

DIGIRAD CORP  
Form 10-Q  
August 07, 2007  
[Table of Contents](#)

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

---

**FORM 10-Q**

---

(Mark One)

**x** **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2007**

**..** **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**FOR THE TRANSITION PERIOD FROM** **TO**

Commission file number: 000-50789

---

**Digirad Corporation**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or Other Jurisdiction)

of Incorporation or Organization)

**13950 Stowe Drive, Poway, CA**  
(Address of Principal Executive Offices)

**(858) 726-1600**

**33-0145723**  
(I.R.S. Employer

Identification No.)

**92064**  
(Zip Code)

## Edgar Filing: DIGIRAD CORP - Form 10-Q

(Registrant's Telephone Number, Including Area Code)

---

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

Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act.)

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

As of July 26, 2007, the registrant had 18,827,534 shares of Common Stock (\$0.0001 par value) outstanding.

---

**Table of Contents**

**DIGIRAD CORPORATION**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	3
	<u>Consolidated Balance Sheets as of June 30, 2007 (Unaudited) and December 31, 2006</u>	3
	<u>Unaudited Consolidated Statements of Operations for the three and six months ended June 30, 2007 and 2006</u>	4
	<u>Unaudited Consolidated Statements of Cash Flows for the three and six months ended June 30, 2007 and 2006</u>	5
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3.	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	18
Item 4.	<u>Controls and Procedures</u>	18

**PART II. OTHER INFORMATION**

Item 1.	<u>Legal Proceedings</u>	18
Item 1A.	<u>Risk Factors</u>	18
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
Item 3.	<u>Defaults Upon Senior Securities</u>	29
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	29
Item 5.	<u>Other Information</u>	30
Item 6.	<u>Exhibits</u>	30

**SIGNATURES**

**EXHIBIT 31.1**

**EXHIBIT 31.2**

**EXHIBIT 32.1**

**EXHIBIT 32.2**

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****Digirad Corporation****Consolidated Balance Sheets****(In thousands, except par value amounts)**

	<b>June 30, 2007 (Unaudited)</b>	<b>December 31, 2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,826	\$ 10,070
Securities available-for-sale	22,394	34,256
Accounts receivable, net	9,704	7,534
Inventories, net	6,020	5,860
Other current assets	1,097	1,499
Total current assets	49,041	59,219
Property and equipment, net	14,418	9,570
Other intangible assets, net	3,219	428
Goodwill	2,699	
Restricted cash	60	60
Total assets	\$ 69,437	\$ 69,277
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,011	\$ 2,643
Accrued compensation	3,348	3,650
Accrued warranty	949	788
Other accrued liabilities	3,274	3,306
Deferred revenue	2,865	2,775
Current portion of long-term debt	262	269
Total current liabilities	12,709	13,431
Long-term debt, net of current portion	5	99
Deferred rent	268	302
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 10,000 shares authorized at June 30, 2007 and December 31, 2006; no shares issued or outstanding at June 30, 2007 and December 31, 2006		
Common stock, \$0.0001 par value: 80,000 shares authorized at June 30, 2007 and December 31, 2006; 18,826 and 18,795 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	2	2
Additional paid-in capital	152,172	151,539
Accumulated other comprehensive loss	(26)	(91)
Accumulated deficit	(95,693)	(96,005)
Total stockholders' equity	56,455	55,445

## Edgar Filing: DIGIRAD CORP - Form 10-Q

Total liabilities and stockholders' equity	\$ 69,437	\$ 69,277
--	-----------	-----------

See accompanying notes.

**Table of Contents****Digirad Corporation****Consolidated Statements of Operations****(In thousands, except per share amounts)****(Unaudited)**

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenues:				
DIS	\$ 13,323	\$ 13,403	\$ 25,520	\$ 26,620
Product	5,489	5,619	10,830	11,357
Total revenues	18,812	19,022	36,350	37,977
Cost of revenues:				
DIS	9,667	9,967	18,605	20,399
Product	3,335	3,383	6,493	7,513
Total cost of revenues	13,002	13,350	25,098	27,912
Gross profit	5,810	5,672	11,252	10,065
Operating expenses:				
Research and development	791	1,117	1,573	2,213
Sales and marketing	1,939	2,066	4,037	4,525
General and administrative	3,117	4,105	6,089	8,234
Amortization of intangible assets	103	20	109	29
Total operating expenses	5,950	7,308	11,808	15,001
Loss from operations	(140)	(1,636)	(556)	(4,936)
Other income (expense):				
Interest income	391	540	866	1,062
Interest expense	(13)	(21)	(24)	(47)
Other		(86)	26	(86)
Total other income	378	433	868	929
Net income (loss)	\$ 238	\$ (1,203)	\$ 312	\$ (4,007)
Net income (loss) per common share basic and diluted	\$ 0.01	\$ (0.06)	\$ 0.02	\$ (0.21)
Shares used in computing net loss per common share:				
Weighted average shares outstanding basic	18,821	18,761	18,818	18,736
Weighted average shares outstanding diluted	19,208	18,761	19,208	18,736

See accompanying notes.

**Table of Contents****Digirad Corporation****Consolidated Statements of Cash Flows****(In thousands)****(Unaudited)**

	<b>Six months ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Operating activities</b>		
Net income (loss)	\$ 312	\$ (4,007)
Adjustments to reconcile net income (loss) to net cash used by operating activities:		
Depreciation	1,914	2,496
Amortization of intangibles	109	34
Loss on disposal of assets	19	98
Amortization of premium on securities available-for-sale	27	63
Stock-based compensation	618	1,045
Changes in operating assets and liabilities:		
Accounts receivable	(1,178)	682
Inventories	(160)	(52)
Other assets	465	(11)
Accounts payable	(632)	585
Accrued compensation	(461)	498
Accrued warranty, deferred rent and other accrued liabilities	95	(986)
Deferred revenue	90	(195)
Net cash provided by operating activities	1,218	250
<b>Investing activities</b>		
Payments made in connection with a business acquisition	(8,904)	
Purchases of securities available-for-sale	(2,750)	(10,260)
Maturities of securities available-for-sale	14,651	11,700
Purchases of property and equipment	(4,331)	(2,334)
Patents and other assets		(78)
Net cash used in investing activities	(1,334)	(972)
<b>Financing activities</b>		
Issuances of common stock	14	34
Repayment of obligations under capital leases	(142)	(491)
Net cash used in financing activities	(128)	(457)
Net decrease in cash and cash equivalents	(244)	(1,179)
Cash and cash equivalents at beginning of period	10,070	16,303
Cash and cash equivalents at end of period	\$ 9,826	\$ 15,124

See accompanying notes.

**Table of Contents****DIGIRAD CORPORATION****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(in thousands, except per share amounts)

**1. Interim Financial Information*****Organization and Business***

Digirad Corporation ( Digirad ), a Delaware corporation, is a provider of diagnostic nuclear and ultrasound imaging systems and services to physicians' offices, hospitals and other medical services providers. Digirad has two reportable segments, Digirad Imaging Solutions ( DIS ) and Product. Substantially all of our revenue arises from sales activity in the United States. Through DIS, we provide in-office services to physicians, offering certified personnel, required licensure, an imaging system and other support and supplies for the performance of nuclear and ultrasound imaging procedures under the supervision of our physician customers. DIS physician customers enter into annual lease contracts for imaging services delivered on a per-day basis. Our Product segment sells solid-state gamma cameras and provides camera service and maintenance contracts. No DIS or product customer accounted for more than 10% of our revenue in any period presented.

***Basis of Presentation***

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America 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 disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Intercompany accounts have been eliminated in consolidation. Operating results for the three and six months ended June 30, 2007 are not necessarily indicative of the results that may be expected for the entire year. For further information see our financial statements and related disclosures thereto for the year ended December 31, 2006 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

***Net Income (Loss) Per Share*** (share data in thousands)

We calculate net income (loss) per share in accordance with SFAS No. 128 ( SFAS 128 ), *Earnings Per Share*. SFAS 128 requires presentation of basic earnings per share and diluted earnings per share. Basic earnings per share ( EPS ) is calculated by dividing the net income or loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents such as options and warrants. Options and warrants are only included in the calculation of diluted earnings per share when their effect is dilutive.

The weighted average shares used to calculate basic EPS was 18,821 and 18,818 for the three and six months ended June 30, 2007, and 18,761 and 18,736 for the three and six months ended June 30, 2006. The difference between the calculation of basic and diluted EPS is attributable to outstanding stock options. Stock options had the effect of increasing the number of shares used in the calculation of shares used in diluted EPS (by application of the treasury stock method) by 387 and 390 for the three and six months ended June 30, 2007. Stock options of 1,405 were not included in the calculation of diluted earnings per share for the three and six months ended June 30, 2007 as the effect of including these options would have been anti-dilutive.

**2. Financial Statement Details**

Inventories consist of the following (in thousands):

	June 30, 2007	December 31, 2006
Raw materials	\$ 2,309	\$ 2,985
Work-in-progress	3,598	3,316



# Edgar Filing: DIGIRAD CORP - Form 10-Q

Finished goods	1,039	471
	6,946	6,772
Less reserves for excess and obsolete inventories	(926)	(912)
	\$ 6,020	\$ 5,860

**Table of Contents**

Property and equipment consist of the following (in thousands):

	June 30, 2007	December 31, 2006
Machinery and equipment	\$ 26,258	\$ 21,276
Computers and software	3,945	3,446
Leasehold improvements	765	749
Furniture and fixtures	185	158
	31,153	25,629
Less accumulated depreciation and amortization	(16,735)	(16,059)
	\$ 14,418	\$ 9,570

Other accrued liabilities consist of the following (in thousands):

	June 30, 2007	December 31, 2006
Radiopharmaceuticals and consumable medical supplies	\$ 720	\$ 579
Professional fees	466	495
Outside services and consulting	343	454
Customer deposits	202	355
Facilities and related costs	419	279
Travel expenses	260	244
Sales and property taxes payable	320	236
Other accrued liabilities	544	664
	\$ 3,274	\$ 3,306

**3. Warranty**

We provide a warranty on certain of our products and accrue the estimated cost at the time revenue is recorded. Warranty expense is charged to product cost of goods sold. The majority of all warranty periods are 12 months before customer-sponsored maintenance begins. Warranty reserves are established based on historical experience with failure rates and repair costs and the number of gamma cameras covered by warranty. Warranty reserves are depleted as gamma cameras are repaired. The costs consist principally of materials, personnel, overhead and transportation. We review warranty reserves quarterly and, if necessary, make adjustments.

