

ANIMAS CORP  
Form 10-Q  
May 16, 2005

Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2005

or

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

For the transition period from                      to

Commission file number 000-50674

**ANIMAS CORPORATION**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**23-2860912**

(I.R.S. Employer  
Identification No.)

**200 LAWRENCE DRIVE, WEST CHESTER, PA**

(Address of principal executive offices)

**19380**

(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 ☒ No ☐.

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

Yes ☐ No ☒.

Common stock, \$0.01 par value, outstanding at May 6, 2005: 20,555,503 shares

**ANIMAS CORPORATION AND SUBSIDIARIES  
FORM 10-Q**

**INDEX**

	Page
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>
	<u>Consolidated Balance Sheets as of March 31, 2005 and December 31, 2004</u> 3
	<u>Consolidated Statements of Operations for the three months ended March 31, 2005 and 2004</u> 4
	<u>Consolidated Statement of Stockholders' Equity for the three months ended March 31, 2005</u> 5
	<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2005 and 2004</u> 6
	<u>Notes to Consolidated Financial Statements</u> 7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 12
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 20
<u>Item 4.</u>	<u>Controls and Procedures</u> 20
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings</u> 21
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 21
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u> 21
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u> 22
<u>Item 5.</u>	<u>Other Information</u> 22
<u>Item 6.</u>	<u>Exhibits</u> 22
<b><u>SIGNATURES</u></b>	
<u>CERTIFICATION BY PRESIDENT AND CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A)/15D-14(A)</u>	
<u>CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A)/15D-14(A)</u>	
<u>CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350</u>	

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements****ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Balance Sheets****(unaudited)**

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
	<b>(in thousands, except share data)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 21,967	\$ 30,867
Accounts receivable, net of allowance for doubtful accounts of \$1,941 in 2005 and \$1,702 in 2004	23,739	22,382
Inventories	12,438	10,924
Prepaid expenses and other current assets	2,634	1,378
 Total current assets	 60,778	 65,551
Property and equipment, net	8,013	6,780
Deposits and other assets	3,554	3,654
 Total assets	 \$ 72,345	 \$ 75,985
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Current portion of long-term debt	\$ 292	\$ 398
Accounts payable	6,613	4,430
Accrued expenses	5,896	4,077
 Total current liabilities	 12,801	 8,905
Other liabilities	1,781	1,820
Long-term debt	218	254
 Total liabilities	 14,800	 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 20,544,504 shares in 2005 and 20,022,765 in 2004

	205	200
Additional paid-in capital	167,653	164,784
Deferred compensation	(124)	(142)
Accumulated deficit	(110,189)	(99,836)

Total stockholders' equity	57,545	65,006
----------------------------	--------	--------

Total liabilities and stockholders' equity	\$ 72,345	\$ 75,985
--	-----------	-----------

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

Table of Contents**ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Statements of Operations****(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
	<b>(in thousands, except share and per share data)</b>	
Net revenues	\$ 19,348	\$ 4,837
Operating expenses:		
Cost of products sold	8,083	2,941
Research and development expenses	1,721	1,437
Selling, general and administrative expenses	10,742	8,439
Purchased in-process research and development	9,265	
Total operating expenses	29,811	12,817
Loss from operations	(10,463)	(7,980)
Interest income	156	1
Interest expense	(46)	(105)
Net loss	\$ (10,353)	\$ (8,084)
Basic and diluted net loss attributable to common stockholders per share	\$ (0.51)	\$ (2.01)
Weighted average shares basic and diluted	20,284,824	4,022,208

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

Table of Contents**ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Statement of Stockholders' Equity**

**Three Months Ended March 31, 2005**  
**(in thousands, except share and per share data)**

**(unaudited)**

	<b>Preferred stock</b>		<b>Common stock</b>		<b>Additional paid-in capital</b>	<b>Deferred compensation</b>	<b>Accumulated deficit</b>	<b>Total stockholders' equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>				
Balance, December 31, 2004		\$	20,022,765	\$ 200	\$ 164,784	\$ (142)	\$ (99,836)	\$ 65,006
Exercise of stock options to purchase common stock			492,002	5	2,551			2,556
Issuance of common stock upon exercise of warrants			17,500		160			160
Issuance of common stock under employee stock purchase plan			12,237		158			158
Amortization of deferred compensation						18		18
Net loss							(10,353)	(10,353)
Balance, March 31, 2005		\$	20,544,504	\$ 205	\$ 167,653	\$ (124)	\$ (110,189)	\$ 57,545

