ANIMAS CORP
Form 10-Q
August 15, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2005

or

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

For the transition period from to

Commission file number 000-50674

ANIMAS CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**23-2860912**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

200 LAWRENCE DRIVE, WEST CHESTER, PA	**19380**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(610) 644-8990**

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 þ No o.

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

Yes o No þ.

Common stock, $0.01 par value, outstanding at August **10**, 2005: **20,696,301** shares

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PART I. FINANCIAL INFORMATION
ITEM 1. Financial Statements

ANIMAS CORPORATION AND SUBSIDIARIES
Consolidated Balance Sheets
(unaudited)

	June 30, 2005	December 31, 2004
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 15,704	$ 30,867
Short-term investments	4,710	
Accounts receivable, net of allowance for doubtful accounts of $2,061 in 2005 and $1,702 in 2004	22,995	22,382
Inventories	12,214	10,924
Prepaid expenses and other current assets	3,193	1,378
Total current assets	58,816	65,551
Property and equipment, net	8,018	6,780
Deposits and other assets	3,532	3,654
Restricted cash	550	
Total assets	$ 70,916	$ 75,985
Liabilities and Stockholders Equity		
Current liabilities:		
Current portion of long-term debt	$ 211	$ 398
Accounts payable	6,251	4,430
Accrued expenses	7,322	4,077
Total current liabilities	13,784	8,905
Other liabilities	1,771	1,820
Long-term debt	183	254
Total liabilities	15,738	10,979

Commitments and contingencies		
Stockholders equity:		
Series A, B, and C Preferred stock, $0.01 par value; authorized 10,000,000 shares; none issued and outstanding		
Common stock, $0.01 par value; authorized 100,000,000 shares; issued and outstanding 20,654,985 shares in 2005 and 20,022,765 in 2004	206	200
Additional paid-in capital	168,365	164,784
Deferred compensation	(116)	(142)
Unrealized losses on available for sale securities	(2)	
Accumulated deficit	(113,275)	(99,836)
Total stockholders equity	55,178	65,006
Total liabilities and stockholders equity	$ 70,916	$ 75,985

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

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ANIMAS CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	**2004**	**2005**	**2004**
	(in thousands, except share and per share data)			
Net revenues	$ 21,440	$ 20,420	$ 40,788	$ 25,257
Operating expenses:				
Cost of products sold	11,586	7,337	19,669	10,278
Research and development expenses	2,060	1,381	3,781	2,818
Selling, general and administrative expenses	10,958	8,982	21,700	17,421
Purchased in-process research and development			9,265	
Total operating expenses	24,604	17,700	54,415	30,517
Income (loss) from operations	(3,164)	2,720	(13,627)	(5,260)
Interest income	135	53	291	54
Interest expense	(57)	(137)	(103)	(242)
Net income (loss)	$ (3,086)	$ 2,636	$ (13,439)	$ (5,448)
Basic net income (loss) attributable to common stockholders per share	$ (0.15)	$ 0.24	$ (0.66)	$ (0.72)
Diluted net income (loss) attributable to common stockholders per share	$ (0.15)	$ 0.14	$ (0.66)	$ (0.72)
Weighted average shares basic	20,588,143	11,037,815	20,437,321	7,530,011
Weighted average shares diluted	20,588,143	18,291,612	20,437,321	7,530,011

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

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ANIMAS CORPORATION AND SUBSIDIARIES
Consolidated Statement of Stockholders Equity
Six Months Ended June 30, 2005
(unaudited)

	Preferred stock		Common stock		Additional paid-in	Deferred	Unrealized losses on available for sale	Accumulated	Total stockholders
	Shares	Amount	Shares	Amount	capital	compensation	securities	deficit	equity
					(in thousands, except share data)				
Balance, December 31, 2004		$	20,022,765	$200	$164,784	$ (142)	$	$ (99,836)	$ 65,006
Exercise of stock options to purchase common stock			600,983	6	3,250				3,256
Issuance of common stock upon exercise of warrants			19,000		173				173
Issuance of common stock under employee stock purchase plan			12,237		158				158
Unrealized losses on investments							(2)		(2)
Amortization of deferred compensation						26			26
Net loss								(13,439)	(13,439)
Balance, June 30, 2005		$	20,654,985	$206	$168,365	$ (116)	$ (2)	$(113,275)	$ 55,178

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

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ANIMAS CORPORATION AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended June 30, 2005	2004
	(in thousands)	
Cash flows from operating activities:		
Net loss	$(13,439)	$ (5,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,366	1,055
Non-cash compensation and interest expense	26	54
Purchase of in-process research and development	9,265	
Bad debt expense	756	442
Other		12
Changes in net assets and liabilities:		
Accounts receivable, net	(1,369)	(4,583)
Inventories	(1,144)	(1,893)
Cost associated with deferred revenue		(239)
Prepaid expenses and other current assets	(1,815)	(403)
Deposits and other assets	137	194
Restricted cash	(550)	550
Accounts payable	1,821	2,637
Accrued expenses and other liabilities	3,196	1,297
Net cash used in operating activities	(1,750)	(6,325)
Cash flows from investing activities:		
Purchases of property and equipment	(1,403)	(2,163)
Purchases of short-term investments	(4,712)	
Payment for acquisition	(10,627)	
Net cash used in investing activities	(16,742)	(2,163)
Cash flows from financing activities:		
Proceeds from lines of credit		12,102
Repayments on lines of credit		(14,759)
Proceeds from issuance of common stock, net of offering costs	3,587	66,374
Repayments on long-term debt	(258)	(271)
Proceeds from sale of preferred stock		407
Net cash provided by financing activities	3,329	63,853

Net increase (decrease) in cash and cash equivalents	(15,163)	55,365
Cash and cash equivalents at beginning of period	30,867	384
Cash and cash equivalents at end of period	$ 15,704	$ 55,749

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

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ANIMAS CORPORATION AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share data)
(unaudited)

(1) Organization and Description of Business

Animas Corporation (the Company) manufactures and distributes insulin pumps as well as ancillary pump supplies required for the use of the pump. The Company, a Delaware corporation founded in 1996, is located in West Chester, Pennsylvania. The Company received clearance from the Food and Drug Administration (the FDA) for its first insulin pump in February 2000 and began shipping this product in July 2000. The Company received clearance for its third-generation pump, the IR 1200, in October 2003 and began shipping it in April 2004. In December 2004, the Company received clearance for its newest pump, the IR 1250, and began shipping it in February 2005. In the United States, the Company generally markets its products through both a direct sales force and distributors. All of the Company s operations are located in the United States. Although most of the Company s sales of product to patients occur in the United States, it has contracted with independent distributors to sell products in Australia, Austria, Canada, the Czech Republic, France, Finland, Greece, Germany, Hungary, the Republic of Ireland, Israel, Italy, New Zealand, Spain, Sweden and the United Kingdom. The Company is also developing a micro-needle and micro-pump technology, as well as, implantable glucose sensor for people with insulin-requiring diabetes.

(2) Summary of Significant Accounting Policies

Unaudited Interim Results. The accompanying consolidated financial statements for the three and six months ended June 30, 2005 and 2004 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position and the results of operations and cash flows for the three and six months ended June 30, 2005 and June 30, 2004 have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or eliminated. The results for the three and six months ended June 30, 2005 are not necessarily indicative of the results to be expected for the year ending December 31, 2005 or for any other interim period.

