

DIGIRAD CORP  
Form 10-Q  
May 10, 2006  
Table of Contents

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

\_\_\_\_\_  
**FORM 10-Q**  
\_\_\_\_\_

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2006

☐ **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)

**33-0145723**  
(I.R.S. Employer Identification No.)

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

**92064**  
(Zip Code)

**(858) 726-1600**

(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 ☐

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Indicate by check mark whether NAI 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 NAI is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

As of April 25, 2006, the registrant had 18,741,662 shares of Common Stock (\$0.0001 par value) outstanding.

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**Table of Contents**

**DIGIRAD CORPORATION**

**TABLE OF CONTENTS**

<b><u>PART I. FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements</u>	3
<u>Consolidated Balance Sheets as of March 31, 2006 (Unaudited) and December 31, 2005</u>	3
<u>Unaudited Consolidated Statements of Operations for the three months ended March 31, 2006 and 2005</u>	4
<u>Unaudited Consolidated Statements of Cash Flows for the three months ended March 31, 2006 and 2005</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosure about Market Risk</u>	17
<u>Item 4. Controls and Procedures</u>	17
<b><u>PART II. OTHER INFORMATION</u></b>	17
<u>Item 1. Legal Proceedings</u>	17
<u>Item 1A. Risk Factors</u>	18
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 3. Defaults Upon Senior Securities</u>	30
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	31
<u>Item 5. Other Information</u>	31
<u>Item 6. Exhibits</u>	31
<b><u>SIGNATURES</u></b>	32
<b>EXHIBIT 31.1</b>	
<b>EXHIBIT 31.2</b>	
<b>EXHIBIT 32.1</b>	
<b>EXHIBIT 32.2</b>	

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

	<b>March 31, 2006 (Unaudited)</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 17,127	\$ 16,303
Securities available-for-sale	29,651	33,202
Accounts receivable, net	9,026	8,132
Inventories, net	4,137	5,136
Other current assets	1,557	1,687
Total current assets	61,498	64,460
Property and equipment, net	9,600	9,582
Intangibles, net	454	402
Restricted cash	60	60
Total assets	\$ 71,612	\$ 74,504
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,565	\$ 2,152
Accrued compensation	2,425	2,585
Accrued warranty	779	825
Other accrued liabilities	4,112	4,614
Deferred revenue	2,869	2,858
Current portion of debt	593	766
Total current liabilities	13,343	13,800
Long-term debt, net of current portion	298	368
Deferred rent	336	348
Commitments and contingencies		
<b>Stockholders' equity</b>		
Preferred stock, \$0.0001 par value: 10,000 shares authorized at March 31, 2006 and December 31, 2005; no shares issued or outstanding at March 31, 2006 and December 31, 2005		
Common stock, \$0.0001 par value: 150,000 shares authorized at March 31, 2006 and December 31, 2005; 18,741 and 18,705 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	2	2
Additional paid-in capital	150,416	150,201
Accumulated other comprehensive loss	(264)	(221)
Deferred compensation		(279)
Accumulated deficit	(92,519)	(89,715)
Total stockholders' equity	57,635	59,988

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Total liabilities and stockholders' equity	\$ 71,612	\$ 74,504
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See accompanying notes.

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

	<b>Three months ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Revenues:		
DIS	\$ 13,217	\$ 12,322
Product	5,738	5,648
Total revenues	18,955	17,970
Cost of revenues:		
DIS	10,432	8,659
Product	4,130	4,154
Total cost of revenues	14,562	12,813
Gross profit	4,393	5,157
Operating expenses:		
Research and development	1,096	922
Sales and marketing	2,459	2,039
General and administrative	4,129	3,405
Amortization of intangible assets	9	16
Total operating expenses	7,693	6,382
Loss from operations	(3,300)	(1,225)
Other income (expense):		
Interest income	522	342
Interest expense	(26)	(90)
Other		(8)
Total other income (expense)	496	244
Net loss	\$ (2,804)	\$ (981)
Net loss per common share basic and diluted	\$ (0.15)	\$ (0.05)
Shares used in computing net loss per common share:		
Weighted average shares outstanding basic and diluted	18,710	18,105
The above results include stock-based compensation as follows:		
Cost of DIS revenue	\$ 20	\$ 34
Cost of product revenue	18	25
Research and development	42	22
Sales and marketing	75	21
General and administrative	316	76
	\$ 471	\$ 178

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See accompanying notes.

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

	<b>Three months ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Operating activities</b>		
Net loss	\$ (2,804)	\$ (981)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	1,335	866
Loss on disposal of assets		8
Amortization of premium on securities available-for-sale	56	120
Amortization of intangibles	14	16
Stock-based compensation	476	178
Changes in operating assets and liabilities:		
Accounts receivable	(894)	(1,601)
Inventories	999	(1,034)
Other assets	130	(67)
Accounts payable	413	699
Accrued compensation	(160)	(447)
Accrued warranty, deferred rent and other accrued liabilities	(560)	590
Deferred revenue	11	564
Net cash used by operating activities	(984)	(1,089)
<b>Investing activities</b>		
Purchases of securities available-for-sale	(4,749)	(9,104)
Maturities of securities available-for-sale	8,200	10,525
Purchases of property and equipment	(1,353)	(1,493)
Patents and other assets	(65)	
Net cash provided (used) by investing activities	2,033	(72)
<b>Financing activities</b>		
Issuances of common stock	18	30
Repayment of obligations under capital leases	(243)	(2,181)
Net cash used by financing activities	(225)	(2,151)
Net increase (decrease) in cash and cash equivalents	824	(3,312)
Cash and cash equivalents at beginning of period	16,303	11,348
Cash and cash equivalents at end of period	\$ 17,127	\$ 8,036
<b>Supplemental information:</b>		
Cash paid during the period for interest	\$ 20	\$ 63

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***

Digirad Corporation ( Digirad ), a Delaware corporation, is a leading provider of cardiovascular imaging services and solid-state nuclear medicine imaging products to physician offices, hospitals and imaging centers. We were the first company to design and commercialize a solid-state medical 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 and improved patient comfort and utilization and, in the case of our Cardius®-3 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 directly in a physician's office, an outpatient hospital setting or within multiple departments of a hospital. Our cardiovascular imaging services are provided through two subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc., collectively DIS, offering certified personnel, required licensure, an imaging system and other support and supplies for the performance of nuclear 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.

***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 months ended March 31, 2006 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, 2005 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

***Net Income (Loss) Per Share***

We calculate net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share ( EPS ) is calculated by dividing the net income or loss available to common stockholders 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 available to common stockholders by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, convertible preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

**2. Financial Statement Details**

Inventories consist of the following (in thousands):

	March 31, 2006	December 31, 2005
Raw materials	\$ 1,847	\$ 2,087
Work-in-progress	2,805	3,431
Finished goods	379	514
	5,031	6,032

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Less reserves for excess and obsolete inventories	(894)	(896)
	\$ 4,137	\$ 5,136

**Table of Contents**

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

	March 31, 2006	December 31, 2005
Machinery and equipment	\$ 20,319	\$ 20,231
Computers and software	3,426	3,309
Leasehold improvements	742	742
Furniture and fixtures	230	230
Construction in process	454	157
	25,171	24,669
Less accumulated depreciation and amortization	(15,571)	(15,087)
	\$ 9,600	\$ 9,582

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

	March 31, 2006	December 31, 2005
Radiopharmaceuticals and consumable medical supplies	\$ 986	\$ 1,101
Customer deposits	573	1,073
Legal and other professional costs	721	644
Other accrued liabilities	1,832	1,796
	\$ 4,112	\$ 4,614

**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 revenues. 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, labor, overhead and transportation. We review warranty reserves periodically and, when appropriate, make adjustments.

