent Imaging, as of February 1, 2002, we are obligated to pay quarterly payments of principal of \$41,667 under the Quintiles Note, plus accrued interest thereon, and one payment of principal of \$500,000 on November 1, 2004, unless the Quintiles Note is previously converted into shares of our common stock. The Quintiles Note bears interest at the rate in effect on the business day immediately prior to the date on which payments are due under the Quintiles Note equal to the three-month LIBOR as published from time to time in The Wall Street Journal plus 3%, compounded annually based on a 365-day year. We have recorded the balance of the Quintiles Note of \$541,663 as a current liability as of September 30, 2004.

On November 1, 2004, we made the final payment on the Quintiles Note. This payment was comprised of the remaining principal balance of \$541,663 and interest of \$7,045.

On September 27, 2004, we signed a non-binding letter of intent to acquire Heart Core B.V., headquartered in Leiden, the Netherlands. Heart Core B.V. provides customized imaging services in the field of cardiovascular, pulmonary and orthopedic clinical research. The acquisition is subject to the execution of a definitive agreement and standard closing conditions.

Table of Contents

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends on our common stock in the foreseeable future.

We have not entered into any off-balance sheet transactions, arrangements or other relationships with unconsolidated entities or other persons that are likely to affect liquidity or the availability of or requirements for capital resources.

We anticipate that our existing capital resources together with cash flow from operations and borrowing capacity under the existing line of credit, will be sufficient to meet our foreseeable cash needs. However, we cannot assure you that our operating results will continue to achieve profitability on an annual basis in the future. The inherent operational risks associated with:

our ability to gain new client contracts;

the variability of the timing of payments on existing client contracts; and

other changes in our operating assets and liabilities

may have a material adverse affect on our future liquidity.

We may seek to raise additional capital from equity or debt sources in order to take advantage of unanticipated opportunities, such as more rapid expansion, acquisitions of complementary businesses or the development of new services. We cannot assure you that additional financing will be available, if at all, on terms acceptable to us.

Our fiscal 2004 operating plan contains assumptions regarding revenue and expenses. The achievement of our operating plan depends heavily on the timing of work performed by us on existing projects and our ability to gain and perform work on new projects. Project cancellation, or delays in the timing of work performed by us on existing projects or our inability to gain and perform work on new projects could have an adverse impact on our ability to execute our operating plan and maintain adequate cash flow. In the event actual results do not meet the operating plan, our management believes it could execute contingency plans to mitigate these effects. Our plans include additional financing, to the extent available, through the line of credit discussed above. Considering the cash on hand and based on the achievement of the operating plan and management's actions taken to date, management believes it has the ability to continue to generate sufficient cash to satisfy our operating requirements in the normal course of business for at least the next 12 months and the foreseeable future.

Changes to Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are set forth in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003. As of September 30, 2004, there have been no changes to such critical accounting policies and estimates.

Table of Contents

Item 3. Controls and Procedures.

Evaluation of disclosure controls and procedures. Based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act) as of September 30, 2004, our president and chief executive officer (principal executive officer) and our chief financial officer (principal accounting and financial officer) have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and are operating in an effective manner.

Changes in internal control over financial reporting. There was no change in our internal controls over financial reporting that occurred during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Table of Contents

PART II. OTHER INFORMATION.

Item 6. Exhibits

- 10.1 Form of executive retention agreement of Bio-Imaging Technologies, Inc.
- 31.1 Certification of principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of principal financial and accounting officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.
- 32.2 Certification of principal financial and accounting officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.

Table of Contents

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIO-IMAGING TECHNOLOGIES, INC.

DATE: November 12, 2004

By: /s/ Mark L. Weinstein

Mark L. Weinstein, President and Chief Executive Officer
(Principal Executive Officer)

DATE: November 12, 2004

By: /s/ Ted I. Kaminer

Ted I. Kaminer, Senior Vice President and
Chief Financial Officer

(Principal Financial and Accounting Officer)

-27-