Principles of Consolidation. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents. The Company considers all highly liquid debt instruments with an original maturity of three months or less when purchased to be a cash equivalent. Cash and cash equivalents include money market funds, short-term commercial paper and various deposit accounts.

Short-term Investments. The Company classifies all of its investments as available for sale and therefore carries these investments at fair market value. Unrealized gains and losses are reported as a separate component of stockholders equity.

Accounts Receivable Allowance for Doubtful Accounts. Accounts receivable consist of amounts due from third party payors (governmental and non-governmental), distributors, and patients. In estimating the collectability of accounts receivable, the Company analyzes historical bad debts, payor and patient concentrations, payor and patient credit-worthiness, and current economic trends. These allowances are recorded in the period when the revenue is recorded. Allowances are adjusted currently for any changes in estimated collections.

Accounts receivable are net of allowances for doubtful accounts of $2,061 and $1,702 at June 30, 2005 and December 31, 2004, respectively. Bad debt expense was $488 and $756 for the three and six months ended June 30, 2005 and $234 and $442 for the three and six months ended June 30, 2004, respectively. The related write-offs of accounts receivable were $368 and $397 for the three and six months ended June 30, 2005 and $191 and $280 for the three and six months ended June 30, 2004, respectively.

Inventories. Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Cost for pumps includes material, labor and manufacturing overhead. Ancillary supplies inventory and raw materials inventory include material costs only.

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Product Warranties. The Company provides a four-year warranty on its insulin pumps. Warranty expense is recorded in the period that product shipment occurs. The expense is based on historical experience and projected trends of warranty claims and the estimated cost to settle the claims. At June 30, 2005 and December 31, 2004, accrued product warranties totaled $2,604 and $1,349, respectively, and are classified as a current liability in accrued expenses ($1,624 and $350, respectively) and as a long-term liability in other liabilities ($980 and $999, respectively) in the accompanying consolidated balance sheets. Given the four-year warranty period of the Company s insulin pumps, the portion of the warranty accrual classified as long-term represents the Company s estimate of costs to settle warranty claims to be incurred in excess of one year from the balance sheet date.

A tabular reconciliation of the changes in the Company s product warranty liability is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	**2004**	**2005**	**2004**
Balance at beginning of period	$ 1,942	$ 1,743	$ 1,349	$ 1,734
Warranty expense	1,872	209	2,985	805
Warranty claims settled	(1,210)	(215)	(1,730)	(802)
Balance at end of period	$ 2,604	$ 1,737	$ 2,604	$ 1,737

Revenue Recognition. Revenues are generated primarily from the sale of insulin pumps and ancillary supplies. Customers do not have any right of return or any right to cancel or terminate the sale once the pumps or ancillary supplies are shipped. Pump and ancillary supplies net revenues are recognized upon shipment in accordance with Staff Accounting Bulletin No. 104 (SAB 104). In accordance with EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21) in instances where the Company provides pump operation training, the Company defers the fair value of the training until it has been delivered. The Company bases the fair value of the training on the historical amount the Company has paid to independent service providers for training patients on the operation of the pump. Though the insulin pump has standalone value, there is no objective evidence as to the pump s fair value since the Company is reimbursed the same amount with or without training. As a result, the residual method under EITF 00-21 is utilized. The Company defers revenues associated with training until it has been delivered.

During the six months ended June 30, 2005, approximately 72% of the Company s products were sold directly to patients. The Company bills these patients directly or bills their healthcare payors. Levels of reimbursements from third party payors vary depending upon the specific benefits provided under each patient s coverage. At the time of sale, the Company records revenue net of a contractual allowance which represents the difference between the established billing rate and third party payor payments.

In October 2003, the Company received FDA clearance for its IR 1200 pump. The Company began shipping the IR 1200 in April 2004. During the period of November 1, 2003 to March 31, 2004, the Company initiated an upgrade program in which the Company offered to each new patient purchasing an IR 1000 pump the option to upgrade to the IR 1200 pump at no additional charge. As required by SAB 104, the Company deferred the recognition of net revenues on all pump shipments with an upgrade obligation. As of September 30, 2004, the Company had completed the upgrade program. As a result of this program, the Company s net revenues for the second and third quarter of 2004 were increased by the recognition of revenues deferred from previous quarters, as the Company shipped upgraded pumps or patients declined the upgrade.

Revenues from products sold directly to domestic and international distributors are recognized upon shipment, and are approximately 28% of the Company s products during the six months ended June 30, 2005. Distributors have no right of return. The Company has no post-shipment obligations to its distributors.

Stock-Based Compensation. In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. This standard amends the transition and disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation. As permitted by SFAS No. 148, the Company applies the intrinsic value-based method of

accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations to account for its stock options. Under this method, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. As allowed by SFAS No. 148, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS No. 148.

Had the Company determined compensation cost for options granted during the three and six months ended June 30, 2005 and 2004 and the employee stock purchase plan in 2005, based on the fair value method at the grant date under SFAS No. 148, the Company s net income (loss) and net income (loss) per share would have been reported as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net income (loss) attributable to common stockholders, as reported	$(3,086)	$2,636	$(13,439)	$(5,448)
Add Non-cash employee compensation, as reported	8	8	16	16
Deduct Total stock-based employee compensation expense determined under fair value-based method	(836)	(154)	(1,462)	(279)
Pro forma net income (loss) attributable to common stockholders	$(3,914)	$2,490	$(14,885)	$(5,711)
Income (loss) attributable to common stockholders per share:				
Basic, as reported	$ (0.15)	$ 0.24	$ (0.66)	$ (0.72)
Basic, pro forma	$ (0.19)	$ 0.23	$ (0.73)	$ (0.76)
Diluted, as reported	$ (0.15)	$ 0.14	$ (0.66)	$ (0.72)
Diluted, pro forma	$ (0.19)	$ 0.14	$ (0.73)	$ (0.76)

Use of Estimates. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Some of the more significant estimates include the allowance for doubtful accounts, contractual allowances, inventory obsolescence, and the warranty accrual. Actual amounts could differ from those estimates.

Reclassifications. Certain amounts in the prior year have been reclassified to conform to the current year presentation.

New Accounting Pronouncements. In November 2004, the FASB issued SFAS No. 151 (SFAS 151), Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material should be recognized as current period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. SFAS 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. SFAS 151 should be applied prospectively. The Company does not expect the adoption of this standard to have a material impact on the consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123(R) (SFAS 123(R)), Share-Based Payment. SFAS 123(R) revises SFAS 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements (with limited exceptions). The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments

issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement, as amended, is effective as of the beginning of the fiscal year that begins after June 15, 2005. The full impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income (loss) and income (loss) per share noted above under Stock-Based Compensation.

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In May 2005, the FASB issued SFAS No. 154 (SFAS 154), Accounting Changes and Error Corrections a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS 154 requires retrospective application to prior periods financial statements for a voluntary change in accounting principle unless it is impracticable to do so. APB Opinion No. 20, Accounting Changes, previously required that most voluntary changes in accounting principles be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005.

(3) Comprehensive Income (Loss)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	**2004**	**2005**	**2004**
Net income (loss)	$(3,086)	$2,636	$(13,439)	$(5,448)
Other comprehensive loss:				
Unrealized losses on available for sale securities	(2)		(2)	
Comprehensive income (loss)	$(3,088)	$2,636	$(13,441)	$(5,448)

(4) Short-term Investments

Short-term investments consist of fixed income securities with original maturities of greater than three months and less than one year. All investments are classified as available for sale. There were no short-term investments at December 31, 2004.