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

	Three months ended March 31, 2006	2005
Balance at beginning of period	\$ 825	\$ 1,219
Charges to cost of revenues	260	382
Applied to liability	(306)	(390)
Balance at end of period	\$ 779	\$ 1,211

**4. Comprehensive Income**

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

	Three months ended March 31,	
	2006	2005
Net loss, as reported	\$ (2,804)	\$ (981)
Unrealized losses on marketable securities	(43)	(117)
Comprehensive loss	\$ (2,847)	\$ (1,098)

## 5. Stock-Based Compensation

### *Adoption of SFAS 123(R)*

Effective January 1, 2006, we adopted the fair value recognition provisions of the Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payment* ( SFAS 123(R) ). We have not restated our financial results for prior periods. In accordance with SFAS 123(R), we utilized the prospective method for equity share options granted prior to our initial public offering as we had used the minimum value method of measuring these options for pro forma disclosure. We utilized the modified prospective method for equity share options granted subsequent to our initial

**Table of Contents**

public offering as we had used the fair-value-based method for pro forma disclosure purposes under SFAS 123. Under these transition methods, compensation cost recognized in the three months ended March 31, 2006 includes the following: (a) share-based compensation cost associated with options granted prior to our initial public offering with exercise prices less than the deemed fair value of the common stock at the date of grant, (b) compensation cost related to any share-based payments granted subsequent to the date of our initial public offering through, but not vested as of, December 31, 2005, and (c) compensation cost for any share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

Prior to the completion of our initial public offering in June 2004, stock options were granted at exercise prices that were below the deemed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation was recorded in accordance with Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations ( APB 25 ). The deferred stock compensation was amortized on a straight-line basis over the vesting period of the related awards. In accordance with SFAS 123(R), we reversed the balance of deferred compensation from shareholders' equity on the date of adoption but, as noted above, we continue to recognize the related compensation cost in the statement of operations.

As a result of adopting SFAS 123(R), our net loss for the three months ended March 31, 2006 is approximately \$403,000 greater than if we had continued to account for share-based compensation under APB 25. Basic and diluted loss per share for the three months ended March 31, 2006, would have been \$0.13 if we had not adopted SFAS 123(R) compared to reported basic and diluted loss per share of \$0.15, respectively.

*Compensation Costs*

As noted on our statement of operations, results of operations for the three months ended March 31, 2006 include stock-based compensation costs of \$0.5 million. Share-based compensation capitalized as part of our inventory was not significant. There were no significant modifications to our share-based employee payment plans during the periods presented that resulted in any incremental compensation cost.

*Valuation of Stock Option Awards*

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton closed-form option valuation model that uses the assumptions noted in the following table. All options granted have a maximum term of ten years. As permitted by SAB 107, we utilized the shortcut approach to estimate the options' expected term, which represents the period of time that options granted are expected to be outstanding. We utilized this approach since our historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term. Expected volatilities are based on historical volatility of our stock as well as the stock of comparable companies. We estimated the forfeiture rate based on historical data for forfeitures and we are recognizing compensation costs only for those equity awards expected to vest. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. We have never declared or paid dividends and have no plans to do so in the foreseeable future.

The following weighted average assumptions were utilized for the calculations during each period:

	Three months ended	
	2006	2005
Expected life (in years)	6.05	5.00
Expected volatility	55%	75%
Forfeiture rate	18.0%	
Risk-free interest rate	4.52%	3.77%
Expected dividend yield		

*Adjusted net loss information*

Prior to adoption of SFAS 123(R), we followed APB 25 in accounting for our employee stock options as permitted by Statement of Financial Accounting Standards ( SFAS ) No. 123, *Accounting for Stock-Based Compensation*. The following table illustrates the effect on net loss and loss per share as if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the quarter ended March 31, 2005, prior to the adoption of SFAS 123(R).



**Table of Contents**

For purposes of this pro forma disclosure, the fair value of the options granted prior to the completion of our initial public offering was estimated at the date of grant using the minimum value pricing model. Upon completion of the initial public offering in June 2004, we began using the Black-Scholes model to estimate fair value. The estimated fair value of the options is amortized on an accelerated basis in accordance with FASB Interpretation ( FIN ) No. 28 over the vesting period. Disclosures for the three months ended March 31, 2006 are not presented in the following table because stock-based payments were accounted for under SFAS 123(R)'s fair-value method during that period.

Our adjusted net loss information for the quarter ended March 31, 2005 is as follows (in thousands):

	<b>Three Months Ended March 31, 2005</b>
Net loss	\$ (981)
Add: total stock-based employee compensation included in reported net loss	178
Less: total stock-based employee compensation determined under the fair value method for all awards	(511)
Pro forma net loss	\$ (1,314)
Basic and diluted net loss per common share as reported	\$ (0.05)
Basic and diluted net loss per common share pro forma	\$ (0.07)

In conjunction with the adoption of FAS 123R, we determined that the pro forma expense related to actual forfeitures was computed incorrectly during fiscal 2005. As a result, pro forma compensation cost during 2005 is different than the amounts previously disclosed as follows (in thousands, except per share data):

	<b>Three months Ended March 31, 2005</b>	<b>Three months Ended June 30, 2005</b>	<b>Three months Ended September 30, 2005</b>	<b>Year Ended December 31, 2005</b>
As previously disclosed:				
Pro forma net loss	\$ (1,342)	\$ (4,087)	\$ (3,741)	\$ (13,099)
Pro forma net loss per share	\$ (0.07)	\$ (0.22)	\$ (0.20)	\$ (0.71)
As revised:				
Pro forma net loss	\$ (1,314)	\$ (3,849)	\$ (3,525)	\$ (12,046)
Pro forma net loss per share	\$ (0.07)	\$ (0.21)	\$ (0.19)	\$ (0.65)

**6. Stock Options***Stock-based Employee Compensation Plans*

We have two stock option plans under which stock options are granted to employees and non-employee members of our Board of Directors, the 2004 Stock Incentive Plan and the 2005 Inducement Stock Incentive Plan. Option grants under these plans generally have ten year terms and vest over four years. As of March 31, 2006, 2,352,000 shares of our common stock were reserved for issuance upon exercise of outstanding options and 412,000 shares were available for future grants under our option plans.