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
	<b>(in thousands)</b>	
Cash flows from operating activities:		
Net loss	\$ (10,353)	\$ (8,084)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	661	554
Non-cash compensation and interest expense	18	28
Write-off of in-process research and development	9,265	
Bad debt expense	268	208
Other		11
Changes in net assets and liabilities:		
Accounts receivable, net	(1,625)	663
Inventories	(1,368)	(1,626)
Cost associated with deferred revenue		(1,115)
Prepaid expenses and other current assets	(1,256)	339
Deposits and other assets	115	121
Restricted cash		550
Accounts payable	2,183	2,660
Accrued expenses and other liabilities	1,780	5,002
 Net cash used in operating activities	 (312)	 (689)
 Cash flows from investing activities:		
Purchases of property and equipment	(693)	(582)
Payment for acquisition	(10,627)	
 Net cash used in investing activities	 (11,320)	 (582)
 Cash flows from financing activities:		
Proceeds from lines of credit		6,104
Repayments on lines of credit		(4,794)
Proceeds from issuance of common stock, net of offering costs	2,874	115
Proceeds from long-term debt		
Repayments on long-term debt	(142)	(129)
Proceeds from sale of preferred stock		147



Net cash provided by financing activities	2,732	1,443
Net increase (decrease) in cash and cash equivalents	(8,900)	172
Cash and cash equivalents at beginning of period	30,867	384
Cash and cash equivalents at end of period	\$ 21,967	\$ 556

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

**Table of Contents**

**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 an 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 months ended March 31, 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 months ended March 31, 2005 and March 31, 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 months ended March 31, 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 and various deposit accounts.

**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 \$1,941 and \$1,702 at March 31, 2005 and December 31, 2004, respectively. Bad debt expense was \$268 and \$208 for the three months ended March 31, 2005 and March 31, 2004, respectively. The related write-offs of accounts receivable were \$29 and \$89 for the three months ended March 31, 2005 and March 31, 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.

***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 March 31, 2005 and December 31, 2004, accrued product warranties totaled \$1,942 and \$1,349, respectively, and are classified as a current liability in accrued expenses (\$962 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.

**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Balance at beginning of period	\$ 1,349	\$ 1,734
Warranty expense	1,113	596
Warranty claims settled	(520)	(587)
Balance at end of period	\$ 1,942	\$ 1,743

**Comprehensive Loss.** Comprehensive loss represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. No separate statement of comprehensive loss has been presented because comprehensive loss was equal to net loss in the three months ended March 31, 2005 and March 31, 2004.

**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 three months ended March 31, 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 three months ended March 31, 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.

**Table of Contents**

Had the Company determined compensation cost for options granted during the three months ended March 31, 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 loss and net loss per share would have been reported as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss attributable to common stockholders, as reported	\$ (10,353)	\$ (8,084)
Add Non-cash employee compensation, as reported	8	8
Deduct Total stock-based employee compensation expense determined under fair value-based method	(626)	(121)
Pro forma net loss attributable to common stockholders	\$ (10,971)	\$ (8,197)
Loss attributable to common stockholders per share:		
Basic and diluted, as reported	\$ (0.51)	\$ (2.01)
Basic and diluted, pro forma	\$ (0.54)	\$ (2.04)

**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. Early adoption is permitted for inventory costs incurred during fiscal years beginning after the date SFAS 151 was issued. 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 and 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 loss and loss per share noted above under Stock-Based Compensation. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company is unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

**Table of Contents****(3) 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.

**(4) Inventories**

Inventories consist of the following as of:

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
Raw materials	\$ 2,337	\$ 2,225
Work in process	5,549	5,367
Finished goods	5,086	3,914
Less reserve for excess and obsolete inventory	(534)	(582)
	\$ 12,438	\$ 10,924

**(5) 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 18% of net revenues for the three months ended March 31, 2005.



**Table of Contents****(6) Loss per Share**

The table below sets forth the reconciliation of the numerators and the denominators of the Company's basic and diluted loss per share computations for the three months ended March 31, 2005 and 2004.