The following summarizes the short-term investments at June 30, 2005:

	Cost	Gross unrealized losses	Fair value
Commercial paper	$3,819	$ (2)	$3,817
Obligations of the U.S. Government	893		893
Total	$4,712	$ (2)	$4,710

(5) Acquired Technology

In March 2005, the Company acquired certain assets of Cygnus, Inc. for $10,627 in cash. The assets include substantially all of Cygnus intellectual property rights, fixed assets, supplier, manufacturing and license agreements, inventory and tangible personal property. The assets acquired were accounted for as an asset purchase as the acquired assets did not constitute a business. The purchase price was allocated as follows:

Inventories	$ 146
Property and equipment	1,201
Patents	15
Purchased in-process research and development	9,265
	$10,627

The $9,265 of purchased in-process research and development was immediately charged to expense as the technology acquired will be used to develop products that have not been approved for sale by regulatory authorities, and the in-process projects to which the patents apply had not yet reached technological feasibility and had no alternative future uses.

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(6) Inventories

Inventories consist of the following as of:

	June 30, 2005	December 31, 2004
Raw materials	$ 2,284	$ 2,225
Work in process	5,119	5,367
Finished goods	5,980	3,914
Less reserve for excess and obsolete inventory	(1,169)	(582)
	$12,214	$ 10,924

In June 2005, the Company recorded a $1.7 million write-down of the IR 1000 insulin pumps returned to inventory under the pump upgrade program as the Company recently decided to concentrate its international marketing efforts in the European market, which is growing rapidly, and shift its marketing focus away from distributing the IR 1000 in third-world markets, as originally planned. Further, the Company increased certain reserves by $1.1 million for the costs of replacing circuit boards containing a now-discontinued component with boards containing a substitute component during the refurbishment process of certain IR 1200 insulin pumps. The replacement circuit boards support the additional functionality of the newer insulin pump models.

(7) Business Segment

A single management team reporting to the President and Chief Executive Officer comprehensively manages the business operations of the Company. The Company does not operate separate lines of business or separate business entities with respect to any of its products. In addition, the Company does not conduct any operations outside the United States. The Company does not prepare discrete financial statements with respect to separate product areas. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. International sales were 13% and 16% of net revenues for the three and six months ended June 30, 2005, respectively.

(8) Income (Loss) per Share

The table below sets forth the reconciliation of the numerators and the denominators of the Company s basic and diluted income (loss) per share computations for the three and six months ended June 30, 2005 and 2004.

	Three Months Ended June 30,			Six Months Ended June 30,		
	Net Income (Loss)	Shares	Per Share Amount	Net Income (Loss)	Shares	Per Share Amount
2005						
Basic	$(3,086)	20,588,143	$(0.15)	$(13,439)	20,437,321	$(0.66)
Dilutive effect of:						
Stock options						
Warrants						
Diluted	$(3,086)	20,588,143	$(0.15)	$(13,439)	20,437,321	$(0.66)
2004						
Basic	$ 2,636	11,037,815	$ 0.24	$ (5,448)	7,530,011	$(0.72)
Dilutive effect of:						
Stock options		1,643,542				

Warrants		482,699				
Preferred Stock		5,127,556				
Diluted	$ 2,636	18,291,612	$ 0.14	$ (5,448)	7,530,011	$(0.72)

For the three and six months ended June 30, 2005 and the six months ended June 30, 2004, diluted loss per share is identical to basic loss per share as the Company is in a net loss position and the common equivalent shares are considered anti-dilutive. For the three and six months ended June 30, 2005, 2,052,616 common stock options and 129,140 common stock warrants were excluded from the diluted calculation because the effect would be anti-dilutive. For the three months ended June 30, 2004, 2,334 common stock options were excluded from the diluted calculation because the effect would be anti-dilutive. For the six months ended June 30, 2004, 2,565,105 common stock options and 153,027 common stock warrants were excluded from the diluted calculation because the effect would be anti-dilutive.

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

CAUTIONARY STATEMENT PURSUANT TO SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES LITIGATION ACT OF 1995:

This report and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in this report and the documents incorporated herein by reference, the words anticipate, believe, estimate, may, expect, intend, and similar expressions are generally intended to identify forward-looking statements. These forward-looking statements include, among others, the statements in Management s Discussion and Analysis of Financial Condition and Results of Operations about our:

- *estimate of the length of time that our existing cash and cash equivalents, short-term investments, expected revenue, and interest income will be adequate to finance our operating and capital requirements;*
- *expected losses;*
- *expectations for future capital requirements;*
- *expectations for increases in operating expenses;*
- *expectations for increases in research and development, marketing, and general and administrative expenses in order to develop products, manufacture commercial quantities of reagents and products, and commercialize our technology;*
- *expectations for the development of an improved insulin pump;*
- *expectations for generating revenue; and*
- *expectations regarding new or expanded collaborations and for the performance of our existing collaboration partners regarding the development and commercialization of products incorporating our technologies.*

Our actual results could differ materially from the results expressed in, or implied by, these forward-looking statements. Potential risks and uncertainties that could affect our actual results include the following:

- *failure to comply with any FDA or foreign regulations;*
- *technical issues relating to the IR 1250 or the IR 1200 or any of the Company s ancillary supplies;*
- *competition;*
- *the failure to develop a market for pumps returned to the Company as a loaner, demo, or a warranty replacement and subsequently refurbished and recertified;*
- *any significant disruption with vendors including parts purchased by the Company that may be discontinued by the vendor;*
- *any failure to achieve and then maintain profitability;*
- *an inability to attract and retain personnel;*
- *the failure to successfully develop and commercialize the technologies acquired from Cygnus, Inc. and Debiotech, SA;*

- *the failure of our ezSet infusion set to be fully-developed or commercially accepted;*
- *technological breakthroughs in diabetes monitoring, treatment, or prevention that could render our products obsolete;*
- *failure to capture recurring purchases of ancillary supplies by patients using our pumps;*
- *an inability to adequately protect our intellectual property;*
- *product liability lawsuits;*
- *the failure to secure or retain third party coverage or reduced reimbursement for our products by third party payors; and,*
- *general economic conditions.*

These and other risks and uncertainties that could affect our actual results are discussed in this report and in our other filings with the Securities and Exchange Commission; particularly the section entitled Risk Factors. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law.

We do not undertake any duty to update after the date of this report any of the forward-looking statements in this report to conform them to actual results.

Overview

We design, develop, manufacture, and sell external insulin pumps for people with diabetes. We were incorporated in Delaware in July 1996 and introduced our first generation pump in July 2000. We began shipping our third generation pump, the IR 1200, in April 2004, and in February 2005, we began to ship the IR 1250. The IR 1250 utilizes the IR 1200 platform but includes additional software which incorporates a food database of up to 500 items and tunes for alerts. We believe that the IR 1200 and the IR 1250 are the smallest full-featured insulin pumps on the market. The IR 1200 and 1250 pumps have a large display, long battery life, precise insulin delivery, and enhanced waterproof integrity. We also provide ancillary supplies on an ongoing basis for patients using our pumps, including insulin cartridges, infusion sets, batteries, and various accessories. We provide extensive education programs and services to people with diabetes.

Our approximately 55 person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximately 75 diabetes educators, or clinical managers, train and provide clinical support to patients in the United States. We also use domestic and international distributors to market, sell, and service our products.