**Table of Contents***Summary of Stock Options*

A summary of options under all of our share-based compensation plans as of March 31, 2006, and activity during the three months then ended, are as follows (in thousands, except per share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2005	2,280	\$ 5.08		
Options granted	237	\$ 4.11		
Options exercised	(36)	\$ 0.49		
Options forfeited	(129)	\$ 8.92		
Options outstanding at March 31, 2006	2,352	\$ 4.82	8.29	\$ 2,025
Options vested and exercisable at March 31, 2006	1,109	\$ 4.62	7.36	\$ 1,758

*Disclosures Pertaining to All Share-Based Compensation Plans*

Of the options outstanding at March 31, 2006, 2,129,000 of the shares are vested or are expected to vest, and have a weighted average exercise price of \$4.81 and an intrinsic value of \$2.0 million. Aggregate intrinsic value is the sum of the amounts by which the quoted market price of our stock exceeded the exercise price of the options at March 31, 2006 ( in-the-money options ). The weighted-average grant-date fair value of options granted during the three months ended March 31, 2006 and March 31, 2005 was \$2.34 and \$4.31, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2006 was \$124,000.

As of March 31, 2006, \$2,132,000 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 1.7 years.

Cash received from option exercises for the three months ended March 31, 2006 and 2005 was \$18,000 and \$30,000, respectively. Because of our net operating losses, we did not realize any tax benefits for the tax deductions from share-based payment arrangements during the three months ended March 31, 2006 and 2005.

**7. Segments**

Digirad has two reportable segments: DIS and Product. DIS collectively refers to our wholly-owned subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc. Through DIS, we offer FlexImaging, our mobile and comprehensive leasing service for physicians who wish to perform nuclear cardiology and nuclear medicine procedures in their offices, but may not have the patient volume, capital, or personnel to justify purchasing an imaging system. Our product revenue results primarily from selling solid-state gamma cameras, imaging chairs, upgrades and accessories, such as printers, viewing workstations and networking solutions, and from our maintenance contracts. We sell our imaging systems to physician offices, hospitals, and imaging centers primarily in the United States. Although we have historically sold a small number of imaging systems internationally, foreign sales were not significant in any of the periods presented below.

We have determined our reporting segments 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.

**Table of Contents**

Segment results are as follows (in thousands):

	<b>Three months ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Gross profit by segment:</b>		
DIS	\$ 2,785	\$ 3,663
Product	1,608	1,494
Consolidated gross profit	\$ 4,393	\$ 5,157
<b>Income (loss) from operations by segment:</b>		
DIS	\$ (1,612)	\$ 166
Product	(1,688)	(1,391)
Consolidated loss from operations	\$ (3,300)	\$ (1,225)
<b>Depreciation, and amortization of intangible assets by segment:</b>		
DIS	\$ 1,038	\$ 609
Product	311	273
Consolidated depreciation and amortization	\$ 1,349	\$ 882
<b>Identifiable assets by segment:</b>		
DIS	\$ 14,764	\$ 17,900
Product	56,848	66,458
Consolidated assets	\$ 71,612	\$ 84,358

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

We are directly or indirectly through our clients, subject to extensive regulation by both the federal government and 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.

***Legal Matters***

In January 2005, a complaint was served on a physician, who is a DIS customer, his medical practice and two DIS technicians, individually and in their capacity as agents of the medical practice. The complaint was filed in the Circuit Court of the Fifth Judicial Circuit, County of Vermilion, Danville, Illinois and alleges negligence claims in connection with the death of a patient purportedly arising from the administration of a stress imaging test. The trial is set for September 2006. While the technicians deny the allegations and we will vigorously defend them in the matter, we cannot assure you that this matter will be resolved in their favor.

On February 17, 2006, we filed a complaint in the United States District Court for the Southern District of California against Gamma Medica IDEAS alleging infringement of two patents, and seeking monetary damages and injunctive relief based thereon.

On February 17, 2006, nine former and present employees filed a complaint against us in the United States District Court, Northern California, Oakland Division, alleging wage and hour violations, wrongful termination and other tort claims. Plaintiffs seek compensatory and punitive damages and penalties. On March 30, 2006, three other employees filed a complaint in the same court, making similar allegations. We have not

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yet responded to the complaints.

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, 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.

Other than the immediately preceding discussion, we are not currently a party to any other material legal proceedings.

## **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, 2005 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2006. 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 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 the revenue growth in DIS as we expand into new markets and continue to penetrate and improve utilization rates within existing markets, expectations of increasing sales shifting from our single head to multi-head cameras, continuing to strengthen our sales team, persistent pricing pressures affecting our sales of dual-headed gamma cameras, the length of the sales cycle in our DIS business for some of our customers, the effect on our business of changes to the Stark Law and the new appropriateness criteria for cardiac imaging, continuing investments in research and development initiatives to enhance our system software, improve system sensitivity, reduce product costs and enhance reliability, the testing and roll-out of our Cardius-3 camera into DIS and the value it can represent to our customers, our belief that DIS revenue will continue to represent a larger percentage of our consolidated revenue than our product business revenue, and the assessment and upgrade of our DIS camera fleet. 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 claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any 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 cardiovascular imaging services and solid-state nuclear medicine imaging products to physician offices, hospitals and imaging centers. We were the first company to design and commercialize a solid-state medical 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 and improved patient comfort and utilization and, in the case of our Cardius®-3 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.

Consolidated revenues were \$19.0 million in the first quarter of 2006, which represented an increase of 5.5% over the comparable prior year period attributable mainly to the growth in our DIS business. In DIS, revenue increased 7.3% to \$13.2 million, and in the product business, revenue increased 1.6% to \$5.7 million. As of March 31, 2006, our DIS segment operated in 25 states and the District of Columbia. During the first quarter of 2006 and in line with our DIS fleet upgrade program, we replaced 5 systems and currently are operating three mobile Cardius-3 systems in DIS. The total number of mobile cameras in our DIS fleet was 80 as of March 31, 2006, and 71 at March 31, 2005. We performed 3,461 service days during the first quarter of 2006 compared to 3,381 service days in the comparable prior year period. Revenue per day increased to \$3,814 for the first quarter of 2006 compared to \$3,644 in the first quarter of 2005. Our DIS gross margins in the first quarter of 2006 declined to 21.1% compared to 29.7% during the first quarter of 2005, principally due to additional depreciation costs of approximately \$441,000 resulting from the reduction of the depreciable lives of our DIS fleet of cameras from seven years to five years in the fourth quarter of 2005, and a decline in staff productivity and system utilization. Our product business gross margins improved to 28.0% for the first quarter of 2006 compared to 26.5% during the first quarter of 2005, mainly as a result of improved margins on our camera service and maintenance contracts. Overall, we ended the first quarter of 2006 with a net loss of \$2.8 million, as compared to a net loss of \$1.0 million for the first quarter of 2005.

#### **Revenues**

Our revenues are generated within two primary operating segments: our DIS business and product sales. DIS collectively refers to our wholly-owned subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc. Through DIS, we offer a comprehensive mobile imaging leasing program, called FlexImaging®. This mobile imaging service is an alternative to purchasing a gamma camera for physicians who wish to perform nuclear imaging procedures in their offices but prefer to outsource the leasing of the imaging system, certified personnel, needed licensure and other resources.



## **Table of Contents**

FlexImaging is provided under the supervision of our physician customers. We also offer DigiTech leases, a service similar to FlexImaging services, except that our customer owns one of our cameras, but we continue 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.

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.