The activities in our warranty reserve are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Balance at beginning of period	\$ 993	\$ 779	\$ 788	\$ 825
Charges to cost of revenues	419	195	942	455
Applied to liability	(463)	(185)	(781)	(491)
Balance at end of period	\$ 949	\$ 789	\$ 949	\$ 789

**4. Comprehensive Income**

## Edgar Filing: DIGIRAD CORP - Form 10-Q

Comprehensive income consists of the following components (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Net income (loss), as reported	\$ 238	\$ (1,203)	\$ 312	\$ (4,007)
Unrealized gains (losses) on marketable securities	(6)	(55)	65	(98)
Comprehensive income (loss)	\$ 232	\$ (1,258)	\$ 377	\$ (4,105)

**Table of Contents****5. Stock-Based Compensation**

We have one stock option plan under which stock options are granted to our employees and directors. Stock options granted under this plan generally have a term of ten years from the date of grant and vest over four years. Prior to June 2004, we were authorized to issue options under various other option plans and programs; however, no additional awards may now be made under such plans.

For purposes of accounting for stock-based compensation, the fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing formula. There were no significant modifications to our share-based employee payment plans during the periods presented that resulted in any incremental compensation cost. As of June 30, 2007, \$2.0 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under our various plans is expected to be recognized over a weighted-average period of 2.0 years.

Following is a summary of stock-based compensation costs, by income statement classification (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Cost of DIS revenue	\$ 19	\$ 71	\$ 44	\$ 91
Cost of product revenue	17	23	43	41
Research and development	21	47	44	89
Sales and marketing	15	74	65	149
General and administrative	279	359	429	675
	\$ 351	\$ 574	\$ 625	\$ 1,045

**6. Acquisition**

On May 1, 2007, we completed the acquisition of substantially all of the assets and liabilities of Ultrascan, Inc. ( Ultrascan ), a provider of ultrasound imaging systems and services to physicians' offices and hospitals, in exchange for cash consideration of \$7.3 million, the assumption of debt obligations totaling \$1.5 million, and direct transaction costs of \$0.1 million. The aggregate purchase price is subject to a working capital adjustment which will be settled in the third quarter ending September 30, 2007. Additional consideration, payable in cash and common stock, of up to \$3.9 million may be payable to the seller or its designees in the event that certain financial milestones are achieved over a four year period commencing on the date of the acquisition. The additional consideration will be added to goodwill if and when it is earned. We repaid all assumed debt obligations at the closing of the acquisition. We acquired Ultrascan for purposes of expansion and diversification, and their results of operations are included in our DIS segment in our consolidated financial statements beginning on the date of the acquisition.

In connection with this transaction, we used a third party specialist to assist us in the valuation of the intangible assets acquired in order to allocate the purchase price in accordance with the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 141, Business Combinations ( SFAS 141 ). We accounted for this acquisition under the purchase method of accounting, and accordingly, the purchased assets and liabilities were recorded at their estimated fair values at the date of the acquisition. The aggregate purchase price exceeded the acquired net tangible assets by approximately \$5.6 million, which has been allocated to intangible assets with finite lives (customer relationships and covenants not to compete) and goodwill in accordance with SFAS 141. The intangible assets are being amortized over their respective estimated useful lives of seven and five years. The preliminary purchase price was allocated as follows (in thousands):

	May 1, 2007
Fair value of net tangible assets acquired and liabilities assumed	
Accounts receivable, net	\$ 992
Other current assets	63
Fixed assets, net	2,409
Accrued compensation	(159)
	3,305

## Edgar Filing: DIGIRAD CORP - Form 10-Q

Fair value of identifiable intangible assets acquired:	
Customer relationships	2,600
Covenants not to compete	300
	2,900
Goodwill	2,699
Total purchase price	\$ 8,904

**Table of Contents**

The accompanying consolidated statement of operations for the three months ended June 30, 2007 reflects the operating results of Ultrascan since the date of the acquisition. These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be an indicator of the results of operations that would have actually resulted had the acquisition occurred on January 1, 2007, or of future results of operations. Assuming the acquisition of Ultrascan occurred on January 1, 2007, the pro forma unaudited results of operations would have been as follows for the three and six months ended June 30, 2007:

	Three months	Six months
	ended June 30, 2007	ended June 30, 2007
Revenues	\$ 19,452	\$ 38,981
Net income	70	9
Net income per share	0.00	0.00

The above pro forma unaudited results of operations do not include pro forma adjustments related to the costs of integration.

**7. Intangible Assets and Goodwill**

The components of intangible assets and goodwill consisted of the following (in thousands):

	Estimated Useful Life (years)	June 30, 2007		Net Book Value
		Gross Amount	Accumulated Amortization	
<b>Intangibles subject to amortization:</b>				
Customer relationships	7	\$ 2,600	\$ 87	\$ 2,513
Covenants not to compete	5	300	10	290
Patents	15	499	117	382
Trademarks	15	56	22	34
Total		3,455	236	3,219
<b>Intangibles not subject to amortization</b>				
Goodwill		2,699		2,699
<b>Total intangibles and goodwill:</b>		<b>\$ 6,154</b>	<b>\$ 236</b>	<b>\$ 5,918</b>

	Estimated Useful Life (years)	December 31, 2006		Net Book Value
		Gross Amount	Accumulated Amortization	
<b>Intangibles subject to amortization:</b>				
Patents	15	\$ 499	\$ 107	\$ 392
Trademarks	15	56	20	36
<b>Total intangibles and goodwill:</b>		<b>\$ 555</b>	<b>\$ 127</b>	<b>\$ 428</b>

The aggregate amortization expense for the three and six months ended June 30, 2007 was \$103,000 and \$109,000, respectively. Estimated future amortization expense related to intangible assets with finite lives at June 30, 2007 is as follows:

# Edgar Filing: DIGIRAD CORP - Form 10-Q

	In Thousands
2007 (remaining 6 months)	\$ 408
2008	714
2009	589
2010	438
2011	342
2012	241
Thereafter	487
<b>Total</b>	<b>\$ 3,219</b>

**Table of Contents****8. Segments**

Our reporting segments have been determined based on the nature of the products and/or services offered to customers or the nature of their function in the organization. We evaluate performance based on the operating income contributed by each segment. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

Segment results are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
<b>Gross profit by segment:</b>				
DIS	\$ 3,656	\$ 3,436	\$ 6,915	\$ 6,221
Product	2,154	2,236	4,337	3,844
Consolidated gross profit	\$ 5,810	\$ 5,672	\$ 11,252	\$ 10,065
<b>Income (loss) from operations by segment:</b>				
DIS	\$ 202	\$ (902)	\$ 325	\$ (2,514)
Product	(342)	(734)	(881)	(2,422)
Consolidated loss from operations	\$ (140)	\$ (1,636)	\$ (556)	\$ (4,936)
<b>Depreciation and amortization of intangible assets by segment:</b>				
DIS	\$ 922	\$ 891	\$ 1,550	\$ 1,929
Product	240	290	473	601
Consolidated depreciation and amortization	\$ 1,162	\$ 1,181	\$ 2,023	\$ 2,530
<b>Identifiable assets by segment:</b>				
DIS	\$ 27,270	\$ 13,605	\$ 27,270	\$ 13,605
Product	42,167	57,289	42,167	57,289
Consolidated assets	\$ 69,437	\$ 70,894	\$ 69,437	\$ 70,894

**9. Commitments and Contingencies*****Compliance with Laws and Regulations***

We are, directly or indirectly through our clients, subject to extensive regulation by the federal government, the states and foreign countries in which we conduct business. The healthcare laws applicable to us are complex and are subject to variable interpretations. We have established a compliance program to identify any compliance issues, correct any identified issues and assist us in remaining in compliance with the applicable healthcare laws, and have instituted other safeguards intended to help prevent any violations of the laws and to remedy any situations that could give rise to violations. We can provide no assurance that these measures will be successful in preventing compliance violations and the resulting fines, penalties or damages.

***Legal Matters***

In the normal course of business, we have been, and will likely continue to be, subject to litigation or administrative proceedings incidental to our business, such as claims related to customer disputes, employment practices, wage and hour disputes, product liability, professional liability, commercial disputes, licensure restrictions or denials, and warranty or patent infringement. Responding to litigation or administrative proceedings, regardless of whether they have merit, can be expensive and disruptive to normal business operations. As litigation and the administrative proceedings are inherently uncertain, we cannot predict the outcome of such matters. We can provide no assurance that the ultimate outcome, either individually or in the aggregate, will not have a material adverse effect on our business or financial results.



## 10. Income Taxes

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), which clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes. The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At January 1, 2007, we had net deferred tax assets of \$36.8 million. These deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carryforwards and federal and state research and development ( R&D ) credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset our net

**Table of Contents**

deferred tax asset. Additionally, the future utilization of our NOL and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. Until we have determined whether such an ownership change has occurred, and until the amount of any limitation becomes known, no amounts are being presented as an uncertain tax position in accordance with FIN 48. Management believes that the amount subject to limitation could be significant. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

We file income tax returns in the U.S. and in various state jurisdictions. We are no longer subject to income tax examination by tax authorities for years prior to 2003; however, our net operating loss and research and development carryforwards arising prior to that year are subject to adjustment. Our policy is to recognize interest and penalties related to income tax matters as a component of income tax expense.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2006 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 20, 2007. Operating results are not necessarily indicative of results that may occur in future periods.