Financial Operations Overview

Net Revenues. We generate revenues primarily from the sale of our external insulin pumps and ancillary supplies, including insulin cartridges and infusion sets. We invoice patients either directly or through their healthcare payors, such as insurance companies and health maintenance organizations. Levels of reimbursement from healthcare payors vary depending upon the specific benefits provided under each patient s coverage. Net revenues for a particular product are the difference between the established billing rate for such product and the contractual allowance given to the healthcare payor.

Pump Upgrade Program. During the period November 1, 2003 to March 31, 2004 (the Period), we implemented a program that allowed patients in the United States, at their option and at no additional cost, to upgrade their IR 1000 pump purchased during the Period to the IR 1200 pump when it became available. In anticipation of the shipment of the IR 1200 in April 2004, we stopped domestic shipments of the IR 1000 for the last three weeks of March 2004. We began shipping the IR 1200 pump in April 2004. As of September 30, 2004, all obligations to ship upgrade pumps under this program were completed. At this time, we do not anticipate the need for additional product upgrade programs, of this nature, in the foreseeable future.

In accordance with U.S. generally accepted accounting principles, we deferred the recognition of all net revenues for IR 1000 pumps shipped under the upgrade program. We did not recognize the net revenue on an IR 1000 pump shipped under this program until either the IR 1200 replacement pump was shipped to the patient requesting an upgrade or the patient declined the upgrade. All IR 1000 pumps shipped to new patients domestically during the Period were subject to this upgrade program. We also deferred the associated cost of products sold on shipments of pumps under the upgrade program. The deferred cost represented the estimated recoverable inventory costs of the IR 1000 pumps when they were returned to us. When we shipped an IR 1200 as a replacement pump, we recorded the cost of the IR 1200 pump as cost of products sold at that time.

Cost of Products Sold. Cost of products sold includes material costs, other direct and indirect manufacturing costs, shipping and handling costs, and product warranty expense. We purchase components and raw materials from third party vendors and assemble them into insulin pumps at our manufacturing facility in West Chester, Pennsylvania. Insulin cartridges and certain other supplies are manufactured for us in Asia and Europe, as well as in the United States under agreements with third party suppliers. All purchases sourced from vendors or suppliers outside the United States are invoiced in U.S. dollars.

Direct and indirect manufacturing costs include material costs, labor costs, electricity and other utilities, maintenance expenses, depreciation and other fixed and variable costs required to operate our plant.

Like most of our competitors, we offer a four-year warranty on our pumps. Warranty expense is recorded in the period that product shipment occurs. The expense is based on historical experience and projected trends of warranty claims and the estimated cost to settle the claims.

Research and Development Expenses. Research and development expenses include costs associated with the design, development and testing of new and existing products. Such costs are charged to expense as incurred and include

salaries and related personnel costs, fees paid to outside consultants, and other direct and indirect costs related to research and product development.

Selling, General and Administrative Expenses. Selling, general and administrative expenses include salaries, commissions and related personnel expenses for employees in sales, marketing, clinical, patient service and administrative functions, as well as overhead costs associated with these activities. Also included are costs associated with promotional literature and videos, trade show participation, education and training and the cost of providing demo pumps and supplies, which are charged to expense as incurred.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our significant accounting policies are more fully described in the accompanying consolidated financial statements. The critical accounting policies described below are those which we believe require estimates based on assumptions that are uncertain at the time the estimates are made, and for which different accounting estimates that management could have reasonably used would have had a material impact on reported financial information. Management has discussed the development and selection of our critical accounting policies and estimates and related disclosures with the Audit Committee of our Board of Directors.

Revenue Recognition. Revenues are generated primarily from the sale of insulin pumps and ancillary supplies. Customers do not have any right of return or any right to cancel or terminate the sale once the pumps or ancillary supplies are shipped. Pump and ancillary supplies net revenues are recognized upon shipment in accordance with Staff Accounting Bulletin No. 104 (SAB 104). In accordance with EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), in instances where we provide pump operation training, we defer the fair value of the pump operation training until the training is delivered. We base the fair value of pump operation training on the historical amount we have paid to independent service providers for training patients on the operation of our pumps. Though the insulin pump has standalone value, there is no objective evidence as to the pump s fair value since we are reimbursed the same amount with or without pump operation training. As a result, the residual method under EITF 00-21 is utilized.

During the six months ended June 30, 2005, approximately 72% of our net revenues were for products sold directly to patients. We bill these patients directly or bill their healthcare payors. Levels of reimbursements from third party payors vary depending upon the specific benefits provided under each patient s coverage. At the time of sale, we record revenues net of third party contractual allowances, which represent the difference between the established billing rate and third party payor payments.

Net revenues for products sold directly to distributors are recognized upon shipment. Distributors have no right of return, and we have no post-shipment obligations.

Accounts Receivable/Allowance for Doubtful Accounts. In estimating the collectability of our accounts receivable, we analyze historical bad debts, payor concentrations, payor and patient credit-worthiness, current economic trends, and changes in patient and/or payor payment terms. These allowances are recorded in the period when the net revenues are recognized based on anticipated future events. If there are unanticipated future events, this allowance may need to be adjusted.

Inventories. Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Costs for pumps include material, labor, and manufacturing overhead. Ancillary supplies inventory and raw materials inventory include material costs only. We review our inventory balances monthly for obsolete inventory. We manage the risk of inventory obsolescence through validating product designs prior to product introduction, as well as through planning of inventory with respect to anticipated design changes. Once inventory is determined to be obsolete, the inventory is charged to cost of products sold, removed from our stockroom, and either scrapped or used for non-inventory purposes.

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Deferred Tax Asset Valuation Allowance. Our estimate for the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Our ability to realize the deferred tax assets depends on our future taxable income as well as limitations on their utilization. A deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our products, competitive conditions, product development efforts, approvals of regulatory agencies and product cost. If actual results differ from these projections, or if our expectations of future results change, it may be necessary to adjust the valuation allowance. As a result of the historic losses, the Company has provided a full valuation allowance for the deferred tax assets.

Warranty Liability. Each of our insulin pumps is sold with a four-year warranty. Our warranty liability represents the total estimated cost for expected future warranty claims related to all products shipped. Warranty expense is accrued in the period that the products are shipped and is based on historical experience, projected trends of warranty claims, and the expected costs to settle the claims. As changes occur in expected warranty claim rates and the estimated cost to settle claims, the warranty liability is adjusted accordingly.

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Three Months Ended June 30, 2005 and 2004

Results of Operations. The following tables set forth, for the periods indicated, certain operational information. A percentage breakdown of net revenues is presented for certain operational items. The breakdown of cost of products sold and gross margin is presented as a percentage of these respective items.