## **Our Market**

The target market for our products and services is comprised of approximately 26,000 cardiologists and the larger group practices of four or more practitioners among the 130,000 internists and family practitioners in the United States that perform or could perform nuclear cardiac procedures. We estimate that there are approximately 8,000 internist practices comprising more than four internists. According to industry sources, 18.4 million nuclear imaging procedures were performed in the United States in 2003, of which 10.2 million procedures were cardiac-specific procedures. To our knowledge, this industry information has not been updated. As a basis of comparison however, through DIS we performed 98,000 imaging procedures in 2005, up approximately 10% from the prior year. We performed approximately 25,000 imaging procedures in the first quarter of 2006. The National Electrical Manufacturers Association, or NEMA, estimates that revenues from sales of nuclear imaging equipment, excluding maintenance revenue, declined approximately 6% in 2005 to \$349 million, and projects further declines of 6%-9% in 2006 and 2007. NEMA attributes the declining sales to questions about reimbursement, lack of technology innovation and shifts to other imaging modalities. In the product business, industry sources predict that purchases of multi-head cameras will far outpace those of single-head cameras.

We believe that our imaging systems' small size, mobility, and ability to accommodate physicians' varying speed and throughput needs offer us competitive advantages that should allow us to capture a larger share of the overall nuclear imaging market, and also to grow in the product sales arena by capitalizing on the shift in delivery of nuclear cardiac imaging from hospitals to physician offices, and from cardiologists to internists and other physicians. To date, we have provided imaging services through DIS to approximately 500 physicians and physician groups, the majority of which are cardiologists; and we have sold approximately 400 cameras to customers through our product segment.

We believe our market is negatively affected by continuing pressures by third party payors to reduce health care expenditures, including changes by some payors requiring physicians to obtain specific accreditations or certifications or restricting the use of mobile cameras. Our market is also adversely affected by reimbursement changes implemented by Medicare and Medicaid.

## **Trends and Drivers**

During our most recent fiscal year, we experienced a decline in the rate of growth of our DIS business as we attracted fewer new customers and the number of lease days per new customer declined. We believe this was driven mainly by sales management vacancies, underperformance of our sales force and to increase proportion of sales to internists whose practice volumes are lower than those of cardiologists, resulting in fewer annual service days. To counter this trend, we have continued our efforts to increase sales visibility through data-driven market strategies and increasing the quality of our sales force, and have seen some improvement in the DIS growth rate in the first quarter of 2006. In addition, we intend to begin pilot programs in selected markets in the delivery of ultrasound services to seek to leverage our existing DIS infrastructure and service delivery knowledge base.

Our efforts in DIS will also focus on improving labor and operational efficiencies; decreasing employee turnover, which was 55% in 2005; increasing system utilization; decreasing costs of delivery to improve service to our existing customers; and attracting new customers in existing and expansion territories. We are continuing to upgrade our DIS camera fleet through a measured roll-out of our Cardius-3 mobile camera with three systems at the end of the first quarter of 2006, which we believe will allow us to increase patient throughput, shorten the work days of our employees and improve customer satisfaction.

Sales of single head gamma cameras have historically represented the majority of the revenue generated by our product segment. However, consistent with the industry data, we saw a decline in sales of single head cameras during 2005, and an increase in the percentage of our sales of dual and triple head cameras. This trend has continued in the first quarter of 2006, when the majority of our sales consisted of multi-headed cameras, and we believe it will continue in the future. We expect to continue to invest in research and development to improve the image

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quality, speed, reliability and overall performance of our multi-headed cameras to enable us to capture an increasing share of the gamma camera market. During the latter part of 2005 and the first quarter of 2006, we also implemented a number of programs to improve operational efficiencies and

**Table of Contents**

improve camera reliability. This has resulted in an improvement in our product business margins in the first quarter of 2006 that we believe will translate into additional margin improvements during the remainder of 2006.

**Results of Operations**

The following table sets forth our results from operations, expressed as percentages of revenues for the three months ended March 31, 2006 and 2005:

	<b>Three months ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
Revenues:		
DIS	69.7%	68.6%
Product	30.3	31.4
Total revenues	100.0	100.0
Cost of revenues:		
DIS	55.0	48.2
Product	21.8	23.1
Total cost of revenues	76.8	71.3
Gross profit	23.2	28.7
Operating expenses:		
Research and development	5.8	5.1
Sales and marketing	13.0	11.4
General and administrative	21.8	18.9
Amortization and impairment of intangible assets	0.0	0.1
Total operating expenses	40.6	35.5
Loss from operations	(17.4)	(6.8)
Other income (expense)	2.6	1.3
Net loss	(14.8)%	(5.5)%

**Comparison of Three Months Ended March 31, 2006 and 2005****Revenues**

*Consolidated.* Consolidated revenue was \$19.0 million in 2006, which represents an increase of \$1.0 million, or 5.5% over the prior year quarter, primarily as a result of the increase in demand for our DIS imaging services. DIS and product revenue accounted for 69.7% and 30.3%, respectively, of total revenues in 2006, compared to 68.6% and 31.4%, respectively, in 2005. We expect DIS revenue to continue to represent the larger percentage of our consolidated revenue in future periods.

*DIS.* Our DIS revenue increased to \$13.2 million in 2006, which represents an increase of \$0.9 million, or 7.3%, over the prior year quarter. The increase in DIS revenue resulted from an increase in the number of DIS service days to 3,461 in 2006 from 3,381 in 2005, which was primarily attributable to an increase in the number of physicians entering into our DIS services contracts. Our DIS business operated 80 mobile and fixed site systems as of March 31, 2006, compared to 71 as of March 31, 2005. We continue to anticipate that our DIS revenue will increase as we continue to penetrate existing markets and expand into new markets. Such growth will fluctuate, however, based on seasonality stemming from physician vacations, holidays, inclement weather and start up time required by sales representatives as we enter new geographical areas.



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*Product.* Our product revenue increased to \$5.7 million in 2006, representing an increase of \$0.1 million, or 1.6%, over the prior year quarter. The increase in product revenue is attributable to an increase in maintenance contract revenues, which more than offset a decline in the sales of gamma cameras and related accessories. Maintenance contract revenues were \$1.7 million in 2006 compared to \$1.1 million in 2005. The decline in camera revenues is the result of selling one less camera during the first quarter of 2006 than in the prior year. We continue to experience pricing pressures on our dual-head gamma cameras and, while we expect this pricing pressure to remain, we also anticipate demand will increase on our multi-head gamma cameras as our sales force's performance improves.

### *Gross Profit*

*Consolidated.* Consolidated gross profit was \$4.4 million in 2006, representing a decrease of \$0.8 million or 14.8%, compared to the prior year quarter. The decrease in consolidated gross profit is principally due to additional depreciation costs of approximately \$441,000 resulting from the reduction of the depreciable lives of our DIS fleet of cameras from seven years to five years in the fourth quarter of 2005, and a decline in staff productivity and system utilization. Consolidated gross profit as a percentage of revenue decreased to the first quarter of 23.2% in 2006 from 28.7% in the first quarter of 2005.

**Table of Contents**

*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 increased to \$10.4 million in 2006, representing an increase of \$1.8 million, or 20.5%, over the prior year quarter, primarily a result of an increase in service costs required to service the increased number of DIS leasing days and additional depreciation costs. DIS gross profit decreased to \$2.8 million in the first quarter of 2006, which represents a decrease of \$0.9 million, or 24.0%. Our clinical and regulatory headcount relating to our DIS business increased to 191 employees as of March 31, 2006 from 167 employees as of March 31, 2005. DIS gross profit as a percentage of revenue decreased to 21.1% in 2006 from 29.7% in 2005.