	<b>Three Months Ended March 31,</b>		
	<b>Net Loss</b>	<b>Shares</b>	<b>Per Share Amount</b>
<b>2005</b>			
Basic	\$ (10,353)	20,284,824	\$ (0.51)
Dilutive effect of:			
Stock options			
Warrants			
Diluted	\$ (10,353)	20,284,824	\$ (0.51)
<b>2004</b>			
Basic	\$ (8,084)	4,022,208	\$ (2.01)
Dilutive effect of:			
Stock options			
Warrants			
Diluted	\$ (8,084)	4,022,208	\$ (2.01)

For the three months ended March 31, 2005 and 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 months ended March 31, 2005, 2,079,601 common stock options and 130,640 common warrants were excluded from the diluted calculation because the effect would be anti-dilutive. For the three months ended March 31, 2004, 2,559,868 common stock options, 1,211,998 Series C warrants and 269,500 common warrants were excluded from the diluted calculation because the effect would be anti-dilutive.

**(7) Subsequent event**

In April 2005, the Company issued a recall of the IR 1250 pump due to a software bug involving use of the food database. The Company identified the software bug as a result of an investigation of a complaint from a customer regarding the use of the food database. There have been no reported adverse events as a result of this software bug. Approximately \$326,000 was charged to expense for the recall and is included in the Consolidated Statements of Operations for the three months ended March 31, 2005.

The Company fixed this software bug and started shipping IR 1250 pumps with modified software on April 25, 2005. The Company has started replacing existing pumps for this recall and anticipates that in the next several months this recall should be completed.

**Table of Contents**

**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, 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, and marketing, 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 sell any of the approximately \$1.5 million of inventory of IR 1000 used pumps as a result of our upgrade program and warranty repair;*

*any significant disruption with vendors;*

*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.*

## **Table of Contents**

### **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 50 person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximately 70 diabetes educators, or clinical managers, train and provide clinical support to patients in the United States. We 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. Net revenues were recognized when we shipped the IR 1200 pump to the patient or when the patient declined to be part of 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. Since the commercial introduction of our first pump in July 2000, the average unit cost of our pump has declined due to improved manufacturing efficiencies and increased absorption of fixed and semi-fixed overhead costs.

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.

## **Table of Contents**

***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 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 three months ended March 31, 2005, approximately 72% of our products were 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 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.

***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.

**Table of Contents**

***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.



**Table of Contents****Three Months Ended March 31, 2005 and 2004**

**Results of Operations.** The following tables set forth, for the quarters 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 March 31,					
	2005		2004		Change, 2005/2004	
	\$	%	\$	%	\$	%
<b>(in thousands)</b>						
<b>Consolidated Statements of Operations</b>						
Net revenues	\$ 19,348	100.0%	\$ 4,837	100.0%	\$ 14,511	300.0%
Operating expenses:						
Cost of products sold	8,083	41.8	2,941	60.8	5,142	174.8
Research and development expenses	1,721	8.9	1,437	29.7	284	19.8
Selling, general and administrative expenses	10,742	55.5	8,439	174.5	2,303	27.3
Purchased in-process research and development	9,265	47.9			9,265	
Total operating expenses	29,811	154.1	12,817	265.0	16,994	132.6
Loss from operations	(10,463)	(54.1)	(7,980)	(165.0)	(2,483)	(31.1)
Interest income	156	0.8	1		155	NM
Interest expense	(46)	(0.2)	(105)	(2.1)	59	56.2
Net loss	\$ (10,353)	(53.5)%	\$ (8,084)	(167.1)%	\$ (2,269)	(28.1)%

	Three Months Ended March 31,					
	2005		2004		Change, 2005/2004	
	\$	%	\$	%	\$	%
<b>(in thousands)</b>						
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net revenues (dollars and as a percent of total)</b>						
Insulin pumps	\$ 12,710	65.7%	\$ 1,171	24.2%	\$ 11,539	985.4%
Ancillary supplies	6,638	34.3	3,666	75.8	2,972	81.1
Total	\$ 19,348	100.0%	\$ 4,837	100.0%	\$ 14,511	300.0%

**Cost of products sold (dollars and as a percent of total)**

Insulin pumps	\$ 4,379	54.2%	\$ 834	28.4%	\$ 3,545	425.1%
Ancillary supplies	3,704	45.8	2,107	71.6	1,597	75.8
Total	\$ 8,083	100.0%	\$ 2,941	100.0%	\$ 5,142	174.8%

**Gross margin (dollars and as a percent of total)**

Insulin pumps	\$ 8,331	74.0%	\$ 337	17.8%	\$ 7,994	2,372.1%
Ancillary supplies	2,934	26.0	1,559	82.2	1,375	88.2
Total	\$ 11,265	100.0%	\$ 1,896	100.0%	\$ 9,369	494.1%