	Three Months Ended June 30,					
	2005		2004		Change, 2005/2004	
	$	%	$	%	$	%
Consolidated Statements of Operations			(in thousands)			
Net revenues	$21,440	100.0%	$20,420	100.0%	$ 1,020	5.0%
Operating expenses:						
Cost of products sold	11,586	54.0	7,337	35.9	4,249	57.9
Research and development expenses	2,060	9.6	1,381	6.8	679	49.2
Selling, general and administrative expenses	10,958	51.1	8,982	44.0	1,976	22.0
Total operating expenses	24,604	114.7	17,700	86.7	6,904	39.0
Income (loss) from operations	(3,164)	(14.7)	2,720	13.3	(5,884)	(216.3)
Interest income	135	0.6	53	0.3	82	154.7
Interest expense	(57)	(0.3)	(137)	(0.7)	80	58.4
Net income (loss)	$ (3,086)	(14.4)%	$ 2,636	12.9%	$(5,722)	(217.1)%

	Three Months Ended June 30,					
	2005		2004		Change, 2005/2004	
	$	%	$	%	$	%
Net Revenues, Cost of Products Sold and Gross Margin			(in thousands)			
Net revenues (dollars and as a percent of total)						
Insulin pumps	$13,748	64.1%	$15,798	77.4%	$(2,050)	(13.0)%
Ancillary supplies	7,692	35.9	4,622	22.6	3,070	66.4
Total	$21,440	100.0%	$20,420	100.0%	$ 1,020	5.0%
Cost of products sold (dollars and as a percent of total)						
Insulin pumps	$ 7,559	65.2%	$ 4,583	62.5%	$ 2,976	64.9%
Ancillary supplies	4,027	34.8	2,754	37.5	1,273	46.2
Total	$11,586	100.0%	$ 7,337	100.0%	$ 4,249	57.9%

Gross margin (dollars and as a percent of total)						
Insulin pumps	$ 6,189	62.8%	$11,215	85.7%	$(5,026)	(44.8)%
Ancillary supplies	3,665	37.2	1,868	14.3	1,797	96.2
Total	$ 9,854	100.0%	$13,083	100.0%	$(3,229)	(24.7)%

	Three Months Ended June 30,	
	2005	2004
Gross margin % (as a percent of net revenues)		
Insulin pumps	45.0%	71.0%
Ancillary supplies	47.6%	40.4%
Total	46.0%	64.1%

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Net Revenues. Net revenues were $21.4 million and $20.4 million, respectively, for the three months ended June 30, 2005 and 2004. Net revenues increased by $1.0 million, or 5.0% in the three months ended June 30, 2005 from the comparable period of 2004. The increase was caused by the continued strong demand for the IR 1250 pump in the U.S., the positive international market response to the IR 1200 pump and the continued growth of ancillary supplies. In the three months ended June 30, 2004, net revenues included $3.8 million of revenue deferred from prior periods due to the pump upgrade program and $2.3 million of revenue delayed from March 2004 in anticipation of the launch of the IR 1200 in April 2004. Net revenues from domestic and foreign sales were $18.6 million and $2.8 million, respectively, in the three months ended June 30, 2005 and $19.5 million and $864,000, respectively, in the three months ended June 30, 2004. Net revenues for insulin pumps were $13.7 million in the three months ended June 30, 2005 compared to net revenues for the comparable prior year s period of $15.8 million, which included $6.1 million of additional net revenue deferred or delayed from prior periods. Our average selling prices of pumps remained relatively stable over this period.

Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges and other ancillary supplies, increased by $3.1 million in the three months ended June 30, 2005 versus the comparable period of 2004. The increase was due to increased unit sales, as prices remained near prior period levels. The growth in unit sales reflected our growth in the number of patients using our pumps in 2005 and our retention of patients from prior years.

We anticipate net revenues for pumps and ancillary supplies to continue to increase in 2005 as we further expand domestically, internationally, and grow the ancillary supplies market.

Cost of Products Sold. Cost of products sold increased by $4.2 million, or 57.9%, to $11.6 million in the three months ended June 30, 2005 from $7.3 million in the comparable period of 2004. The increase was primarily due to the increased volume of sales and an inventory write-down and additional reserve charges of $2.8 million. We recorded a $1.7 million write-down of the IR 1000 insulin pumps returned to inventory under the pump upgrade program as we recently decided to concentrate our international marketing efforts in the European market, which is growing rapidly, and shift our marketing focus away from distributing the IR 1000 in third-world markets, as originally planned. Further, we increased certain reserves by $1.1 million for the costs of replacing circuit boards containing a now-discontinued component with boards containing a substitute component during the refurbishment process of certain IR 1200 insulin pumps. The replacement circuit boards support the additional functionality of our newer insulin pump models. As a percentage of net revenues, cost of products sold increased to 54.0% in the three months ended June 30, 2005 from 35.9% in the comparable period of 2004. Cost of insulin pumps sold increased by $3.0 million, or 64.9% in the three months ended June 30, 2005 as compared to the comparable period of 2004, primarily from the inventory write-down, increased reserve charges and the incurred costs of replacing circuit boards of certain IR 1200 pumps.

Gross Margin. Gross margin decreased to 46.0% in the three months ended June 30, 2005 from 64.1% in the comparable period of 2004. Gross margin for pumps decreased to 45.0% in the three months ended June 30, 2005 from 71.0% in the comparable period of 2004 due to the inventory write-down, increased reserve charges and the incurred costs of replacing circuit boards of certain IR 1200 pumps. Additionally, gross margins from the prior period benefited from the recognition of $6.1 million of additional revenue deferred or delayed from prior periods. Ancillary supplies gross margin increased to 47.6% in the three months ended June 30, 2005 from 40.4% in the comparable period of 2004. Gross margin improvement for ancillary supplies was due to lower cost sources of supply.

It is anticipated that the gross margin and gross margin percentage will improve for the remainder of 2005. Reasons for this improvement include the introduction of our ezSet infusion sets, further reductions of the costs of our existing disposables, and increased absorption of manufacturing overheads.

Research and Development. Research and development expenses increased $679,000, or 49.2%, to $2.1 million in the three months ended June 30, 2005 from $1.4 million in the comparable period of 2004 reflecting increased spending on activities to improve existing products and develop new products and the costs of developing products associated with the Debiotech and Cygnus acquired technology. As a percentage of net revenues, research and development expenses increased to 9.6% in the three months ended June 30, 2005 from 6.8% in the comparable period of 2004. We anticipate a similar increase in research and development costs in 2005 from 2004 as the increase in 2004 from 2003. In 2005, we expect approximately 80% of our research and development budget to be allocated to the

development of next generation pumps and ancillary supplies. We expect future net revenues from these products to supplant net revenues from existing products. The remaining approximately 20% of our research and development budget in 2005 is allocated towards development of long-term products, including micro-needles and continuous glucose sensors.

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Selling, General and Administrative (SG&A) Expenses. SG&A expenses increased by $2.0 million, or 22.0%, to $11.0 million in the three months ended June 30, 2005 from $9.0 million in the comparable period of 2004. As a percentage of net revenues, SG&A expenses increased to 51.1% in the three months ended June 30, 2005 from 44.0% in the comparable period of 2004.

Of the increase, $477,000 was related to higher costs principally associated with increased headcount in the sales, clinical, and marketing functions supporting increased selling activity for existing pumps and ancillary supplies. In addition, higher bad debt expense of $253,000, insurance costs of $172,000, depreciation expense of $152,000 and professional services of $133,000 contributed to higher SG&A costs in the three months ended June 30, 2005. The remaining increase is primarily attributable to increased marketing and promotional expenses and general and administrative expenses associated with operating as a public company.

We expect SG&A expenses to increase in absolute dollars in 2005 from 2004 as we expand our sales, clinical, and marketing efforts to support our growing business. However, we expect that SG&A expenses as a percent of net revenues should decline as we continue to leverage our existing infrastructure.

Interest Income. Interest income increased to $135,000 in the three months ended June 30, 2005 from $53,000 in the comparable period of 2004. The increase was primarily due to a higher investment balance as a result of the initial public offering in May 2004.