*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 \$4.1 million in the first quarter of 2006, representing a decrease of \$24,000, or 0.6%, compared to the prior year quarter. Product gross profit increased to \$1.6 million in 2005, which represents an increase of \$0.1 million, or 7.6%, mainly as a result of improved margins on our camera service and maintenance contracts. Product gross profit as a percentage of revenue increased to 28.0% in 2006 from 26.5% in 2005.

*Operating Expenses*

*Research and Development.* Research and development expenses consist primarily of costs associated with the design, development, testing, and enhancement of our products. The primary costs are salaries and fringe benefits, consulting fees, development material costs, facility and overhead costs and non-recurring engineering costs. Research and development expenses increased to \$1.1 million in 2006, which represents an increase of \$0.2 million, or 18.9%, over the prior year quarter. This increase was primarily attributable to increased spending on new product development, including a mobile version of our Cardius-3 triple-head camera and our software development initiatives. Research and development related stock-based compensation costs associated with the adoption of FAS 123R were \$42,000 during the first quarter of 2006, which was \$20,000 higher than the stock based compensation costs recorded in the comparable prior year quarter. Research and development headcount remained unchanged from its prior year level of 20 employees. Research and development expenses were 5.8% of total revenue in 2006 compared to 5.1% for 2005. Our research and development efforts occur principally within our products segment. In the future, we expect to continue to invest in research and development as we innovate and seek to continue 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 tradeshow costs. Sales and marketing expenses increased to \$2.5 million in 2006, representing an increase of \$0.4 million or 20.6%, over the prior year quarter, primarily as a result of an increase in marketing costs, including personnel, advertising and travel. Sales and marketing related stock-based compensation costs associated with the adoption of FAS 123R were \$75,000 during the first quarter of 2006, which was \$54,000 higher than the stock based compensation costs recorded in the comparable prior year quarter. Sales and marketing expenses were 13.0% of total revenue in 2006 compared to 11.4% for 2005. We expect future sales and marketing costs to increase as our sales representatives begin selling more products and services, resulting in higher commission costs and as we focus on increasing market awareness of our products and offerings, begin marketing to internists and general practitioners and launch a marketing program for echocardiography and vascular ultrasound.

*General and Administrative.* General and administrative expenses consist primarily of salaries and other related costs for finance and accounting, human resources and other personnel, and legal and other professional fees and insurance. General and administrative expenses increased to \$4.1 million in the first quarter of 2006, representing an increase of \$0.7 million, or 21.2%, over the prior year quarter. The increase in headcount and recruiting costs were the primary contributors to the increase in general and administrative expenses in the first quarter of 2006. Stock-based compensation costs associated with the adoption of FAS 123R were \$316,000 during the first quarter of 2006, which was \$240,000 higher than the stock based compensation costs recorded in the comparable prior year quarter. General and administrative headcount increased to 51 employees in 2006 from 50 employees in 2005. General and administrative expenses were 21.8% of total revenue in 2006 compared to 18.9% for 2005. In the normal course of business, we have been and will likely continue to be subject to routine litigation incidental to our business, such as claims related to customer disputes, employment practices, product and professional liability, warranty or patent infringement. As we continue to grow, we anticipate that the volume of these claims is likely to increase. The substantial costs of litigation or an unexpected adverse outcome could materially increase our anticipated operating expenses.

*Stock-Based Compensation Charges.* As of January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R), which is a revision of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123) using the modified prospective method, which requires measurement of compensation of all stock based awards at fair value on the date of grant and recognition of

## **Table of Contents**

compensation over the service period for awards expected to vest. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in net income in the periods after adoption. The fair value of adoptions is determined using the Black-Scholes valuation model, which is consistent with valuation techniques previously utilized for options in footnote disclosures required under SFAS 123. Such value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line method under SFAS 123R.

Prior to the adoption of SFAS 123R, we applied APB Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations, in accounting for our equity plans. Deferred compensation for stock options granted to employees was determined as the difference between the exercise price and the fair value of our common stock on the date of grant. Those amounts were initially recorded as a component of stockholders' equity and were amortized, on an accelerated basis, as a non-cash charge to cost of revenues and operations over the vesting period of the options.

In connection with the grant of stock options to employees, we recorded stock-based compensation of \$0.5 million and \$0.2 million for the three months ended March 31, 2006 and 2005, respectively.

### *Other Income (Expense)*

Interest income increased to \$0.5 million in 2006 from \$0.3 million in 2005, reflecting the increase in market yields on our cash and investment balances.

Interest expense decreased to \$26,000 in 2006 from \$90,000 in 2004, as a result of the reduction of amounts outstanding on capital leases.

### *Net Loss*

Our net loss was \$2.8 million in 2006 compared to \$1.0 million in 2005, primarily as a result of the factors described above.

## **Liquidity and Capital Resources**

We require capital principally for debt service, capital expenditures 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 cameras and vans, computer hardware and software. As of March 31, 2006, we had cash, cash equivalents and investments totaling \$46.8 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.

Primarily as a result of the net cash loss for the period (net loss adjusted for non-cash expenses including depreciation and amortization expenses and stock-based compensation), net cash used by operations totaled \$1.0 million in 2006. Net cash provided by investing activities amounted to \$2.0 million in 2006, and reflects \$3.5 million of net maturities of our securities available-for-sale, partially offset by \$1.4 million of capital expenditures primarily associated with our DIS operations. Net cash used by financing activities amounted to approximately \$0.2 million in 2006, and primarily reflects the repayment of capital lease obligations, net of proceeds of \$18,000 arising from the exercise of stock options.

## **Critical Accounting Policies**

There were no significant changes in critical accounting policies or estimates from those at December 31, 2005, other than the item discussed below.

We estimate the fair value of stock options granted using the Black-Scholes-Merton option-pricing formula. This fair value is then amortized over the requisite service periods of the awards. This option-pricing model requires the input of highly subjective assumptions, including the options' expected life, price volatility of the underlying stock, risk free interest rate and expected dividend rate. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience.



## **Table of Contents**

### **Corporate Information**

As of March 31, 2006, we hold trademark registrations in the United States for the following marks: 2020tc Imager®, CardiusSST®, Digirad®, Digirad Logo®, Digirad Imaging Solutions®, FlexImaging®, Cardius®, SPECTour®, DigiServ®, DigiTech®, SPECTpak Plus® and Solidium®. We have trademark applications pending in the United States for the following marks: DigiServ, DigiTech, Solidium, SeeQuanta, AcqSmart, Stasys, Cardius X-Act, and TruAcq CountBased Imaging. We have obtained and sought trademark protection for some of these listed marks in the European Community and Japan.

### **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 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, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and 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.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision 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 December 31, 2005. 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.**

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 affect materially, our internal controls over financial reporting.

## **PART II. OTHER INFORMATION**

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

In January 2005, a complaint was served on a physician, who is a DIS customer, his medical practice and two DIS technicians, individually and in their capacity as agents of the medical practice. The complaint was filed in the Circuit Court of the Fifth Judicial Circuit, County of Vermilion, Danville, Illinois and alleges negligence claims in connection with the death of a patient purportedly arising from the administration of a stress imaging test. The trial is set for September 2006. While the technicians deny the allegations and we will vigorously defend them in the matter, we cannot assure you that this matter will be resolved in their favor.