This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption Risk Factors. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, product development, cost savings initiatives, industry, economic and market conditions, financial condition, liquidity and capital resources and results of operations. In this report, for example, we make forward-looking statements regarding our expectations about revenue growth in DIS as we expand into new markets and continue to improve utilization rates within existing markets, growth in our ultrasound services, integration of Ultrascan and the resultant expansion of our services, competition in local and regional markets, our efforts to obtain accreditation for our DIS hubs, the effects of changes to the Stark Law, the size and impact of potential Medicare and other third party payor reimbursement decreases, the roll-out of our multi-headed Cardius XPO camera into DIS and the value it represents to our customers, persistent pricing pressures affecting our sales of gamma cameras, our expectation regarding future sales of our general purpose single-head camera and continuing investments in research and development initiatives. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, projects, can, could, may, will, would, or similar expressions. For those statements, we undertake no obligation to update or revise our forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

**Overview**

We are a leading provider of diagnostic nuclear and ultrasound imaging systems and services to physicians' offices, hospitals and other medical services providers. We designed and commercialized the first solid-state nuclear gamma camera for the detection of cardiovascular disease and other medical conditions. Our imaging systems are mobile as well as fixed and provide enhanced operability, improved patient comfort and, in the case of our triple-headed Cardius®-3 XPO system, shorter image acquisition time when compared to traditional vacuum tube cameras. The cameras and accompanying equipment fit easily into floor spaces as small as seven feet by eight feet and facilitate the delivery of nuclear medicine procedures in a physician's office, an outpatient hospital setting or within multiple departments of a hospital.

**First Half 2007 Financial Highlights**

Our consolidated revenues were \$36.4 million during the six months ended June 30, 2007 (2007), which represented a decrease of \$1.6 million, or 4.3%, over the comparable prior year period (2006) due to a decrease in revenue in both segments of our business. In DIS, revenue decreased \$1.1 million, or 4.1%, to \$25.5 million, primarily due to DIS having phased out the delivery of stress agents in June of 2006, partially offset by an increase in ultrasound imaging services revenue due to the acquisition of Ultrascan, Inc. (Ultrascan) on May 1, 2007 (see Note 6 of the condensed consolidated financial statements included in Part I, Item 1). DIS began to phase out providing stress agents used in some imaging procedures in June 2006. As a result, we recognized no stress agent revenue in 2007 compared to \$2.0 million recognized in the first half of 2006. In the product business, revenue decreased \$0.5 million, or 4.6%, to \$10.8 million due to a change in product mix and lower average sales prices of our gamma cameras. Consolidated net income for the six months ended June 30, 2007 increased to \$0.3 million compared to a net loss of \$4.0 million during the same period in 2006, primarily due to lower operating expenses, including lowering our research and development, sales, and general and administrative headcount during the fourth quarter of 2006.

As of June 30, 2007, our DIS segment operated 130 nuclear and ultrasound systems in 22 states and the District of Columbia. On May 1, 2007, we acquired all the assets and assumed some liabilities and debt from Ultrascan, expanding our ultrasound services primarily in the Southeast. DIS imaging system utilization was 60% during the three months ended June 30, 2007 and in the same period of 2006. Our DIS gross margins in 2007 increased to 27.1% compared to 23.4% in 2006, due primarily to lower pharmaceutical costs and a reduction in depreciation expense.

As of June 30, 2007, DIS operated 87 nuclear cameras compared to 80 as of June 30, 2006. In connection with our plan to upgrade our DIS nuclear camera fleet over the next few years, we placed 23 additional multi-headed cameras into our DIS

## **Table of Contents**

business in the first half of 2007, bringing the total number of such cameras in the fleet to 42. We continue to obtain additional hub accreditation to respond to the reimbursement requirements of some third party payors. As of June 30, 2007, we had obtained accreditation from the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories for 27 of our 42 DIS hub locations. We are also in the process of submitting an application to obtain ultrasound imaging accreditation through the Intersocietal Commission for the Accreditation of Echocardiography Laboratories.

Our product business delivered 38 gamma cameras in the first half of 2007, an increase of one system compared to 2006. Product revenue decreased as compared to the prior year period by \$0.5 million, primarily due to a change in the mix of cameras sold and reduced average selling prices due to continuing competitive pricing pressures. Product gross margins improved to 40.0% in 2007 compared to 33.8% during 2006, due primarily to reduced labor and overhead expenses and improved manufacturing yields. During the first half of 2007, we expanded our product portfolio by adding the XPO features already available on our Cardius-3 camera to the Cardius-1 and Cardius-2 cameras. Our new Cardius XPO camera series allows physicians to choose among single-, dual- and triple-head cameras to accommodate their practices' speed and throughput needs, or to upgrade a single head camera to a dual- or triple- head configuration as their practice grows and changes. These cameras can image patients weighing up to 500 pounds and include our latest image acquisition and processing software.

## **Our Market**

The target market for our products and services is comprised of approximately 26,000 cardiologists, 130,000 internists and family practitioners, and hospitals in the United States that perform or could perform nuclear cardiac and ultrasound procedures. As of June 30, 2007, we have provided imaging services through DIS to approximately 741 physicians and physician groups. We have sold 496 cameras through our product segment. As of the second quarter of 2007, over half of our DIS nuclear and ultrasound imaging customers are internists and other practitioners, and the remainder are cardiologists.

According to IMV Medical Information, U.S. procedure volume in nuclear medicine (excluding PET studies) grew by 15% between 2002 and 2005 to an estimated 19.7 million nuclear imaging procedures in 2005, of which some 11.2 million were cardiovascular-specific procedures. According to data from the National Electrical Manufacturers Association, or NEMA, sales of general nuclear imaging equipment declined approximately 10% during 2006 from \$326 million to \$295 million. According to Kalorama Information, the number of ultrasound imaging studies grew by 19% from 62.8 million in 2003 through 74.8 million in 2005, and is projected to grow by 21% to 90.6 million from 2005 through 2007.

We believe our market has been negatively affected by declining reimbursement, significant pricing pressures in the product business, and continuing efforts by some third party payors to reduce health care expenditures by requiring physicians to obtain specific accreditations or certifications, or disallowing reimbursement if imaging is performed with mobile or leased cameras. In addition, one company is selling a mobile nuclear imaging camera for cardiac applications, and competition from local or regional companies providing mobile imaging services has increased. We expect each of these trends to continue.

## **Revenue Sources**

We generated revenues within two primary operating segments: our DIS business and our product sales business. Through DIS, we offer a comprehensive mobile imaging services leasing program as an alternative to purchasing a gamma camera or ultrasound machine for physicians who wish to perform nuclear imaging, echocardiography, vascular ultrasound or any combination of these procedures in their offices by leasing the imaging system, certified personnel and other support required to perform imaging in the physician office. The flexibility of our products and our DIS leasing service allows physicians more control over the diagnosis and treatment of their patients in their offices and to retain revenue from procedures they would otherwise refer elsewhere. We also offer DigiTech leases to customers who own one of our nuclear gamma cameras or ultrasound machines but contract with us to provide staffing and other support services. DIS leasing services are primarily provided to cardiologists and internists. Physicians enter into annual contracts for imaging services delivered on a per-day basis. Our typical lease contracts provide service coverage ranging from once per month to three times per week, adjusted for holidays and vacations. We experience some seasonality in our DIS business related to summer slowdowns (principally relating to vacations), holidays and inclement weather. Historically, the DIS results have been most negatively affected by seasonality in the third quarter.

Our product revenue results primarily from selling solid-state gamma cameras and other ancillary items, and from our camera maintenance contracts. We sell our imaging systems to physician offices, hospitals, and imaging centers primarily in the United States, although we have sold a small number of imaging systems internationally. We do not anticipate that the international market will be a significant source of revenues in the foreseeable future.



**Table of Contents****Trends and Drivers**

We have generated net income for two consecutive quarters and improved gross margins in both our business segments in this quarter as the result of our efforts to enhance operating efficiencies, lower material costs and reduce operating expenses. We accelerated the diversification of our mobile service model with the acquisition of Ultrascan and are now delivering mobile ultrasound imaging services, primarily in the Southeast.

The decrease in DIS revenue is primarily attributable to the decision to stop the delivery of stress agents, which contributed revenue of approximately \$2.0 million to our 2006 results. The number of physicians each quarter who either bought their own cameras, terminated their mobile imaging service contracts or switched to other mobile imaging service providers increased during the second half of 2006, and has remained at approximately the same number over the past three quarters. We attribute this trend primarily to increasing competition from local and regional companies offering mobile imaging products or services.

We also note that the Centers for Medicare and Medicaid Services, or CMS, implemented reimbursement cuts of approximately 8.5% and 2% for 2007, as compared to 2006, for the imaging procedures most often performed by our nuclear imaging and ultrasound physician customers, respectively. In July 2007, CMS proposed regulations that could result in additional reimbursement reductions of approximately 10% and 18% for 2008 for these nuclear and ultrasound procedures, respectively; furthermore, an additional CMS proposal could result in the elimination of our commonly used ultrasound reimbursement code. In the product business, industry sources have predicted that the rate of decline of sales of cardiac-specific nuclear cameras will slow to approximately 5% in 2007, and that purchases of multi-head cameras will far outpace those of single-head cameras. Data from NEMA further indicates that sales of general nuclear imaging equipment increased approximately 1% in the first quarter of 2007 when compared to the first quarter of 2006, and the market for cardiac-specific nuclear cameras increased 7% in the first quarter of 2007 when compared to the first quarter of 2006. Pricing pressures persist in the cardiac-specific camera market, evidenced by the declining average selling price of nuclear cameras. We have invested in research and development to improve the image quality, speed, reliability, cost structure and overall performance of our multi-headed cameras and software. The hospital market has expressed a renewed interest in our general purpose single-head camera, and we expect to continue to sell more cameras in this market in 2007.

For the quarter ended June 30, 2007, we are also reporting a new asset utilization metric to track the productivity of our DIS assets and drive margin improvements. The metric counts the number of nuclear gamma cameras and ultrasound imaging machines, and measures the number of days, out of the total available days during the period, in which they were actually used to deliver services to DIS customers. For the quarter ended June 30, 2007, DIS operated 130 units with an overall utilization rate of 60% as compared to 80 units and a utilization rate of 60% for the same period in 2006. The increase in units was attributable primarily to the Ultrascan acquisition.