Interest Expense. Interest expense decreased to $57,000 in the three months ended June 30, 2005 from $137,000 in the comparable period of 2004. This reflects a lower outstanding debt balance than in the comparable period.

Net Income (Loss). We reported a net loss of $3.1 million in the three months ended June 30, 2005 as compared to net income of $2.6 million in the comparable period of 2004. The loss for the three months ended June 30, 2005 was primarily due to the inventory write-down and the additional reserves charged to expense. The net income for the three months ended June 30, 2004 resulted from the additional revenue associated with the shipment of the additional pumps under the pump upgrade program and the unfulfilled orders from March 2004.

Six Months Ended June 30, 2005 and 2004

Results of Operations. The following tables set forth, for the periods indicated, certain operational information. A percentage breakdown of net revenues is presented for certain operational items. The breakdown of cost of products sold and gross margin is presented as a percentage of these respective items.

	Six Months Ended June 30,					
	2005		2004		Change, 2005/2004	
	$	%	$	%	$	%
Consolidated Statements of Operations			(in thousands)			
Net revenues	$ 40,788	100.0%	$25,257	100.0%	$15,531	61.5%
Operating expenses:						
Cost of products sold	19,669	48.2	10,278	40.7	9,391	91.4
Research and development expenses	3,781	9.3	2,818	11.1	963	34.2
Selling, general and administrative expenses	21,700	53.2	17,421	69.0	4,279	24.6
Purchased in-process research and development	9,265	22.7			9,265	
Total operating expenses	54,415	133.4	30,517	120.8	23,898	78.3
Loss from operations	(13,627)	(33.4)	(5,260)	(20.8)	(8,367)	(159.1)
Interest income	291	0.7	54	0.2	237	438.9
Interest expense	(103)	(0.2)	(242)	(1.0)	139	57.4
Net loss	$(13,439)	(32.9)%	$ (5,448)	(21.6)%	$ (7,991)	(146.7)%

	Six Months Ended June 30,					
	2005		2004		Change, 2005/2004	
	$	%	$	%	$	%
Net Revenues, Cost of Products Sold and Gross Margin			(in thousands)			
Net revenues (dollars and as a percent of total)						
Insulin pumps	$26,458	64.9%	$16,969	67.2%	$ 9,489	55.9%
Ancillary supplies	14,330	35.1	8,288	32.8	6,042	72.9
Total	$40,788	100.0%	$25,257	100.0%	$15,531	61.5%
Cost of products sold (dollars and as a percent of total)						
Insulin pumps	$11,938	60.7%	$ 5,418	52.7%	$ 6,520	120.3%
Ancillary supplies	7,731	39.3	4,860	47.3	2,871	59.1
Total	$19,669	100.0%	$10,278	100.0%	$ 9,391	91.4%

Gross margin (dollars and as a percent of total)						
Insulin pumps	$14,520	68.8%	$11,551	77.1%	$ 2,969	25.7%
Ancillary supplies	6,599	31.2	3,428	22.9	3,171	92.5
Total	$21,119	100.0%	$14,979	100.0%	$ 6,140	41.0%

	Six Months Ended June 30,	
	2005	**2004**
Gross margin % (as a percent of net revenues)		
Insulin pumps	54.9%	68.1%
Ancillary supplies	46.1%	41.4%
Total	51.8%	59.3%

Net Revenues. Net revenues were $40.8 million and $25.3 million, respectively, for the six months ended June 30, 2005 and 2004. Net revenues increased by $15.5 million, or 61.5% in the six months ended June 30, 2005 from the comparable period of 2004. The increase was caused by the positive reception to the IR 1250 pump launch in the U.S., the positive international market response of the IR 1200 pump and continued growth of ancillary supplies. Net revenues from domestic and foreign sales were $34.5 million and $6.3 million, respectively, in the six months ended June 30, 2005 and $23.5 million and $1.8 million, respectively, in the six months ended June 30, 2004. Pump net revenues increased by $9.5 million primarily due to increases in unit shipments due to the continued strong demand for the IR 1250 within the United States and the IR 1200 internationally. Our average selling prices of pumps remained relatively stable over this period.

Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges and other ancillary supplies increased by $6.0 million in the six months ended June 30, 2005 versus the comparable period of 2004. The increase was due to increased unit sales, as prices remained near prior period levels. The growth in unit sales reflected our growth in the number of patients using our pumps in 2005 and our retention of patients from prior years.

Cost of Products Sold. Cost of products sold increased by $9.4 million, or 91.4%, to $19.7 million in the six months ended June 30, 2005 from $10.3 million in the comparable period of 2004. The increase was primarily due to the increased volume of sales and an inventory write-down and additional reserves charged to expense of $2.8 million. As a percentage of net revenues, cost of products sold increased to 48.2% in the six months ended June 30, 2005 from 40.7% in the comparable period of 2004. Primary factors that contributed to the increase included the $2.8 million of inventory write-down and increased reserve charges which offset the improved absorption of manufacturing overhead costs associated with increased production volumes and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by $6.5 million, or 120.3% in the six months ended June 30, 2005 as compared to the comparable period of 2004.

Gross Margin. Gross margin decreased to 51.8% in the six months ended June 30, 2005 from 59.3% in the comparable period of 2004. Gross margin for pumps decreased to 54.9% in the six months ended June 30, 2005 from 68.1% in the comparable period of 2004 due to the inventory write-down, increased reserve charges and increased international sales, which are typically made at a lower selling price than domestic sales. Ancillary supplies gross margin increased to 46.1% in the six months ended June 30, 2005 from 41.4% in the comparable period of 2004. Gross margin improvement for ancillary supplies was due to lower cost sources of supply.

Research and Development. Research and development expenses increased $963,000, or 34.2%, to $3.8 million in the six months ended June 30, 2005 from $2.8 million in the comparable period of 2004 reflecting increased spending on activities to improve existing products and develop new products and the costs of developing products associated with the Debiotech and Cygnus acquired technology. As a percentage of net revenues, research and development expenses decreased to 9.3% in the six months ended June 30, 2005 from 11.1% in the comparable period of 2004.

Selling, General and Administrative (SG&A) Expenses. SG&A expenses increased by $4.3 million, or 24.6%, to $21.7 million in the six months ended June 30, 2005 from $17.4 million in the comparable period of 2004. However, as a percentage of net revenues, SG&A expenses decreased to 53.2% in the six months ended June 30, 2005 from 69.0% in the comparable period of 2004.

Of the increase, $1.2 million was related to higher costs principally associated with increased headcount in the sales, clinical, and marketing functions supporting increased selling activity for existing pumps and ancillary supplies, as well as the launch of the IR 1200 and IR 1250. In addition, higher insurance costs of $506,000, bad debt expense of $314,000, depreciation expense of $290,000, expenses of approximately $326,000 related to correcting a software bug in the IR 1250, and professional fees of $219,000 contributed to higher SG&A costs in the six months ended June 30, 2005. The remaining increase is primarily attributable to increased marketing and promotional expenses and general and administrative expenses associated with operating as a public company.

Purchased in-process research and development. In March 2005, we completed our acquisition of certain assets of Cygnus, Inc. for $10.6 million in cash, of which $9.3 million was immediately charged to expense to purchased in-process research and development as the technology acquired will be used to develop products that have not been approved for sale by regulatory authorities, and the in-process projects to which the patents apply had not yet reached technological feasibility and had no alternative future uses.