On February 17, 2006, we filed a complaint in the United States District Court for the Southern District of California against Gamma Medica IDEAS alleging infringement of two patents, and seeking monetary damages and injunctive relief based thereon.

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On February 17, 2006, nine former and present employees filed a complaint against us in the United States District Court, Northern California, Oakland Division, alleging wage and hour violations, wrongful termination and other tort claims. Plaintiffs seek compensatory and punitive damages and penalties. On March 30, 2006, three other employees filed a complaint in the same court, making similar allegations. We have not yet responded to the complaints

## **Table of Contents**

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, 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 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.

Other than the immediately preceding discussion, we are not currently a party to any other material legal proceedings.

### **ITEM 1A. RISK FACTORS**

#### **Risks Related to Our Business and Industry**

*Our industry is highly competitive, and we often compete against large, well-established competitors that have significantly greater financial resources than we have.*

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 several large medical device manufacturers, including Philips Medical Systems, General Electric Healthcare, Siemens Medical Systems and Toshiba Medical Systems. All of these competitors offer a full line of imaging cameras for each diagnostic imaging technology, including x-ray, magnetic resonance imaging, computerized tomography, ultrasound and nuclear medicine, or a combination of them. For example, there are hybrid modalities commercially available that combine the technologies of positron emission tomography, or PET, with computed tomography, or CT, as well as others that combine single photon emission computed tomography, or SPECT, with CT technology. The existing imaging systems sold by our competitors have been in use for a longer time than our products and are more widely recognized and used by physicians and hospitals for nuclear imaging. Many of our competitors and potential competitors enjoy significant competitive 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.

We are aware of certain major medical device companies that are developing solid-state cameras that may compete with our product offerings. In addition, we are aware of a privately-held company, Gamma Medica, that is currently marketing a solid-state gamma camera for breast imaging. We do not believe that this camera can be used in a cardiac application. However, we cannot assure you that Gamma Medica will not attempt to modify its existing camera for use in the cardiac segment in the future, or develop another gamma camera for cardiac applications. We are also aware of a second company, Spectrum Dynamics, that has demonstrated a proof-of-concept solid-state gamma camera that we believe it may market in the cardiac segment. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products and services. Current or future competitors may develop technologies and products, including hybrid technologies, that demonstrate better image quality, ease of use or mobility than our imaging systems. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are less expensive and/or perform better than alternatives available for the same purpose. If we are unable to compete effectively against our existing and future competitors, our sales will decline and our business will be harmed.

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The competitive nature of the nuclear imaging industry has had an impact on the volume of sales and pricing of our gamma cameras. We anticipate that pricing pressures will continue to impact our gamma camera product revenue and gross profit.

In providing comprehensive mobile nuclear imaging solutions, we generally compete against small businesses employing traditional vacuum tube cameras that must be transported in large vehicles and cannot be moved in and out of physician offices. We also compete against a number of physicians or companies who use Digirad cameras in relatively small mobile imaging businesses which have the advantage of a lower cost structure. In addition, we compete against imaging centers that install nuclear gamma cameras and make them available to referring physicians in their geographic vicinity.



**Table of Contents**

We plan to pilot the leasing of ultrasound equipment and personnel. In this market, we expect to compete against many large companies who will enjoy many of the same competitive advantages outlined above, as well as small companies with established relationships in local markets who may be able to take advantage of their lower cost structures.

***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.***

The National Electrical Manufacturers Association, or NEMA, estimates that sales of nuclear imaging equipment, excluding maintenance revenue, declined approximately 6% in 2005 to \$349 million, and projects further declines of 6%-9% in 2006 and 2007. 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, position emission tomography, and hybrids among these modalities. In addition, the market for single-headed cameras, our predominant camera sales market until recently, has significantly declined, and we cannot assure you that we will be able to compensate for this decline by the introduction of our triple-headed camera or other alternative or more competitive products. If this decline continues and we are unable to offset its effects on our business by expanding our market share or successfully introducing alternative products and services, our sales will continue to decline and our business will be significantly harmed.

***Changes in laws, regulations, or coverage and reimbursement policies of third-party payors may adversely impact our ability to market and sell our products and services.***

Our physician and hospital customers rely on adequate third-party payor coverage and reimbursement to maintain their operations. Changes in laws, regulations or coverage and reimbursement policies of third-party payors with respect to purchases of our nuclear imaging cameras and the delivery of our services may adversely affect the demand for products and services, resulting in a decline in our sales and harm to our business. We cannot predict what changes may be made to such laws, regulations, or coverage and reimbursement policies, but we believe that future coverage and reimbursement may be subject to increased restrictions. Additionally, we cannot be certain that under prospective payment systems, or established fee schedule payment formulas, under which healthcare providers may be reimbursed a fixed amount based on the patient's condition or the type of procedure performed, the costs of our products and services will be justified and incorporated into the overall payment for the procedure.

Effective January 1, 2007, under the federal anti-self-referral or Stark Laws, nuclear medicine will be listed among the designated health services that 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. These changes will make the Stark Laws applicable to DIS annual lease contracts. DIS physician customers may be able to meet the in-office ancillary services exception to the Stark Law if they 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. 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. Recently proposed changes to the Medicare reimbursement system that would have decreased overall reimbursements for procedures performed by our physician clients were not implemented, and reimbursement levels have remained the same over those of 2005. However, because we charge customers based on a flat lease rate, we cannot predict whether or to what extent any future Medicare reimbursement reduction would impact our business. If reimbursement reductions are implemented, sales of our gamma cameras and our services could continue to suffer and we may receive pressure from our customers to terminate or otherwise materially modify the lease arrangements for our DIS services. 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. A number of third party payors in geographic locations currently served by us issued guidelines prohibiting 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, in order to obtain reimbursement for nuclear imaging procedures. These privileging standards also exclude physicians who are not radiologists or cardiologists from obtaining reimbursements for nuclear imaging procedures. We cannot assure you that these guidelines will be changed, or that they will not be adopted by other third party payors, including Medicaid, Medicare and private insurers. These continued efforts have resulted in several instances where third-party payors have refused to reimburse patients or healthcare providers for our imaging services. Further, in October 2005, the American College of Cardiology Foundation and the American Society of Nuclear Cardiology issued new appropriateness criteria for cardiac imaging that we believe may result in a decrease of the overall number of nuclear imaging procedures being performed. Any such decrease could negatively affect our DIS business and product sales.

## **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. The loss of any 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. Furthermore, our future growth will depend in part upon our ability to identify, hire and retain nuclear imaging technologists, certified cardiographic technicians, 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. In addition, in the first quarter of 2006, we experienced a 38% rate of employee turnover for the combined service and product segments, a decrease from the annualized rate for 2005. If we are unable to improve upon this metric, our business and financial condition will continue to be adversely affected.