**Three Months Ended March  
31,**

	<b>2005</b>	<b>2004</b>
<b>Gross margin % (as a percent of net revenues)</b>		
Insulin pumps	65.5%	28.8%
Ancillary supplies	44.2%	42.5%
Total	58.2%	39.2%

## **Table of Contents**

**Net Revenues.** Net revenues were \$19.3 million and \$4.8 million, respectively, for the three months ended March 31, 2005 and 2004. Net revenues increased by \$14.5 million, or 300.0% in the three months ended March 31, 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 increased sales of ancillary supplies. In the three months ended March 31, 2004, net revenues excluded \$4.5 million of revenue deferred due to the pump upgrade program and \$2.3 million of revenue delayed as we stopped shipping orders in March 2004 in anticipation of the launch of the IR 1200 in April 2004. Net revenues from domestic and foreign sales were \$15.9 million and \$3.4 million, respectively, in the three months ended March 31, 2005 and \$3.9 million and \$0.9 million, respectively, in the three months ended March 31, 2004. Pump net revenues increased by \$11.5 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 price 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 \$3.0 million in the three months ended March 31, 2005 versus the comparable period of 2004. The increase was due to increased unit sales, while prices remained near prior period levels. The growth also 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 \$5.1 million, or 174.8%, to \$8.1 million in the three months ended March 31, 2005 from \$2.9 million in the comparable period of 2004. The increase was primarily due to the increased volume of sales. However, as a percentage of net revenues, cost of products sold decreased to 41.8% in the three months ended March 31, 2005 from 60.8% in the comparable period of 2004. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by \$3.5 million, or 425.1% in the three months ended March 31, 2005 as compared to the comparable period of 2004. The rate of this increase was lower than the rate of increase of pump sales due to the economies and efficiencies described above.

**Gross Margin.** Gross margin increased to 58.2% in the three months ended March 31, 2005 from 39.2% in the comparable period of 2004. Gross margin for pumps increased to 65.5% in the three months ended March 31, 2005 from 28.8% in the comparable period of 2004 due to better absorption of overhead associated with increased sales volume and lower cost of raw materials, which offset the adverse effect of the higher international sales and increased warranty charges. Ancillary supplies gross margin increased to 44.2% in the three months ended March 31, 2005 from 42.5% 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 continue to improve in 2005. Reasons for this improvement include the introduction of our ezSet infusion system, further reductions of the costs of our existing disposables, and increased absorption of manufacturing overheads.

**Research and Development.** Research and development expenses increased \$284,000, or 19.8%, to \$1.7 million in the three months ended March 31, 2005 from \$1.4 million in the comparable period of 2004 reflecting increased spending on activities to improve existing products and develop new products. As a percentage of net revenues, research and development expenses decreased to 8.9% in the three months ended March 31, 2005 from 29.7% in the comparable period of 2004.

Although we anticipate a similar increase in research and development costs in 2005 from 2004 as compared to the increase in 2004 from 2003, we also anticipate a decrease in these costs as the percentage of net revenues. 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.

***Selling, General and Administrative ( SG&A ) Expenses.*** SG&A expenses increased by \$2.3 million, or 27.3%, to \$10.7 million in the three months ended March 31, 2005 from \$8.4 million in the comparable period of 2004. However, as a percentage of net revenues, SG&A expenses decreased to 55.5% in the three months ended March 31, 2005 from 174.5% in the comparable period of 2004.

Of the increase, \$678,000 was primarily 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 \$334,000, depreciation expense of \$138,000, expenses of approximately \$326,000 related to correct the software bug in the IR 1250, and rent expense of \$99,000 contributed to higher SG&A costs in the three months ended March 31, 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.

**Table of Contents**

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 should continue to decline as a percent of net revenues as we continue to leverage our existing infrastructure.

***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 \$156,000 in the three months ended March 31, 2005 from \$1,000 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 \$46,000 in the three months ended March 31, 2005 from \$105,000 in the comparable period of 2004. This reflects a lower outstanding debt balance than in the comparable period.

***Net Loss.*** We reported a net loss of \$10.4 million in the three months ended March 31, 2005 as compared to a net loss of \$8.1 million in the comparable period of 2004. The loss for the three months ended March 31, 2005 was primarily due to the write-off of \$9.3 million of the Cygnus asset purchase as purchased in-process research and development and the charge associated with the recall of the IR 1250 pumps of \$326,000. The net loss for the three months ended 2004 was impacted by the pump upgrade program and the delay of shipments of pumps from March to April 2004.