Interest Income. Interest income increased to $291,000 in the six months ended June 30, 2005 from $54,000 in the comparable period of 2004. The increase was primarily due to a higher investment balance as a result of the initial public offering in May 2004.

Interest Expense. Interest expense decreased to $103,000 in the six months ended June 30, 2005 from $242,000 in the comparable period of 2004. This reflects a lower outstanding debt balance than in the comparable period.

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Net Loss. We reported a net loss of $13.4 million in the six months ended June 30, 2005 as compared to a net loss of $5.4 million in the comparable period of 2004. The loss for the six months ended June 30, 2005 was primarily due to the $9.3 million of purchased in-process research and development and the write-down of inventory and additional reserves charged to expense of $2.8 million. The net loss for the six months ended June 30, 2004 was favorably impacted by the pump upgrade program.

Seasonality and Quarterly Results

Our business is affected by the reimbursement practices of third party payors. Many patients defer purchasing discretionary durable medical equipment, such as our insulin pumps, until they have satisfied their insurance deductibles which typically occur in the latter half of the calendar year.

	Quarterly Results					
	2005		2004			
	1st Qtr	2nd Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Net revenues	$ 19,348	$21,440	$ 4,837	$20,420	$22,654	$ 20,015
Gross margin	11,265	9,854	1,896	13,083	13,988	11,973
Net income (loss)	(10,353)	(3,086)	(8,084)	2,636	2,819	(14,033)
Basic net income (loss) per share	(0.51)	(0.15)	(2.01)	0.24	0.15	(0.71)
Diluted net income (loss) per share	(0.51)	(0.15)	(2.01)	0.14	0.14	(0.71)

In the first quarter of 2004, our net revenues were $4.8 million as we deferred $4.5 million of net revenues resulting from the pump upgrade program initiated in November 2003. Additionally, our net revenues, in the first quarter of 2004, were impacted by our decision to stop shipment of pumps for the last three weeks in March 2004 in anticipation of the launch of the IR 1200 in April 2004. Revenue for the second quarter of 2004 benefited from the shipment of $2.3 million in revenue delayed at the end of the first quarter and an additional $3.8 million of revenue previously deferred as a result of the pump upgrade program and due to increased demand for our pumps and ancillary supplies. Revenue for the third quarter of 2004 benefited from $5.5 million of revenue previously deferred as a result of the pump upgrade program and due to increased demand for our pumps and ancillary supplies. Net revenue in the fourth quarter of 2004 fell slightly, despite increased demand, as we completed the upgrade program during the third quarter of 2004 and there was no recognition of revenues previously deferred from prior periods. Net revenue in the first quarter of 2005 fell slightly from fourth quarter 2004 as the first quarter revenues tend to decline from the prior year s fourth quarter as patients typically have met their insurance deductibles and by the higher proportion of revenues stemming from international sales, which typically have lower selling prices than domestic sales. Net revenue for the second quarter of 2005 increased due to the continued strong demand of the IR 1250 in the U.S. and the IR 1200 internationally.

In the first quarter of 2004, the gross margin percentage was 39.2% due to the deferral of net revenues and associated costs due to the upgrade program and the decision to stop shipments of pumps for the last three weeks of March 2004. The gross margin in the second quarter of 2004 increased to 64.1% as a result of the increased absorption of overhead due to the increased volume of pumps from the pump upgrade program and the shipment in the second quarter of the unfulfilled orders from the first quarter, that combined contributed 3.7% to the improvement of gross margins. Gross margin in the third quarter of 2004 was 61.7%, which reflected a benefit of approximately 4.9% from the increased volume of the pump upgrade program, which offset the additional costs of approximately $439,000 due to increased costs associated with production ramp-up of the IR 1200. Gross margin in the fourth quarter of 2004 was 59.8%, with no benefit from the pump upgrade program as our obligation was completed in September 2004. Gross margin in the first quarter of 2005 was 58.2%. Gross margin was adversely affected by a higher proportion of revenues stemming from international sales and increased warranty reserve charges. Gross margin in the second quarter of 2005 was 46.0%. Gross margin was adversely affected by the inventory write-down and additional reserves charged to expense of $2.8 million and the additional costs to replace circuit boards of certain IR 1200 pumps during the refurbishment process.

In the first quarter of 2004 the net loss was $8.1 million. Approximately $4.7 million of the net loss was attributed to the pump upgrade program and the resulting deferral of net revenues and associated costs and our decision to stop the shipment of pumps for the last three weeks of March 2004. In the second quarter of 2004, net income increased to $2.6 million. This was the result of additional revenue associated with the shipment of additional pumps due to the pump upgrade program, the shipment in the second quarter of the unfulfilled orders from the first quarter and the increased demand. Net income increased to $2.8 million in the third quarter of 2004 due to the additional revenue associated with the shipment of additional pumps due to the pump upgrade program and the increased demand for both pumps and ancillary supplies. The net loss in the fourth quarter of 2004 was due to the write-off of purchased in-process research and development of $14.5 million. Of the $10.4 million of net loss in the first quarter of 2005, $9.3 million was due to the write-off of the purchased in-process research and development and $326,000 was due to a charge taken for the recall of the IR 1250 pump. The $3.1 million net loss in the second quarter of 2005 was primarily due to the inventory write-down and additional reserves charged to expense of $2.8 million.

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reserves charged to expense of $2.8 million.

Liquidity and Capital Resources

Historically, we have funded our operations primarily through the sale of equity securities. On May 25, 2004, we closed our IPO of 4,250,000 shares of our common stock at $15.00 per share. Additionally, the underwriters exercised the over-allotment option for the purchase of 637,500 additional shares of our common stock at the offering price of $15.00. Net proceeds, including the exercise of the over-allotment option, were approximately $65.7 million.

In addition, we have funded our operations through lines of credit and long-term debt and lease financing. Our existing line of credit expired, unused, in May 2005. We have received proposals to extend and expand the line of credit. We anticipate completing this negotiation by the end of the third quarter.

Cash Used in Operating Activities. Cash used in operating activities was $1.8 million and $6.3 million in the six months ended June 30, 2005 and 2004, respectively. The major use of cash for the six months ended June 30, 2005 was primarily for working capital and the funding of the loss of $13.4 million, which included the write-off of $9.3 million of purchased in-process research and development. The major use of cash for the six months ended June 30, 2004 was to fund the loss of $5.4 million and working capital, which offset the increases in accounts payable and accrued expense and other liabilities. Accounts receivable increased by $1.4 million during the six months ended June 30, 2005 primarily due to the growth of our business and increased sales to Medicare and Medicaid patients, which are traditionally slow payment payors. Our inventory increased by $1.1 million during the six months ended June 30, 2005 due primarily to the growth of our business and the introduction of new products. The working capital increases were partially offset by increases in accounts payable and accrued expense and other liabilities.

Cash Used in Investing Activities. Cash used in investing activities was $16.7 million and $2.2 million for the six months ended June 30, 2005 and 2004, respectively. The major uses of cash during 2005 were primarily for the Cygnus, Inc. technology acquisition and purchases of short-term investments. Additionally, investing activities consisted of the purchase of approximately $1.4 million and $2.2 million of capital expenditures for the six months ended June 30, 2005 and 2004, respectively, primarily for manufacturing equipment and computer equipment to support the growth in our business during the period and to position us for expected growth in 2005 and beyond.