**Results of Operations**

The following table sets forth our results from operations, expressed as percentages of revenues for the three and six months ended June 30, 2007 and 2006:

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Revenues:				
DIS	70.8%	70.5%	70.2%	70.1%
Product	29.2	29.5	29.8	29.9
Total revenues	100.0	100.0	100.0	100.0
Total cost of revenues	69.1	70.2	69.0	73.5
Gross profit	30.9	29.8	31.0	26.5
Operating expenses:				
Research and development	4.2	5.9	4.3	5.8
Sales and marketing	10.3	10.8	11.1	11.9
General and administrative	16.6	21.6	16.8	21.7
Amortization of intangible assets	0.5	0.1	0.3	0.1
Total operating expenses	31.6	38.4	32.5	39.5

## Edgar Filing: DIGIRAD CORP - Form 10-Q

Loss from operations	(0.7)	(8.6)	(1.5)	(13.0)
Other income	2.0	2.3	2.4	2.4
Net income (loss)	1.3%	(6.3)%	0.9%	(10.6)%

## **Table of Contents**

### ***Comparison of Three Months Ended June 30, 2007 and 2006***

#### ***Revenues***

*Consolidated.* Consolidated revenue was \$18.8 million for 2007, which represents a decrease of \$0.2 million, or 1.1% over 2006, primarily as a result of lower DIS revenues, partially offset by an increase in ultrasound imaging services revenue from the acquisition of Ultrascan. DIS and product revenue accounted for 70.8% and 29.2%, respectively, of total revenues for 2007, compared to 70.5% and 29.5%, respectively, for 2006. We expect DIS revenue to continue to represent the larger percentage of our consolidated revenue in future periods.

*DIS.* Our DIS revenue was \$13.3 million for 2007, which represents a decrease of \$0.1 million, or 0.6%, over the prior year quarter. This decrease was primarily the result of our decision to discontinue the sale of stress agents in June 2006 (stress agent revenue was \$0.9 million for the second quarter of 2006) and from an increase in lost business rates during the past few quarters. This decrease in revenue was partially offset by the ultrasound imaging services revenue generated from the assets recently acquired from Ultrascan. We seek to increase our DIS revenue by broadening our services with ultrasound imaging, penetrating existing markets and expanding into new markets. Any growth will fluctuate, however, based on seasonality stemming from physician vacations, holidays, inclement weather, lost business and the start up time required as we enter new geographic areas.

*Product.* Our product revenue was \$5.5 million for 2007, representing a decrease of \$0.1 million, or 2.3%, over the prior year quarter. The decrease in product revenue is attributable to a decline in the average selling prices for our gamma cameras and selling more used cameras in 2007 than in 2006.

#### ***Gross Profit***

*Consolidated.* Consolidated gross profit was \$5.8 million for 2007, representing an increase of \$0.1 million or 2.4%, compared to the prior year quarter. The increase in consolidated gross profit is principally the result of our efforts to improve operational efficiencies, lower material and supply costs. Consolidated gross profit as a percentage of revenue increased to 30.9% for 2007 from 29.8% for 2006.

*DIS.* Cost of DIS revenue consists primarily of labor, radiopharmaceuticals, equipment depreciation, and other costs associated with the provision of services. Cost of DIS revenue decreased to \$9.7 million for 2007, representing a decrease of \$0.3 million, or 3.0%, over the prior year quarter, primarily a result of a reduction in pharmaceutical costs associated with our decision to discontinue the sale of stress agents. DIS gross profit increased to \$3.7 million for 2007, which represents an increase of \$0.2 million, or 6.4%. DIS gross profit as a percentage of revenue increased to 27.4% for 2007 from 25.6% for 2006.

*Product.* Cost of goods sold primarily consists of materials, labor and overhead costs associated with the manufacturing and warranty of our products (warranty costs are charged to cost of goods sold in the period our cameras are sold and are based on our historical experience with failure rates and repair costs). Cost of goods sold was \$3.3 million for 2007, which was unchanged from the prior year quarter. Product gross profit decreased to \$2.2 million for 2007, which represents a decrease of \$0.1 million, or 3.7%. Product gross profit as a percentage of revenue decreased to 39.2% for 2007 from 39.8% for 2006. The decline in product margin is due to the decline in the average selling prices for our gamma cameras.

#### ***Operating Expenses***

*Research and Development.* Research and development expenses consists primarily of costs associated with the design, development and enhancement of our products. The primary costs are salaries and fringe benefits, development material costs, facility and overhead costs, consulting fees, and non-recurring engineering costs. Research and development expenses were \$0.8 million for 2007, which represents a decrease of \$0.3 million, or 29.2%, compared to the prior year quarter. This was primarily attributable to a reduction in the number of research personnel and decreased spending on indirect materials associated with new product development. Research and development expenses were 4.2% of total revenue for 2007 compared to 5.9% for 2006. In the future, we expect to maintain our investment in research and development as we innovate and seek to improve our existing technology.

*Sales and Marketing.* Sales and marketing expenses consist primarily of salaries, commissions, bonuses, recruiting costs, travel, marketing and collateral materials and trade show costs. Sales and marketing expenses were \$1.9 million for 2007, representing a decrease of \$0.1 million or 6.1%, compared to the prior year quarter, primarily as a result of a reduction in personnel related expenses. Sales and marketing expenses were 10.3% of total revenue for 2007 compared to 10.8% for 2006. We expect to increase our sales and marketing efforts as we expand into new territories and launch a marketing program for echocardiography and vascular ultrasound.



## Edgar Filing: DIGIRAD CORP - Form 10-Q

*General and Administrative.* General and administrative expenses consist primarily of salaries and other related costs for finance, accounting, human resources and other personnel, and legal and other professional fees and insurance. General and administrative expenses were \$3.1 million for 2007, representing a decrease of \$1.0 million or 24.1%, compared to the prior year quarter. This resulted from lower legal costs and a reduction in spending associated with recruiting and other outside services. Additionally, we experienced a \$0.2 million reduction in stock based compensation costs. General and administrative expenses were 16.6% of total revenue for 2007 compared to 21.6% for 2006.

---

**Table of Contents**

*Other Income (Expense)*

Other income (expense) consists primarily of interest income net of interest expense and other expenses. The decrease in other income reflects the lower levels of average cash and investments balances in 2007 compared to 2006 as a result of the acquisition of Ultrascans net assets.

*Net Income (Loss)*

Our net income was \$0.2 million for 2007 compared to a net loss of \$1.2 million for 2006, primarily as a result of the factors described above.

***Comparison of Six Months Ended June 30, 2007 and 2006***

*Revenues*

*Consolidated.* Consolidated revenue was \$36.4 million for 2007, which represents a decrease of \$1.6 million, or 4.3% over 2006, primarily as a result of a decrease in revenues in DIS. DIS and product revenue accounted for 70.2% and 29.8%, respectively, of total revenues for 2007, compared to 70.1% and 29.9%, respectively, for 2006.

*DIS.* Our DIS revenue was \$25.5 million for 2007, which represents a decrease of \$1.1 million, or 4.1%, over the prior year period. This decrease was primarily the result of our decision to discontinue the sale of stress agents in June 2006 (stress agent revenue was \$2.0 million for 2006). This decrease in revenue was partially offset by the revenue generated from the recent Ultrascan acquisition.

*Product.* Our product revenue was \$10.8 million for 2007, representing a decrease of \$0.5 million, or 4.6%, over the prior year period. The decrease in product revenue is attributable to a decline in the average selling prices for our gamma cameras and selling more used cameras in 2007 than in 2006, which was partially offset by increasing maintenance contract revenues.

*Gross Profit*

*Consolidated.* Consolidated gross profit was \$11.3 million for 2007, representing an increase of \$1.2 million or 11.8%, compared to the prior year. The increase in consolidated gross profit is principally the result of our efforts to improve operational efficiencies, lower material and supply costs and lower depreciation. Consolidated gross profit as a percentage of revenue increased to 31.0% for 2007 from 26.5% for 2006.

*DIS.* Cost of DIS revenue decreased to \$18.6 million for 2007, representing a decrease of \$1.8 million, or 8.8%, over the prior year, primarily a result of a reduction in pharmaceutical costs associated with our decision to discontinue the sale of stress agents discussed above, and a decrease in depreciation expenses of \$0.5 million. DIS gross profit increased to \$6.9 million for 2007, which represents an increase of \$0.7 million, or 11.2%. DIS gross profit as a percentage of revenue increased to 27.1% for 2007 from 23.4% for 2006.

*Product.* Cost of goods sold was \$6.5 million for 2007, representing a decrease of \$1.0 million, or 13.6%, compared to the prior year. Product gross profit increased to \$4.3 million for 2007, which represents an increase of \$0.5 million, or 12.8%. Product gross profit as a percentage of revenue increased to 40.0% for 2007 from 33.8% for 2006. Product margin improvement is due to a reduction in material costs and an improvement in operating efficiency.

*Operating Expenses*

*Research and Development.* Research and development expenses were \$1.6 million for 2007, which represents a decrease of \$0.6 million, or 28.9%, compared to the prior year. This was primarily attributable to a reduction in the number of research personnel and decreased spending on indirect materials associated with new product development. Research and development expenses were 4.3% of total revenue for 2007 compared to 5.8% for 2006.

*Sales and Marketing.* Sales and marketing expenses were \$4.0 million for 2007, representing a decrease of \$0.5 million or 10.8%, compared to the prior year. This was primarily attributable to a reduction in personnel and travel costs. Sales and marketing expenses were 11.1% of total revenue for 2007 compared to 11.9% for 2006.

*General and Administrative.* General and administrative expenses were \$6.1 million for 2007, representing a decrease of \$2.1 million or 26.1%, compared to the prior year, as a result of lower personnel, legal and recruiting costs and a reduction in spending on outside services. General and administrative expenses were 16.8% of total revenue for 2007 compared to 21.7% for 2006.



## **Table of Contents**

### *Other Income (Expense)*

Other income (expense) consists primarily of interest income, net of interest and other expenses. The decrease in other income reflects the lower levels of average cash and investments balances in 2007 compared to 2006 as a result of the acquisition of Ultrascans net assets.

### *Net Income (Loss)*

Our net income was \$0.3 million for 2007 compared to a net loss of \$4.0 million for 2006, primarily as a result of the factors described above.