**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.

	<b>Quarterly Results</b>				
	<b>2005</b>	<b>2004</b>			
	<b>1st Qtr</b>	<b>1st Qtr</b>	<b>2nd Qtr</b>	<b>3rd Qtr</b>	<b>4th Qtr</b>
Net revenues	\$ 19,348	\$ 4,837	\$ 20,420	\$ 22,654	\$ 20,015
Gross margin	11,265	1,896	13,083	13,988	11,973
Net income (loss)	(10,353)	(8,084)	2,636	2,819	(14,033)
Basic net income (loss) per share	(0.51)	(2.01)	0.24	0.15	(0.71)
Diluted net income (loss) per share	(0.51)	(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 \$3.7 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.

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, which 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.

## **Table of Contents**

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.

## **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. We have a line of credit with a bank, totaling \$6.0 million, of which no amount was outstanding at March 31, 2005.

**Cash Used in Operating Activities.** Cash used in operating activities was \$312,000 and \$689,000 in the three months ended March 31, 2005 and 2004, respectively. The major use of cash for the three months ended March 31, 2005 was primarily for working capital and the funding of the loss of \$10.4 million, which included the write-off of \$9.3 million of purchased in-process research and development. The major use of cash for the three months ended March 31, 2004 was to fund the loss of \$8.1 million offset by changes in working capital, principally deferred revenue and accounts payable. Accounts receivable increased by \$1.6 million due primarily to the growth of our business and increased sales to Medicare and Medicaid patients, which are traditionally slow payment payors. Our inventory increased by \$1.4 million during the three months ended March 31, 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 \$11.3 million and \$582,000 for the three months ended March 31, 2005 and 2004, respectively. The major use of cash during 2005 was primarily for the Cygnus, Inc. technology acquisition. Additionally, investing activities consisted of the purchase of approximately \$693,000 and \$582,000 of capital expenditures for the three months ended March 31, 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 \$2.7 million and \$1.4 million for the three months ended March 31, 2005 and 2004, respectively. The net cash provided by financing activities during the three months ended March 31, 2005 was primarily due to the exercises of stock options and warrants. These amounts were partially offset by the repayment of debt. The net cash provided by financing activities during the three months ended March 31, 2004 was primarily due to net proceeds of \$1.3 million from borrowings.

**Bank Credit Facilities.** We have a line of credit with a bank under which we can borrow a maximum of \$6.0 million at an interest rate of 1.75% above the bank's prime rate. This line of credit contains a debt covenant that requires that we maintain a certain net worth throughout the term of this line of credit. We were in compliance with this covenant at

March 31, 2005. Borrowings under this facility are limited to 75% of our eligible accounts receivable, which generally consist of our accounts receivable that are less than 120 days old and 25% of our eligible inventory. Borrowings are secured by a pledge of substantially all of our assets. As of March 31, 2005, there was no amount outstanding on this line of credit.



## **Table of Contents**

**Equipment Financing.** In November 2002, we entered into an equipment lease loan with a bank for \$1.0 million. This loan bears interest at a rate of 1.5% above the prime rate and matures on November 4, 2005. The principal is paid in monthly installments of \$28,000. As of March 31, 2005, the principal amount outstanding was \$140,000.

**Operating Leases.** At March 31, 2005, commitments related to future lease payments under operating leases, including the lease for our new facility, are \$863,000 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 March 31, 2005. At March 31, 2005, we had \$550,000 outstanding on a letter of credit for a security deposit on the lease for our facility.

As of March 31, 2005, we had cash and cash equivalents of \$22.0 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 well as, we continue to increase spending for personnel and infrastructure improvement. We believe that our current cash, line of credit, 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 an additional 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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Market risks related to our operations result primarily from changes in interest rates. As of March 31, 2005, cash equivalents of \$19.7 million were maintained in money market funds of short-term duration. The interest rate on our credit facilities is based off the prime rate of our lenders. As of March 31, 2005, we had no amounts outstanding under our credit facilities.

Although approximately 18% of our net revenues for the three months ended March 31, 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 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 and the cost of our foreign-sourced components. As of March 31, 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 March 31, 2005 which materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

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

(a) None.

(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	18,361,516
Cash equivalents	19,747,980
	\$ 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.

**Table of Contents**

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

No matters were submitted to a vote of security holders during the three months ended March 31, 2005.

**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.

**Table of Contents**

**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: May 16, 2005

Animas Corporation  
(Registrant)