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

Our nuclear imaging systems and DIS services may become obsolete or unmarketable if other products or services utilizing new technologies or the development of hybrid imaging modalities, such as those combining PET and CT or SPECT and CT, or any other imaging modality, are introduced by our competitors or new industry standards emerge. For example, we have begun to upgrade our existing single-head DIS mobile camera fleet with our mobile triple-head cameras because we believe some of our single-head cameras have become obsolete. In addition, we cannot assure you that our triple head cameras will not also become obsolete, or that we will be able to develop or market successful new products and services or enhancements to our existing products. Nor can we assure you that our future products and enhancements will be accepted by our current or potential customers or by the third-party payors who financially support many of the procedures performed with our products. 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 efforts 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 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;

obtain appropriate coverage and receive adequate reimbursement notifications and respond to them in a commercially viable way;

comply with changing or new regulatory requirements; and

develop an effective marketing, sales and distribution network.

If we do not develop and obtain required regulatory approvals or clearances for new products, necessary licensure, services or product enhancements in time to meet market demand, or if there is insufficient demand for these products, services or enhancements, our business, financial condition and results of operations will likely suffer. In addition, even if our customers acquire such 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 such products, services or enhancements.

***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 several new states, adding new hub locations in states in which we currently operate and increasing existing hub utilization by adding physician customers and routes. As we undertake this expansion, we have hired and will need to continue to hire, train and retain qualified personnel. Our progress in expanding

## **Table of Contents**

into new geographies has been slower than anticipated, our hub utilization and customer density have decreased, and we cannot assure you that the new sales personnel we hire 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. Our expansion into additional domestic markets is subject to inherent risks, including those associated with compliance with applicable state laws and regulations, including but not limited to laws and regulations concerning the use, storage, handling and disposal of radioactive materials, the acquisition of required licensures, compliance with state scope-of-practice laws, and difficulties in staffing and managing operations. 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. 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, Cardius-3, 2020rc Imager and SPECTpak PLUS camera systems, each of which is designed for use in the nuclear imaging market segment and all of which utilize the same solid-state technology. In addition, we offer a mobile imaging leasing service through DIS, which includes an imaging system, certified personnel, required licensure and other support for nuclear imaging procedures. 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 recover because we do not have the breadth of products or services that would enable 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 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 the next three years, as the period of use of our cameras increases, other significant defects may occur. Equipment failures could result from any number of causes, including equipment aging, ordinary wear and tear due to regular transportation and relocation, failure to perform routine maintenance and latent hardware or software defects of which we are unaware. If significant defects do arise with our gamma cameras, our reputation among physicians and hospitals could be damaged and our business would be harmed.

Additionally, physicians rely on our DIS services to provide nuclear 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 new mobile Cardius-3 camera, weather and the availability of staffing, transportation and necessary supplies. If we are unable to provide physicians or hospitals our DIS services in a timely and effective manner, our reputation among physicians and hospitals could be damaged and 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 make the required payments under the terms and provisions of their lease commitments. Our DIS business is also affected by the ability of physicians to pay us, which in turn may be affected by general economic and business conditions and the availability of reimbursement for the physicians. In addition, typically, a small number of our DIS customers decide to purchase their own cameras, made by us or by one of our competitors, rather than continue to use our DIS leasing service. If purchases by DIS customers of cameras made by our competitors were to increase beyond the levels we have historically experienced, 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. 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. To



## **Table of Contents**

be successful, our contract manufacturers and suppliers must provide us with the components of our systems in requisite quantities, in compliance with regulatory requirements, in accordance with agreed-upon specifications, at acceptable cost and on a timely basis. Segami Corporation, or Segami, has developed image processing software for our camera under a non-exclusive license agreement. In the event that Segami attempts to terminate the license agreement, refuses to extend the term of the license or seeks to impose unreasonable pricing or terms, we would have to find an alternative software system to use in our gamma camera that may not be readily available. As a result, we could have delays in the production of our gamma cameras for an extended period of time that could cause the loss of customers and revenue.

Our reliance on these outside suppliers subjects us to a number of risks that could harm our business, including:

suppliers may make errors in manufacturing components that could adversely affect the efficacy or safety of our products or cause delays in shipment of our products;

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

we may have difficulty locating and qualifying alternative suppliers for our components;

once we identify alternative suppliers, we could experience significant delays in production due to the need to evaluate and test the products delivered by alternative suppliers and to obtain regulatory qualification for them;

we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;

we use some suppliers that are small, privately-held companies, and these suppliers could encounter financial or other difficulties that could cause them to modify or discontinue their operations at any time;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products or services. These events could harm our business and operating results.

### ***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 will likely be 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 one independent distributor in the United States and an independent, international sales distributor to market, sell and distribute our products and services. Our domestic third-party distributor is generally permitted to market, sell and distribute competing imaging products that are used or refurbished and meet specified age requirements. Our international distributor is prohibited from promoting or distributing any other gamma camera product, but not prohibited from offering competing services. We face intense 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, which would negatively affect our ability to compete effectively as a distributor of nuclear imaging devices. Additionally, even if we are able to expand our sales force and enter into agreements with additional

third-party distributors on commercially reasonable terms, they may not commit the necessary resources effectively to market, sell and distribute our products and services domestically and internationally. 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 accordingly.

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

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 difficult to obtain, 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 at all. If we

## **Table of Contents**

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, including workers compensation insurance, could become prohibitively expensive, and our ability to become profitable could be diminished.

***If we choose to acquire new or complementary businesses, products or technologies instead of developing them ourselves, we may be unable to complete those acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.***

Our success depends on our ability to continually enhance and broaden our product and service offerings in response to changing customer demands, competitive pressures and technologies. We may in the future choose to pursue collaborations or acquisitions instead of developing businesses, products or technologies ourselves. We cannot assure you, however, that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology into our company in a cost-effective and non-disruptive manner. Furthermore, there is no certainty that we would be able to attract, hire or retain key employees associated with any acquired businesses, products or technologies.

Integrating any acquired businesses, products or technologies could be expensive and time consuming, disrupt our ongoing business and divert the attention and resources of our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will likely suffer. Additionally, any amortization of assets or charges resulting from the costs of acquisitions could negatively impact our operating results.

***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. This facility is located a short distance from the wildfires that destroyed many homes and businesses in San Diego County, California in 2003. 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. A disaster could significantly harm our business and results of operations. The insurance we maintain against fires and other natural disasters may not be adequate to cover our losses in any particular case.

Additionally, electrical power is vital to our operations and we rely on a continuous power supply to conduct our business. California has experienced significant electrical power shortages and price volatility in recent years, and such shortages and price volatility may occur in the future. In the event of an acute power shortage, the California system operator has on some occasions implemented, and may in the future implement, rolling blackouts throughout California. If our energy costs substantially increase or blackouts interrupt our power supply frequently or for more than a few days, we may have to reduce or temporarily discontinue our normal operations. In addition, the cost of our research and development efforts may increase because of the disruption to our operations. Any such reduction or disruption of our operations at our facilities could harm our business.

## **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 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.

Although we believe that our procedures for use, handling, storing and disposing of these hazardous materials comply with legally prescribed standards, 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.





## **Table of Contents**

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. The laws that directly or indirectly affect our ability to operate our business include 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 federal False Statements Statute; 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 either require specific licenses or certifications for our personnel or that require direct supervision of our personnel 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 Medicare Physician Fee Schedule only if certain conditions are satisfied, including the requirement that the physician personally perform, or adequately supervise the performance of, the test 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 the foregoing.