## **Liquidity and Capital Resources**

We require capital principally for debt service, capital expenditures, acquisitions, and working capital to finance accounts receivable and inventory. Our working capital requirements vary from period to period depending on manufacturing volumes, the timing of deliveries and the payment cycles of our customers. Our capital expenditures consist primarily of DIS nuclear cameras, ultrasound machines, vans, and computer hardware and software. As of June 30, 2007, we had cash, cash equivalents and investments of \$32.2 million. We currently invest our cash reserves in money market funds, high-grade auction rate securities and U.S. government or corporate debt securities. Based upon our current level of expenditures, we believe our current working capital together with cash flows from operating activities, will be adequate to meet our anticipated cash requirements for working capital, debt service and capital expenditures for at least the next 12 months.

Net cash provided by operations totaled \$1.2 million for the six months ended June 30, 2007 due to positive cash flow from net income and non-cash charges (including depreciation, amortization and stock-based compensation). The cash used in operations is due to increases in receivables and the reduction of accounts payable and accrued compensation. The increase in receivables is due to the increase in sales during our second quarter (in comparison to our traditionally slow fourth quarter sales) and an increase in overall days-sales-outstanding (DSO) principally related to the Ultrascan acquisition. The decrease in accounts payable reflects routine fluctuation in vendor activity and the decrease in accrued compensation is primarily associated with the payment of year end bonuses to our employees. Net cash used in investing activities amounted to \$1.3 million for the six months ended June 30, 2007. Cash used in investing activities is comprised of \$8.9 million in payments made for the acquisition of assets and liabilities of Ultrascan, cash flow from net maturities of securities available-for-sale of \$11.9 million, and \$4.3 million used for capital expenditures primarily associated with our DIS operations. Net cash used in financing activities amounted to approximately \$0.1 million for the six months ended June 30, 2007, and represents the repayment of capital lease obligations, net of proceeds arising from the exercise of stock options.

The acquisition of assets and liabilities of Ultrascan may require additional consideration of cash and common stock of up to \$3.9 million to be paid to the seller or its designees in the event that certain financial milestones are achieved over the next four years.

## **Critical Accounting Policies**

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related 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. We continually evaluate our estimates and judgments, the most critical of which are those related to revenue recognition and inventory valuation. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

There were no significant changes during the quarter ended June 30, 2007 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

*New accounting requirement.* Effective January 1, 2007, we adopted Financial Accounting Standards Board, or FASB, Interpretation No. 48,

Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109, or FIN No. 48, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN No. 48 provides guidance on the derecognition, classification, accounting within interim periods and reporting requirements for uncertain tax positions. The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. We do not anticipate that the adoption of FIN No. 48 will have a material effect on our effective tax rate in future periods.



## **Table of Contents**

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments. Changes in interest rates over time will increase or decrease our interest income.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures and internal controls that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures and internal controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost benefit relationship of possible controls and procedures and internal controls.

As required by the Securities and Exchange Commission Rule 13a-15(e) and Rule 15d-15(e), we carried out an evaluation, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting.**

In addition, an evaluation was performed under the supervision and participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal controls over financial reporting that has occurred during our last fiscal quarter that has materially affected, or is reasonably likely to affect materially, our internal controls over financial reporting. There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Due to the acquisition of Ultrascan, we implemented processes and controls over revenue and operating expenses to mitigate the risks associated with the acquisition. However, as of June 30, 2007, we have not tested the operating effectiveness of the new internal controls related to the integration of Ultrascan. Other than this change, there have been no significant changes in our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In the normal course of business, we have been and will likely continue to be subject to litigation or administrative proceedings incidental to our business, such as claims related to customer disputes, employment practices, wage and hour disputes, product liability, professional liability, commercial disputes, licensure restrictions or denials, and warranty or patent infringement. Responding to litigation or administrative proceedings, regardless of whether they have merit, can be expensive and disruptive to normal business operations. As litigation and the administrative proceedings are inherently uncertain, we cannot predict the outcome of such matters. We can provide no assurance that the ultimate outcome, either individually or in the aggregate, will not have a material adverse effect on our business or financial results.

**ITEM 1A. RISK FACTORS**

**Risks Related to Our Business and Industry**

*Our industry is highly competitive.*

The nuclear imaging industry is highly competitive, subject to rapid change and significantly affected by new product introductions and market activities of other industry participants. Our primary competitors with respect to nuclear imaging systems include Philips Medical Systems, General Electric Healthcare and Siemens Medical Systems. All of these competitors offer

## **Table of Contents**

a full line of imaging cameras for each diagnostic imaging technology, including x-ray, magnetic resonance imaging, computerized tomography, ultrasound and nuclear medicine, as well as hybrid modalities that combine, for example, the technologies of positron emission tomography, or PET, with computed tomography, or CT. Many of our competitors and potential competitors enjoy significant advantages over us, including significantly greater name recognition and financial, technical, service and marketing resources; established relationships with healthcare professionals, customers and third-party payors; established distribution networks; technical features our current products do not possess; multiple product lines and the ability to offer rebates or bundle products to offer discounts or incentives; and greater resources for product development, sales and marketing.

Certain medical device companies are developing solid-state cameras that may compete with our product offerings. A privately-held company, Gamma Medica, is marketing a solid-state gamma camera for breast imaging. A second company, Spectrum Dynamics, is marketing a solid-state gamma camera that we believe may be marketed in the cardiac segment. A third company, Mid-Atlantic Imaging, is marketing a mobile cardiac camera based on vacuum tube technology. We anticipate that additional companies will dedicate resources to developing competing products and services that may demonstrate better image quality, ease of use or mobility than our imaging systems. If we are unable to compete effectively against our existing and future competitors, our sales will decline and our business will be harmed.

In providing DIS lease services, we compete against small businesses employing traditional vacuum tube cameras that cannot be moved in and out of physician offices. We also compete against physicians and companies that use Digirad and other cameras in local and regional mobile imaging businesses, some of which have the advantage of a lower cost structure, and competition from these mobile operations may increase. In addition, we compete against imaging centers that install nuclear gamma cameras and make them available to referring physicians in their geographic vicinity. If these competitors are able to win significant portions of our business, our sales will decline and our business will be harmed.

The competitive nature of the nuclear imaging industry has affected the volume of both our camera sales and our leasing services, and the pricing of our gamma cameras. We anticipate that these pressures will continue.

In providing ultrasound imaging lease services, we compete against many small businesses, many of which have lower operating costs. If we cannot win business from these competitors, our plans of increasing our ultrasound leasing business may fail and our overall business may be harmed.

***If the market for nuclear imaging cameras continues to decrease, or if we are not successful in expanding our market share or product and service offerings, our revenues will decline and our business will be harmed.***

Data from the National Electrical Manufacturers Association, or NEMA, indicates that sales of nuclear imaging equipment, excluding maintenance revenue, declined approximately 10% in 2006, and NEMA forecasts the rate of descent to slow in 2007 to approximately 5%; data from NEMA further indicates that sales of general nuclear imaging equipment increased approximately 1% in the first quarter of 2007 when compared to the first quarter of 2006, and the market for cardiac-specific nuclear cameras increased 7% in the first quarter of 2007 when compared to the first quarter of 2006. We believe this decline may be attributable to concerns about reimbursement changes and the increasing adoption of alternative imaging modalities, such as magnetic resonance imaging, computerized tomography, positron emission tomography, and hybrids among these modalities. We believe our market has been negatively affected by declining and more restricted reimbursement, significant pricing pressures in the product business and increased competition in the mobile imaging business. We expect each of these trends to continue.

If these trends continue and we are unable to offset their effects on our business by expanding our market share or successfully introducing alternative products and services, our business will be significantly harmed.

***Changes in coverage and reimbursement policies of third-party payors may adversely affect our ability to market and sell our products and services.***

Private third-party payors continue to act to contain or reduce healthcare costs through various means, including the movement to managed care systems where healthcare providers contract to provide comprehensive healthcare for a fixed fee per patient. Some third party payors in geographic locations currently served by us issued guidelines preventing our physician customers from obtaining reimbursement for procedures they perform unless they own or lease our cameras on a full time basis. These and other payors are also requiring physicians to be accredited by either the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL) or by the American College of Radiology, and to meet certain other privileging standards. Some of these privileging standards also exclude physicians who are not radiologists or cardiologists from obtaining reimbursements for the professional component of nuclear imaging procedures. An increasing number of our DIS customers are non-cardiologists who would not currently meet the certifications required by payors in certain geographic areas. We have obtained accreditation from the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories for 27 of our hub locations to



address certification requirements.

## **Table of Contents**

Third party payors have also begun to require accreditation for certain ultrasound imaging procedures, and we are in the process of submitting an application to obtain ultrasound imaging accreditation through the Intersocietal Commission for the Accreditation of Echocardiography Laboratories. We cannot assure you that we will be successful in obtaining additional certifications, or that obtaining them will satisfy the requirements of these payors. We also cannot assure you that these third party payor guidelines will be changed, or that they will not be adopted by other third party payors, including Medicaid and Medicare. These continued efforts to restrict reimbursement have resulted in the denial of reimbursement in some instances. An increase in such denials will negatively affect our DIS business and product sales.

### ***Acquisitions could adversely affect our operations and create unanticipated liabilities and other harmful consequences.***

We have acquired substantially all of the assets of Ultrascan and may make additional acquisitions and strategic investments in the future. We cannot assure you that we would be able to successfully complete any acquisition or that we will be able to successfully integrate any acquired business, product or technology into our company in a cost-effective and non-disruptive manner. The Ultrascan acquisition, as well as any future transactions, may also result in dilutive issuances of equity securities, use of our cash resources, incurrence of debt and amortization of expenses related to intangible assets. Such transactions could be material to our financial condition and results of operations. In addition, the process of integrating an acquired company, business or technology may create unforeseen operating difficulties and expenditures and is risky. Acquisitions involve risks, including:

the difficulty of assimilating the operations and personnel of our acquired companies into our operations;

the potential disruption of our ongoing business and distraction of management;

additional operating losses and expenses of the businesses we acquired or in which we invested;

the difficulty of integrating acquired technology and rights into our services and unanticipated expenses related to such integration;

the failure of strategic investments to perform as expected;

the potential for patent and trademark infringement claims against the acquired company;

the impairment of relationships with customers and partners of the companies we acquired or in which we invested or our customers and partners as a result of the integration of acquired operations;

the impairment of relationships with employees of the acquired companies or our employees as a result of integration of new management personnel;

the difficulty of integrating the acquired company's accounting, management information, human resources and other administrative systems; and

the impact of known potential liabilities or unknown liabilities associated with the companies we acquired or in which we invested. Our failure to be successful in addressing these risks or other problems encountered in connection with our past or future acquisitions and strategic investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, incur unanticipated liabilities and harm our business generally.