Cash Provided by Financing Activities. Net cash provided by financing activities was $3.3 million and $63.9 million for the six months ended June 30, 2005 and 2004, respectively. The net cash provided by financing activities during the six months ended June 30, 2005 was primarily due to the exercises of stock options and warrants. The net cash provided by financing activities during the six months ended June 30, 2004 was primarily due to net proceeds of $65.7 million from our IPO, which were partially offset by the repayment of debt.

Operating Leases. At June 30, 2005, commitments related to future lease payments under operating leases, including the lease for our new facility, are $575,000 in 2005, $1.2 million in 2006, $1.2 million in 2007, $1.2 million in 2008, $1.3 million in 2009, and $5.7 million beyond 2009. There were no material commitments related to future capital expenditures on approved projects at June 30, 2005. At June 30, 2005, we had $550,000 outstanding on a letter of credit for a security deposit on the lease for our facility. This letter of credit is collateralized by restricted cash.

As of June 30, 2005, we had cash, cash equivalents and short-term investments of $20.4 million. We expect to have negative cash flows for 2005 resulting primarily from the $10.6 million acquisition of the Cygnus technology. Additionally, we expect increased selling and administrative expenses, as we continue to increase spending for personnel and infrastructure improvement. We believe that our current cash and any cash generated from our operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into 2006 and the foreseeable future. If existing cash and any cash generated from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and sales and marketing efforts.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our operations result primarily from changes in interest rates. As of June 30, 2005, cash, cash equivalents and short-term investments of $20.4 million were maintained in money market funds, deposit accounts, commercial paper and obligations of the U.S. government of short-term duration. Due to the short duration and nature of these instruments, we do not believe that we have a material exposure to interest rate risk related to our investment portfolio.

Although approximately 13% and 16% of our net revenues for the three and six months ended June 30, 2005 were derived from sales outside of the United States and certain of our product components are sourced from suppliers outside of the United States, all of our transactions are invoiced in U.S. dollars. Accordingly, we have no material direct exposure to currency exchange risk. However, future fluctuations in the value of the U.S. dollar may affect demand for our products sold in foreign countries, alternatively causing us to possibly reduce selling prices, and the cost of our foreign-sourced components. As of June 30, 2005, we were not engaged in any foreign currency hedging activities.

Item 4. Controls and Procedures

(a) **Evaluation of disclosure controls and procedures.** Our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were designed and functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) **Changes in internal controls.** There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control over financial reporting that occurred during the fiscal quarter ended June 30, 2005 which materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Set forth below is information regarding shares of common stock that we issued during the fiscal quarters ended December 31, 2004, March 31, 2005 and June 30, 2005. Also included is the consideration, if any, received by us for those shares, and information relating to the section of the Securities Act of 1933, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed**.**

1. During November and December of 2004, our stockholders exercised warrants to acquire 2,400 shares of common stock at a weighted average exercise price of $6.28 per share. We received an aggregate of $15,076 from the exercise of these warrants.

2. During December of 2004, warrants to purchase 6,666 shares of our common stock were exercised by cashless exercise resulting in the issuance of an aggregate of 2,503 shares of our common stock. We did not receive any proceeds from the exercise of these warrants.

3. During the fiscal quarter ended March 31, 2005, stockholders exercised warrants to acquire 17,500 shares of common stock at a weighted average exercise price of $9.17 per share. We received an aggregate of $160,390 from the exercise of these warrants.

4. During the fiscal quarter ended June 30, 2005, stockholders exercised warrants to acquire 1,500 shares of common stock at a weighted average exercise price of $8.13 per share. We received an aggregate of $12,190 from the exercise of these warrants.

As used above, the term cashless exercise refers to the surrender of a portion of a warrant as payment for the exercise price of the portion of the warrant exercised. No underwriters were involved in the foregoing sales of securities. We issued these securities in reliance upon the exemption from the registration requirements of Section 3(b) or 4(2) of the Securities Act because the subject securities were either (i) issued pursuant to a compensatory benefit plan or contract pursuant to Rule 701 under the Securities Act or (ii) sold to a limited group of persons, each of whom was believed to have been a sophisticated investor or to have had a preexisting business or personal relationship with us or our management and to have been purchasing for investment without a view to further distribution. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

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(b) On May 19, 2004, the Company s Registration Statement on Form S-1 covering the offering of 4,250,000 shares of the Company s common stock, Commission file number 333-113008 was declared effective (the Registration Statement). The offering closed on May 25, 2004 and did not terminate before any securities were sold. As of the date of the filing of this report, the offering has terminated. The offering was managed by Piper Jaffray & Co., J.P. Morgan Securities Inc. and Thomas Weisel Partners LLC as representatives of the several underwriters named in the Registration Statement (the Underwriters).

The Underwriters exercised an over-allotment option to purchase an additional 637,500 shares of the Company s common stock. The total price to the public for the shares offered and sold by the Company, including the over-allotment, was $73,312,500.

The amount of expenses incurred for the Company s account in connection with the offering is as follows:

Underwriting discounts and commissions	$5,131,875
Finders fees	
Expenses paid to or for the Underwriters	
Other expenses	2,435,264
Total expenses	$7,567,139

All of the foregoing expenses were direct or indirect payments to persons other than (i) directors, officers or their associates; (ii) persons owning ten percent (10%) or more of the Company s common stock; or (iii) affiliates of the Company.

The net proceeds of the offering, including the exercise of the over-allotment option, to the Company (after deducting the foregoing expenses) were $65,745,361. From the effective date of the Registration Statement, the net proceeds have been used for the following purposes:

Purchases of real estate	
Acquisitions of technology	22,868,631
Repayment of indebtedness	4,767,234
Working capital	22,405,947
Cash equivalents	15,703,549
	$65,745,361

All of the foregoing payments were direct or indirect payments to persons other than (i) directors, officers or their associates; (ii) persons owning ten percent (10%) or more of the Company s common stock; or (iii) affiliates of the Company.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

(c) None.

Item 3. Defaults Upon Senior Securities

(a) None.

(b) None.

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

(a) The Company s annual meeting of stockholders was held on May 17, 2005 at our corporate headquarters in West Chester, Pennsylvania.

(b) The following is a tabulation of the results of voting by security holders for the election of three directors for terms of three years each:

Nominees	Votes For	Votes Withheld	Abstain
Graeme Crothall	11,362,631		4,059,462
David Joseph	15,291,273		130,820
A. Peter Parsons	15,243,677		178,416

Our directors who continued after the meeting include two directors whose term expires in 2006, John J. McDonough and Edward L. Cahill, and three directors whose term expires in 2007, Katherine D. Crothall, William A. Graham, IV, and Thomas Morse.

(c) The following is a tabulation of the results of voting by security holders for other matters:

Proposal to ratify the selection of KPMG LLP as the independent registered public accounting firm to audit the consolidated financial statements of the Company and its subsidiaries and the internal controls over financial reporting and management s assessment of the effectiveness of the internal controls over financial reporting for the fiscal year ending December 31, 2005:

For	15,420,805
Against	600
Abstain	688

Item 5. Other Information

None.

Item 6. Exhibits

(31.1) Certification by President and Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).

(31.2) Certification by Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).

(32.1) Certification Furnished Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURES

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

/s/ Richard Baron

Richard Baron
Vice President, Finance and Chief Financial Officer

DATE: August 15, 2005

Animas Corporation

(Registrant)

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