We implemented a compliance program in 2002 to help assure that we identify and correct any compliance issues and remain in compliance with the above and other applicable laws, to provide training of employees, to conduct auditing and monitoring of the Company's operations, to provide for a compliance hotline, and to achieve other compliance goals. Like most companies with active and effective compliance programs, we occasionally discover compliance concerns. In such cases, and in accordance with our compliance program, 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 such 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 governmental laws or regulations to which we or our customers are subject, or if the interpretation of the foregoing changes, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licensure under these laws that we do not already 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. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. 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.***

In the United States, federal and state lawmakers regularly propose and, at times, enact new legislation establishing significant changes in the healthcare system. Changes in the Medicare Modernization Act and other legislation reduced payment amounts for some of the drugs used in conjunction with our imaging procedures. Because the new reimbursement system is based on the prices of radiopharmaceuticals and other drugs reported to CMS by manufacturers on a quarterly basis, we cannot predict the amount of future reimbursement, however downward changes to Medicare reimbursement rates may adversely impact reimbursement to customers or potential customers that use or could use our cameras and services, and may therefore affect us. If these reimbursement limitations 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. Effective January 1, 2007 nuclear medicine will be listed in the federal anti-self-referral laws known as the Stark Laws among the designated health services that 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. These changes will make the Stark Laws applicable to DIS annual lease contracts. DIS physician customers may be able to meet the in-office ancillary services exception to



## **Table of Contents**

the Stark Law if they 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. 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

***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 that operate our cameras be licensed or certified and such licensing and certification requirements are subject to change. Obtaining such licenses may take significant time as we expand into additional states or if the applicable 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 lease services business involves administering and furnishing radiopharmaceuticals and 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 were to determine 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 in any of the states in which we currently conduct business, or in states where we plan to expand, would require us to modify the types of business models we can utilize in the affected jurisdictions. In either case, we would incur substantial expense and could encounter substantial operational burdens.

In the healthcare industry, various types of organizations are accredited to facilitate meeting certain Medicare certification requirements, expedite third-party payment and fulfill state licensure requirements. Some managed care providers prefer to contract with accredited organizations. We are aware of a number of third party payors in geographies in which we do business that are requiring physicians to obtain certain accreditations or certifications in order to obtain reimbursement for imaging procedures, and to meet specified privileging standards. In our DIS business, although the majority of our customers continue to be cardiologists, an increasing number of new customers are non-cardiologists who would not currently meet the certifications required by payors in certain geographies. We have obtained accreditation from the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories for seventeen of our hub locations, and are working towards obtaining accreditation in five others. We cannot assure you that we will be successful in obtaining those additional certifications, or that obtaining them will satisfy the requirements of these payors. If it becomes necessary for us or our customers to obtain any additional accreditations or certifications in the future in order to satisfy the requirements of third-party payors or regulatory agencies, there can be no assurances that we or they will be able to obtain or continuously maintain this accreditation, and our business could be adversely affected.

***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 if the malfunction were to recur. 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. A



## **Table of Contents**

recall involving one of our products could harm the reputation of the product and our company and would be particularly harmful to our business and financial results.

***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, or injunctions. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, 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. In particular, unless exempt, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved 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. Because we cannot assure you that any new products we develop, or any product enhancements, will be subject to the generally shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancements may occur. While we have not been required to obtain PMA approval for any of our products, there is no assurance that the FDA will not require a new product or product enhancement to go through the more lengthy, burdensome, and expensive PMA approval process. Further, pursuant to FDA regulations, we can only market our products for cleared or approved uses.

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.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we now or in the future market and sell our products in foreign countries, we may be subject to rigorous regulation by those foreign governmental authorities. In such circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

***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 that 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.

## **Table of Contents**

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

*Our quarterly and annual financial results are difficult to predict and are likely to fluctuate significantly from period to period because our business prospects are uncertain and our DIS leasing services business is seasonal.*

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 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;

reimbursement prohibitions imposed by third party payors on providers of mobile imaging services;

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;

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

timing and magnitude of our expenditures;

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;

our addition or termination of research programs or funding support; and

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interruption in the manufacturing or distribution of our products and services; and 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. For example, our daily services have typically declined from our second fiscal quarter to our third fiscal quarter due to summer holidays and vacation schedules. We have also experienced declining daily services in December due to holidays and in our first quarter due to weather conditions in certain parts of the United States. 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.

In addition, due to the way that customers in our target markets acquire our products, a large percentage of our orders of gamma cameras 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.

For these reasons, we believe that quarterly and annual sales and operating results may vary significantly in the future and that 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. Accordingly, 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 period 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 expect to 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 expect to incur such losses and increased operating expenses in the near term as we, among other things:

expand our manufacturing operations and 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.



## **Table of Contents**

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.

*The sales cycle for our gamma cameras is typically lengthy, which may result in significant fluctuations in our revenue.*

Our sales efforts for our gamma cameras are dependent on the capital expenditures budgets of the physicians and hospitals to which we market. Often physicians and hospitals require a significant amount of lead time to plan for a major acquisition such as the purchase of our imaging systems. We may spend substantial time, effort and expense long before we actually consummate an order of our cameras and with no assurance that we will ultimately be successful in achieving any such orders. As a result, we may experience significant fluctuations in our revenues. Furthermore, evaluating and predicting our future sales and operating performance is difficult and may not be as accurate as it could be if we had shorter sales cycles.

## **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 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. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, advisors and corporate partners, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

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.*

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our products, their components or the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, they may claim that their patents have priority over ours because their patents were filed or invented earlier. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our products may infringe. There could also be existing patents that one or more components of our products may be infringing of which we are unaware. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

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.



## **Table of Contents**

### ***We may be subject to lawsuits and actions brought by our employees.***

We may from time to time be subject to employment litigation or administrative actions resulting from claims against us by current or former employees including claims for wrongful termination, wage and hour law violations, or other alleged wrongful conduct. Any employment litigation could significantly divert our management's time and attention and could result in monetary or other damages that could negatively impact our financial results.

### ***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 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.***

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.

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## **Table of Contents**

***Our common stock has been publicly traded for a short time 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;

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 <sup>2</sup>/<sub>3</sub>% 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**

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

We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-113760) that was declared effective by the Securities and Exchange Commission on June 9, 2004.

As of March 31, 2006, we had used approximately \$14.2 million of the net proceeds from our initial public offering to repay our lines of credit, capital leases and notes payable, none of which was paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. In addition, we had used \$10.3 million to fund operations and capital equipment purchases. We invested the remainder of the proceeds in investment-grade, interest bearing instruments, pending their use to fund working capital and capital expenditures.

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

None.

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**Table of Contents**

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

None.

**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
4.2(4)	Amended and Restated Investors Rights Agreement by and among Digirad Corporation and the investors listed on the schedule attached thereto, dated April 23, 2002, as amended
10.1(1)	Digirad Corporation 2004 Stock Incentive Plan as Amended and Restated April 27, 2006
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

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- (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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2004.
- (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 November 2, 2004.

**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: May 10, 2006

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

(Principal Executive Officer)

Date: May 10, 2006

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

(Principal Financial and Accounting Officer)



**Table of Contents**

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