## Edgar Filing: DIGIRAD CORP - Form 10-Q

In addition, Ultrascan has not been required to prepare a report on the effectiveness of its internal controls over financial reporting because it was not subject to the informational requirements of the Securities Exchange Act of 1934, as amended. We have implemented process and controls over revenue and operating expenses since we acquired Ultrascan in May 2007, but, as of June 30, 2007, we have not tested the operating effectiveness of the new internal controls related to the integration of Ultrascan. While we expect to complete this process by the end of the second quarter of 2008, we cannot assure you that the measures we have taken to date or any future measures will be sufficient. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our prior period financial statements. Ineffective internal controls could also cause investors to lose confidence in our reported financial reporting.

## **Table of Contents**

***Failure to attract qualified managers, engineers and imaging technologists, or high employee attrition rates, could limit our growth and adversely affect our business.***

Our success is dependent on the efforts of our key executives and technical, sales and managerial personnel and our ability to retain them. Losing one or more of these individuals could place a significant strain on our remaining management team and we may have difficulty replacing any of these individuals. Our future growth and ability to generate profits will depend in part upon our ability to identify, hire and retain nuclear imaging technologists, certified cardiographic technicians, trained and registered sonographers, nurses, radiation safety officers, engineers, management, sales personnel and other highly skilled personnel.

Hiring qualified management and technical personnel will be difficult due to the limited number of qualified candidates. Competition for these types of employees, particularly nuclear imaging technologists and engineers, is intense in the medical imaging field. Failure to attract, hire and retain key personnel could have an adverse effect on our business, financial condition and results of operations. For the six months ended June 30, 2007, we experienced a 22% rate of employee turnover for the combined service and product segments. If we are unable to improve upon this metric, our business and financial condition may continue to be adversely affected.

***Our imaging systems and DIS services may become obsolete, and we may not be able to timely develop new products, product enhancements or services that will be accepted by the market.***

Our nuclear and ultrasound imaging systems and DIS services may become obsolete or unmarketable as other products or services utilizing new technologies or the development of hybrid imaging modalities are introduced by our competitors or new industry standards emerge. We cannot assure you that any future products and enhancements will be accepted by the market. To be successful, we will need to enhance our products or services and to design, develop and market new products that successfully respond to competitive developments, all of which may be expensive and time consuming.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to properly identify and anticipate physician and patient needs; develop or acquire new products or enhancements in a timely manner; obtain the necessary regulatory approvals or clearances for new products or product enhancements in a timely manner; provide adequate training to users of our products; price our products competitively; obtain required licensure; continue to offer cost-competitive products and services despite increasing reimbursement restrictions and pricing pressures; comply with changing or new regulatory requirements; and develop an effective marketing, sales and distribution network.

If we are unable to meet these requirements, our business, financial condition and results of operations will suffer. In addition, even if our customers acquire new products, services or product enhancements, the revenues from such sales may not be sufficient to offset the significant costs associated with developing and offering such products, services or enhancements to customers. In addition, any announcements of new products, services or enhancements may cause customers to decline or cancel their purchasing decisions in anticipation of replacements.

***If we are unable to expand our DIS business, our growth rates could be significantly diminished and our business could be materially harmed.***

We plan to grow our DIS business by expanding into new states, adding new hub locations in states in which we currently operate and increasing existing hub and asset utilization by adding physician customers and routes. Our progress in expanding into new geographies has been slower than anticipated, we have closed unprofitable hubs, our hub utilization and customer density in some geographies have decreased, and we cannot assure you that we will be able to sell our leasing services at the rates we anticipate, or that physicians or hospitals in these new markets will accept our imaging products or services, or that we can retain our current customers. Our expansion into additional markets is subject to inherent risks, including those associated with compliance with applicable state laws and regulations. We may find the laws of states in which we do not currently operate preclude us from operating our DIS business, or require us to change the structure in which we operate our DIS business in such states. In addition, our inability to build awareness of our DIS business through alliances with centers of influence, such as academic institutions and medical centers, could also limit our ability to succeed in these potential markets. Our inability to expand into new markets for any of these reasons could diminish our prospects for growth and profitability.

***Because our imaging systems and DIS services are not widely diversified, a decrease in sales of our products and leasing services could seriously harm our business.***

Our current product and service offerings consist primarily of our line of gamma cameras, including our Cardius-1, Cardius-2, and Cardius-3 XPO Series, 2020tc Imager and SPECTpak PLUS camera systems, all designed for use in the nuclear imaging market segment. We deliver ultrasound imaging services using equipment developed and sold by third parties. In addition, our DIS nuclear



## **Table of Contents**

imaging leasing service utilizes our own line of cameras and at present is focused nearly exclusively on nuclear cardiology. As such, our line of products and services is not as diversified as those of some of our competitors. If the sales of our products or leasing services decline, our business would be seriously harmed, and it would likely be difficult for us to sustain our business while seeking to develop new types of products or services or other markets for our existing products and services. In addition, because our technical know-how and intellectual property have limited applications, we may be unable to leverage these assets to diversify our products and services or to develop other products or sources of revenue outside of the nuclear and ultrasound imaging market.

***If we experience problems with the technologies used in our imaging systems or if delivery of our DIS services is delayed, public perception of our products and service offerings could be harmed and we may lose customers and revenue.***

We have experienced some reliability issues with our camera detector heads and other parts of our imaging systems, and some of the cameras in our DIS fleet are more than four years old. Although we have embarked on a program to upgrade our fleet over a three year horizon, as the period of use of our cameras and ultrasound equipment increases, other defects may occur. Additionally, physicians rely on our DIS services to provide nuclear and ultrasound imaging procedures to their patients on the dates and at the times they have leased. Many factors could prevent us from delivering our DIS services on a timely basis, including equipment failures, unanticipated problems with our mobile Cardius-3XPO camera, weather and the availability of staffing, transportation and necessary supplies. If we are unable to provide physicians or hospitals with our DIS services in a timely and efficient manner, our business would be harmed.

***We are subject to the financial risks associated with providing services through our DIS business.***

There are numerous risks associated with any leasing arrangement, including the possibility that physicians may fail to pay us because of general economic and business conditions, the availability of reimbursement or other reasons. In addition, the number of physicians each quarter who either bought their own cameras, terminated their mobile imaging service contracts or switched to other mobile imaging service providers increased during the second half of 2006, and has remained at approximately the same number over the past three quarters. If this trend were to increase, our business and financial condition could be adversely affected.

***Our manufacturing operations are highly dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.***

We rely on a limited number of third parties to manufacture and supply certain of the key components of our products and services. While many of the components used in our products are available from multiple sources, we obtain some components from single sources, and alternative sources for them may not be readily available. For example, key components of the detector heads and the processing and control software utilized in our gamma cameras are manufactured or supplied by a single source. If we were unable to obtain these components, our ability to build gamma cameras could be materially affected, and we could experience delays in the production of our gamma cameras for an extended period of time that could cause the loss of customers and revenue. Also, we rely on third parties to supply us with radionuclides for use in our nuclear imaging leasing service. If such supplies become subject to a recall or are disrupted, our leasing services could be materially disrupted.

***We have limited marketing, sales and distribution capabilities.***

Our future revenue growth will depend in large part on our success in maintaining and expanding our marketing, sales and distribution channels, which is an expensive and time-consuming process. We are highly dependent upon the efforts of our sales force and third-party distributors to increase our revenue. We use eight independent distributors in the United States and two independent, international sales distributors to market, sell and distribute our products and services. Seven of our domestic distributors are either prohibited from selling competitive products or must use their best efforts not to do so. One of our domestic distributors may sell imaging products that are used or refurbished, meet specified age requirements and are non-cardiac nuclear imaging systems. Our international distributors may sell competing imaging products that are used or refurbished and meet specified age requirements. We face competition for qualified sales employees and may be unable to hire, train, manage and retain such personnel, which could adversely affect our ability to maintain and expand our marketing, sales and distribution network. If we are unable to maintain and expand our direct and third-party marketing, sales and distribution networks, we may be unable to sell enough of our products and imaging services for our business to be profitable and our financial condition and results of operations will likely suffer.

***We are exposed to risks relating to product liability, product recalls, property damage and personal injury and death for which insurance coverage is expensive and potentially inadequate, and our business may be negatively affected by insufficiently insured claims and increased insurance costs.***



## **Table of Contents**

Our operations entail risks relating to claims or litigation relating to product liability, warranty, product recalls, property damage, misdiagnosis, personal injury and death. We may incur significant liability in the event of any such litigation, regardless of the merit of the action. We currently maintain insurance that we believe is adequate with respect to the nature of the risks insured against, including product liability insurance, professional liability insurance, automobile insurance, property insurance, workers compensation insurance and general liability insurance. In many cases such insurance is expensive, and no assurance can be given that we will be able to maintain our current insurance or that we will be able to obtain or maintain comparable or additional insurance in the future on reasonable terms. If we are unable to obtain insurance, or if our insurance is inadequate to cover claims, our cash reserves and other assets could be jeopardized. Additionally, costs associated with maintaining our insurance could become prohibitively expensive, and our ability to become profitable could be diminished.

***Our manufacturing operations and executive offices are located at a single facility that may be at risk from fire, earthquakes or other natural or man-made disasters or crises.***

Our manufacturing operations and executive offices are located at a single facility in Poway, California, near known fire areas and earthquake fault zones. We have taken precautions to safeguard our facilities, including insurance and health and safety protocols. However, any future natural disaster, such as a fire or an earthquake, could cause substantial delays in our operations, damage to or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires and other natural disasters may not be adequate to cover our losses in any particular case.

***The substitution of generic radiopharmaceuticals for one of the patent-protected radiopharmaceutical commonly used by our physician clients could affect our financial results.***

We generate revenue by providing radiopharmaceuticals used in nuclear imaging to our physician customers under our radioactive materials licenses. If the loss of patent protection by one or more such radiopharmaceuticals results in the use of generic versions at significantly lower prices, our revenue and earnings could decline.

## **Risks Related to Government Regulation**

***We must be licensed to handle and use hazardous materials and may be liable for contamination or other harm caused by hazardous materials that we use.***

We use hazardous and radioactive materials in our research and development and manufacturing processes, as well as in the provision of our nuclear imaging services. We are subject to federal, state and local laws and regulations governing use, storage, handling and disposal of hazardous and radioactive materials and waste products, or hazardous materials. We are currently licensed to handle such hazardous materials in all states in which we operate, but there can be no assurances that we will be able to maintain those licenses in the future. In addition, we must become licensed to handle hazardous materials in all states into which we plan to expand. Obtaining and maintaining those additional hazardous materials licenses is an expensive and time consuming process. If we are unable to obtain and maintain the requisite licenses, we will not be able to expand into a state and our ability to grow and become profitable will be reduced. Additionally, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines and the liability and associated legal costs could exceed our resources.

We have also incurred and may continue to incur expenses related to compliance with environmental laws. Such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations. Further, we cannot assure you that the cost of complying with these laws and regulations will not materially increase in the future.

***We spend considerable time and money complying with federal and state laws, regulations, and other rules, and, if we are unable to comply with such laws, regulations and other rules, we could face substantial penalties.***

We are directly, or indirectly through our clients, subject to extensive regulation by both the federal government and the states in which we conduct our business, including the federal Medicare and Medicaid anti-kickback laws; other Medicare laws, regulations, rules, manual provisions, and policies that prescribe the requirements for coverage and payment for services performed by us and our DIS customers; the federal False Claims statutes; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA; the Stark Law; the federal Food, Drug and Cosmetic Act; federal and state radioactive materials laws; state food and drug and pharmacy laws and regulations; state laws that prohibit the practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians; state scope-of-practice laws that require either specific licenses or certifications for our personnel or their direct supervision by the site physician to perform certain tasks in the absence of such licensures or certifications; federal laws, regulations, rules and policies that permit physicians to bill



and receive payment for certain diagnostic tests under the

**Table of Contents**

Medicare Physician Fee Schedule only if certain conditions are satisfied, including the requirement that the physician either personally perform, or adequately supervise the performance of, the tests using equipment they own or lease, and that prohibit physicians from marking up the cost of tests they purchase, rather than perform or supervise, for Medicare patients; and state law equivalents to any of the foregoing federal laws.

We maintain a compliance program to help identify and correct any compliance issues and remain in compliance with all applicable laws, to train employees, to audit and monitor the Company's operations, to provide for a compliance hotline, and to achieve other compliance goals. Like most companies with compliance programs, we occasionally discover compliance concerns. In such cases, we take responsive action, including, when necessary, corrective measures. There can be no assurance that the Company's responsive actions will insulate us from liability associated with any detected compliance concerns.

If our past or present operations are found to be in violation of any of the laws, regulations, rules or policies described above or the other laws or regulations to which we or our customers are subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from federal or state health care programs, or the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could have a negative impact on us. If we are excluded from federal or state health care programs, our customers who participate in those programs could not do business with us. In addition, if we are required to obtain permits or licensure that we do not possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products.***

Federal and state lawmakers from time to time enact new legislation establishing significant changes in the healthcare system. Downward changes to Medicare reimbursement rates for items such as the procedures our physician clients perform or the drugs used in conjunction with them may adversely affect reimbursement to customers or potential customers that use or could use our cameras and services, and may therefore affect us. Effective January 2007, the technical component of Medicare reimbursement for nuclear imaging services performed in physicians' offices was capped at the lesser amount of either the Hospital Outpatient Prospective Payment System rates or the Medicare Part B Physician Fee Schedule rates. As a result of this and other reimbursement changes, the average Medicare reimbursement rate for the nuclear imaging procedures most commonly performed by our physician clients declined by 8.5% from 2006 to 2007, and the average Medicare reimbursement rate for the ultrasound procedures most commonly performed by our physician customers declined by 2% from 2006 to 2007. In July 2007, the Centers for Medicare and Medicaid Services, or CMS, proposed regulations that could result in an additional reimbursement reduction of approximately 10% in 2008 for these procedures. Reimbursement by Medicare for the procedures most commonly performed by our ultrasound imaging customers decreased by 2% for 2007 as compared to 2006, and CMS has proposed additional reimbursement reductions in 2008 for these ultrasound procedures of approximately 18%. An additional proposal, if adopted, would eliminate one commonly used reimbursement code. CMS has also proposed to prohibit physicians and physician groups from marking-up the price of professional interpretations of diagnostic imaging they obtain from anyone not a full-time employee of the physician or physician group, such as a part-time group member. If finalized, this proposed reimbursement restriction may provide a disincentive for some physicians to purchase our gamma cameras. CMS has also proposed to prohibit independent diagnostic testing facilities from sharing space, personnel, or equipment with any other imaging suppliers, a proposal that could further prohibit certain existing and new diagnostic imaging arrangements among physician groups and reduce sales of our gamma cameras. Other reimbursement reductions remain under consideration, and we cannot predict whether and to what extent implementation of these reductions will be delayed or whether and how the specific reimbursement rates applicable to procedures performed by our physician clients will be affected. If reimbursement reductions increase, sales of our gamma cameras would suffer and we may receive pressure from our customers to terminate or otherwise modify the lease arrangements for our DIS services. Under such circumstances, our business, financial condition and results of operations could be materially adversely affected. In addition, nuclear medicine is a designated health service under the federal anti-self-referral laws known as the Stark Law. Under this law, a physician may not refer to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies. DIS physician customers may be able to meet the in-office ancillary services exception to the Stark Law if they meet the definition of a Group Practice under Stark, personally supervise the individuals performing the nuclear imaging services and bill for them, and if the services are performed in the same building in which the physicians regularly practice medicine. In July 2007, CMS proposed to modify the Stark regulations in a manner that may restrict physicians in some business arrangements from utilizing the in-office ancillary services exception to Stark. CMS could at any time propose or implement other Stark modifications to limit use of the in-office ancillary services exception. If DIS customers are unable or unwilling to comply with the Stark Law, utilization rates of our services and products will decline and our business will be harmed. The potential for adoption of healthcare reform proposals on a state-by-state basis could require us to develop state-specific marketing and sales approaches and adversely affect the results of operations.



## **Table of Contents**

***Regulatory changes could have a negative impact on camera sales to and leases with hospitals desiring to use our cameras and services in their outpatient facilities.***

In order for hospitals to receive certain payments for their outpatient facilities as hospital outpatient services, including services that utilize our products, these services must be furnished in a provider-based organization or facility, or be covered services furnished under arrangement with the hospital. Failure to meet these requirements may result in reduced payments to the hospitals for their services. The Medicare program has published and revised rules establishing criteria for classifying a facility as provider-based or a service as furnished under arrangement. These rules require an analysis of the facts and circumstances surrounding the delivery by a hospital of a particular service, and hospitals that use our products or DIS services in their outpatient facilities will need to determine if they meet the applicable provider-based or under arrangement requirements. Hospitals that cannot obtain sufficient payments for these services may not purchase a camera from us or enter into arrangements with us for provision of services.

***If we fail to comply with various licensure or certification laws, regulations or standards, we may be subject to civil, criminal and/or administrative penalties, which would adversely affect our operations.***

All of the states in which we operate require that the imaging technicians operating our cameras be licensed, registered or certified and such licensing, registration and certification requirements are subject to change. Obtaining licenses may take significant time as we expand into additional states or if requirements change. Any lapse in the licensure or certification of our technicians could increase our costs and adversely affect our operations and financial results.

In addition, our DIS nuclear services model involves administering and furnishing radiopharmaceuticals and, until recently, pharmacological stress agents, which are regulated as drugs by state and federal agencies, including the FDA and state pharmacy boards. If a state regulatory authority determines that we have operated our business without required permits or licensure, we could be subject to civil, criminal and/or administrative penalties, including the curtailing or halting of our business. In addition, an inability to obtain required licenses or permits where we currently conduct business, or in states where we plan to expand, would require us to modify the business models we can utilize in the affected jurisdictions. In either case, we could incur substantial expense and could encounter substantial operational burdens.

***Our products are subject to reporting requirements and recalls even after receiving FDA clearance or approval, which could harm our reputation, business and financial results.***

We are subject to medical device reporting regulations that require us to report to the FDA or similar governmental bodies in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury. In addition, the FDA and similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture that could cause adverse health consequences. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert management attention and financial resources and harm our reputation with customers.

***If we fail to obtain, or are significantly delayed in obtaining, FDA or foreign regulatory clearances or approvals for future products or product enhancements, or if we or our third party contractors fail to comply with FDA's Quality System Regulation, or the quality regulations of foreign governments, our ability to market and distribute our products will suffer.***

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. In the U.S., the FDA regulates virtually all aspects of a medical device's testing, manufacture, safety, labeling, storage, recordkeeping, reporting, promotion and distribution. Our failure to comply with those regulations could lead to the imposition of administrative or judicial sanctions, including Warning Letters, injunctions, suspensions or the loss of regulatory clearances or approvals, product recalls, termination of distribution, product seizures, injunctions, criminal sanctions or closure of our manufacturing facilities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. Commercial distribution of a new medical device generally requires 510(k) clearance or an approved pre-market approval (PMA). The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to a legally marketed predicate device. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process, and must be supported by extensive data, including data from preclinical studies and human clinical trials. We cannot assure you that we will receive marketing clearance or PMA approval for any of our new products or product enhancements, or that significant delays in the introduction of any new products or product enhancements may not occur. While we have not been required to obtain PMA approval for any of our products, we may in the future have to undergo the lengthier, burdensome, and expensive PMA approval process. Further, pursuant to FDA regulations, we can only market our products for cleared or approved uses.



## **Table of Contents**

Our manufacturing processes and those of our third-party manufacturers are required to comply with the FDA's Quality System Regulation, which covers the design, testing, production processes, controls, quality assurance, labeling, packaging, storage and shipping of our devices. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facility and records for periodic unscheduled inspections by federal, state and foreign agencies, including the FDA. Our failure or our third-party manufacturers' failure to pass a Quality System Regulation inspection or to comply with these and other applicable regulatory requirements could result in disruption of our operations and manufacturing delays, and a failure to take adequate corrective action could result in, among other things, Warning Letter(s), withdrawal of our medical device clearances, seizure or recall of our devices, or other civil or criminal enforcement actions.

***Modifications to our products may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.***

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA requires us to seek 510(k) clearance or PMA approval for modification of a previously cleared product for which we have concluded that no clearances or approvals are necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement for which we seek additional approvals or clearances could result in delays, fines, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA, any of which would harm our business.

## **Risks Related to Our Financial Results**

***Our quarterly and annual financial results are difficult to predict and are likely to fluctuate from period to period.***

Our revenue and results of operations at any given time will be primarily based on the following factors, many of which we cannot control:

physician, healthcare provider and patient acceptance of our products and services;

demand for and pricing of our products and services;

levels of and restrictions upon third-party payor reimbursement for our products and services;

accreditation and credentialing requirements imposed by third-party payors on physicians and providers of mobile imaging services;

our ability to retain our DIS customers;

success and timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

camera purchases by DIS customers;

our ability to establish and maintain a productive manufacturing, marketing, sales and distribution force;

## Edgar Filing: DIGIRAD CORP - Form 10-Q

the ability of our suppliers to provide us with an adequate supply of necessary components on a timely basis;

our ability to reduce our expenses quickly enough to respond to any declines in revenue;

regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;

the effect of competing technological and market developments; and

interruption in the manufacturing or distribution of our products and services.

Furthermore, we have experienced seasonality in the leasing services offered by DIS. While our physicians are obligated to pay us for all lease days to which they have committed, our contracts permit some flexibility in scheduling when services are to be performed. This accounts for some of the seasonality of our DIS revenues. We cannot predict with certainty the degree to which seasonal circumstances such as the summer slowdown, winter holiday variations and weather conditions may make our revenue unpredictable or lead to fluctuations in our quarterly operating results in the future.

## **Table of Contents**

In addition, due to the way that customers in our target markets acquire our products, a large percentage of our camera orders is booked during the last month of each quarterly accounting period. As such, a delivery delay of only a few days may significantly impact our quarter-to-quarter comparisons. Moreover, the sales cycle for our cameras is typically lengthy, which may cause us to experience significant revenue fluctuations.

For these reasons, quarterly and annual sales and operating results may vary in the future and period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indicators of future performance. We cannot assure you that our sales will increase or be sustained in future periods. We have experienced, and may continue to experience, significant, unanticipated quarterly and annual losses. Because of these and other factors, our operating results in one or more future reporting periods may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

***We have incurred significant and recurring operating losses since our inception in 1985 and we may incur such losses and increased operating expenses in the near term.***

We have incurred significant cumulative net losses since our inception in November 1985 and may incur such losses and increased operating expenses in the near term as we, among other things, expand our DIS business, increase marketing, sales and distribution of our current products, and conduct research and development to develop next-generation products and to enhance our existing products.

As a result of these activities, we may not be able to become profitable or, if we do, maintain profitability. If our revenue grows more slowly than anticipated, or if our operating expenses exceed our expectations, our ability to achieve our development and expansion goals would be adversely affected.

## **Risks Related to Our Intellectual Property and Potential Litigation**

***Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.***

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights, be enforceable or permit us to gain or keep any competitive advantage. Our pending U.S. and foreign patent applications, which include claims to material aspects of our products and procedures that are not currently protected by issued patents, may not issue as patents in a form that will be advantageous to us. Any patents we have obtained or do obtain may be challenged by re-examination or otherwise invalidated or eventually found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may attempt to challenge or invalidate our patents, or may be able to design alternative techniques or devices that avoid infringement of our patents, or develop products with functionalities that are comparable to ours.

In the event a competitor infringes upon our patent or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from our management. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others.

***The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of our management's time and efforts, and require us to pay damages.***

Any litigation or claims against us, or claims we bring against others, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of our management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to be inadvertently infringing, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our system to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to commercialize one or more of our products, which could severely harm our business.

***We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or our employees have





## **Table of Contents**

inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hinder or preclude our ability to commercialize our products, which could severely harm our business.

### **Risks Related to the Securities Markets and Ownership of Our Common Stock**

#### ***Our stock price may be volatile.***

The market price for our common stock has been and is likely to continue to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

volume and timing of orders for our products and services;

declining sales of nuclear imaging products and other adverse conditions affecting our target markets;

the results of delays in introduction of new products, product enhancements, services or technologies by us or our competitors;

period-to-period variations in our or our competitors' results of operations;

conditions or trends in the medical device industry and the imaging service industry;

disputes or other developments with respect to intellectual property rights, product liability claims or other litigation;

our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis, or changes in governmental regulations or in the status of our regulatory approvals or applications;

additions or departures of key personnel;

sales of large blocks of our common stock, including sales by our executive officers and directors;

changes in the availability of third-party reimbursement in the United States or other countries;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

***Future sales of our common stock may cause our stock price to decline.***

## Edgar Filing: DIGIRAD CORP - Form 10-Q

A small number of our current stockholders hold a substantial number of shares of our common stock that they may sell in the public market. Sales by our current stockholders of a substantial number of shares, or the expectation that such sale may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of our shares of common stock, including shares issued upon the exercise of certain of our warrants, have rights, subject to some conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all common stock that we may issue under our employee benefit plans. Accordingly, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws and the lock-up agreements described above. If any of these stockholders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

***Our common stock is thinly traded and an active trading market may not be sustained.***

Although we are currently listed for trading on the Nasdaq National Market, an active trading market for our common stock may not be sustained. An inactive market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. Furthermore, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, products and technologies by using our shares as consideration.

***Anti-takeover provisions in our organizational documents, our Stockholders Rights Plan and Delaware law may prevent or delay removal of current management or a change in control.***

Our restated certificate of incorporation and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions include:

prohibiting our stockholders from calling a special meeting of stockholders unless they hold not less than 20% of the total number of votes to be cast at such a meeting;

## **Table of Contents**

permitting the issuance of additional shares of up to 10,000,000 shares of preferred stock without stockholder approval upon terms and conditions, and with the rights, preferences and privileges as a board of directors may determine;

prohibiting our stockholders from making certain changes to our restated certificate of incorporation or restated bylaws except with 66 2/3% stockholder approval; and

requiring advance notice for raising matters of business or making nominations at stockholders' meetings.

The rights issued pursuant to our Stockholder Rights Plan will become exercisable, subject to certain exceptions, the tenth day after a person or group announces acquisition of 15% or more of our common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203.

These provisions alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

*If our officers, directors and principal stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not in the best interests of other stockholders.*

Our officers, directors and holders of 5% or more of our outstanding common stock beneficially own a significant amount of our outstanding common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders. As a result of their actions or inactions our stock price may decline.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

The Annual Meeting of Stockholders was held on May 7, 2007 at 13950 Stowe Drive, Poway, California at 11:00 a.m. Of the 18,817,951 shares of common stock entitled to vote at the meeting, 15,750,597 shares, representing 84% of the votes eligible to be cast, were represented at the meeting in person or by proxy, constituting a quorum. The voting results are presented below.

(a) The stockholders elected seven directors for a one-year term to expire at the 2008 Annual Meeting of Stockholders. Our present Board of Directors has nominated and recommends for election as director the following persons:

<b>Name</b>	<b>Votes in Favor</b>	<b>Votes Withheld</b>
Timothy J. Wollaeger	14,668,314	1,082,282

## Edgar Filing: DIGIRAD CORP - Form 10-Q

Mark L. Casner	14,670,250	1,080,346
Gerhard F. Burbach	14,670,404	1,080,192
Raymond V. Dittamore	14,529,377	1,221,219
R. King Nelson	14,670,404	1,080,192
Kenneth E. Olson	14,667,054	1,083,542
Douglas Reed, M.D.	14,669,254	1,081,342

(b) The Stockholders ratified the selection of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2007 by a vote of 14,770,987 in favor, 79,059 votes against and 900,641 votes withheld.

---

**Table of Contents**

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1(1)	Restated Certificate of Incorporation
3.2(2)	Restated Bylaws
4.1(3)	Form of Specimen Stock Certificate
10.1	Digirad Corporation 2004 Stock Incentive Plan as Amended and Restated August 3, 2007
10.2(4)	Asset Purchase Agreement by and between Digirad Corporation, Digirad Imaging Solutions, Inc., Digirad Ultrascan Solutions, Inc. and Ultrascan, Inc. dated May 1, 2007
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<hr/>	
(1)	Incorporated by reference to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2006.
(2)	Incorporated by reference to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2007.
(3)	Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-113760) originally filed with the Securities and Exchange Commission on March 19, 2004, as amended thereafter.
(4)	Incorporated by reference to the Company's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2007.

**Table of Contents**

**SIGNATURES**

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

DIGIRAD CORPORATION

Date: August 7, 2007

By: /s/ MARK L. CASNER  
Mark L. Casner  
President and Chief Executive Officer

(Principal Executive Officer)

Date: August 7, 2007

By: /s/ TODD P. CLYDE  
Todd P. Clyde  
Chief Financial Officer

(Principal Financial and Accounting Officer)

---

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1(1)	Restated Certificate of Incorporation
3.2(2)	Restated Bylaws
4.1(3)	Form of Specimen Stock Certificate
10.1	Digirad Corporation 2004 Stock Incentive Plan as Amended and Restated August 3, 2007
10.2(4)	Asset Purchase Agreement by and between Digirad Corporation, Digirad Imaging Solutions, Inc., Digirad Ultrascan Solutions, Inc. and Ultrascan, Inc. dated May 1, 2007
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<hr/>	
(1)	Incorporated by reference to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2006.
(2)	Incorporated by reference to the Company's current report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2007.
(3)	Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-113760) originally filed with the Securities and Exchange Commission on March 19, 2004, as amended thereafter.
(4)	Incorporated by reference to the Company's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2007.