ANIMAS CORP
Form 10-Q
November 15, 2004

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2004

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 x 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 x.

Common stock, $0.01 par value, outstanding at November 11, 2004: 19,670,684 shares

ANIMAS CORPORATION AND SUBSIDIARIES
FORM 10-Q

INDEX

Table of Contents

PART I. FINANCIAL INFORMATION
ITEM 1. Financial Statements

ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Balance Sheets
(unaudited)

	September 30, 2004	December 31, 2003
	(in thousands except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 48,608	$ 384
Accounts receivable, net of allowance for doubtful accounts of $1,645 in 2004 and $1,285 in 2003	20,410	13,178
Inventories	8,083	3,335
Cost associated with deferred revenue		1,025
Prepaid expenses and other current assets	1,309	575
Total current assets	78,410	18,497
Property and equipment, net	5,681	3,899
Deposits and other assets	93	297
Restricted cash		550
Total assets	$ 84,184	$ 23,243
Liabilities and Stockholders Equity		
Current liabilities:		
Line of credit	$	$ 2,657
Current portion of long-term debt	502	462
Accounts payable	5,683	2,752
Accrued expenses	4,595	3,283
Deferred revenue	592	5,179
Total current liabilities	11,372	14,333
Other liabilities	876	1,140
Long-term debt	294	467
Total liabilities	12,542	15,940

Commitments and contingencies		
Stockholders equity:		
Series A, B, and C Preferred stock, $0.01 par value; authorized 8,353,200 shares; none issued and outstanding in 2004 and 7,097,724 in 2003		71
Common stock, $0.01 par value; authorized 100,000,000 shares in 2004 and 24,000,000 shares in 2003; issued and outstanding 19,230,283 shares in 2004 and 3,987,282 in 2003	192	40
Additional paid-in capital	157,422	90,544
Deferred compensation	(169)	(178)
Accumulated deficit	(85,803)	(83,174)
Total stockholders equity	71,642	7,303
Total liabilities and stockholders equity	$ 84,184	$ 23,243

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

Table of Contents

ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(in thousands except share and per share data)			
Net revenues	$ 22,654	$ 11,291	$ 47,911	$ 27,876
Operating expenses:				
Cost of products sold	8,805	4,602	19,338	12,934
Research and development expenses	1,723	1,244	4,395	3,732
Selling, general and administrative expenses	9,403	7,612	26,715	22,472
Total operating expenses	19,931	13,458	50,448	39,138
Income (loss) from operations	2,723	(2,167)	(2,537)	(11,262)
Interest income	155	4	209	19
Interest expense	(59)	(49)	(301)	(143)
Net income (loss)	2,819	(2,212)	(2,629)	(11,386)
Deemed dividend beneficial conversion feature of preferred stock				(5,063)
Net income (loss) attributable to common stockholders	$ 2,819	$ (2,212)	$ (2,629)	$ (16,449)
Basic net income (loss) attributable to common stockholders per share	$ 0.15	$ (0.57)	$ (0.23)	$ (4.25)
Diluted net income (loss) attributable to common stockholders per share	$ 0.14	$ (0.57)	$ (0.23)	$ (4.25)
Weighted average shares basic	19,215,289	3,870,716	11,453,535	3,869,429
Weighted average shares diluted	20,804,281	3,870,716	11,453,535	3,869,429

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

Table of Contents

ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Statements of Stockholders Equity
Nine Months Ended September 30, 2004
(unaudited)

	Preferred stock		Common stock		Additional paid-in capital	Deferred compensation	Accumulated deficit	Total stockholders equity
	Shares	Amount	Shares	Amount				
	(in thousands except share and per share data)							
Balance, December 31, 2003	7,097,724	$ 71	3,987,282	$ 40	$ 90,544	$ (178)	$ (83,174)	$ 7,303
Exercise of stock warrants to purchase preferred stock	55,084	1			406			407
Conversion of preferred stock into common stock	(7,152,808)	(72)	9,522,604	95	(23)			
Sale of common stock at $15.00 per share, net of offering costs			4,887,500	49	65,696			65,745
Cashless exchange of warrants			637,378	6	(6)			
Exercise of stock options and warrants to purchase common stock			190,186	2	729			731
Deferred compensation associated with stock grants			5,333		76	(76)		
Amortization of deferred compensation						85		85
Net loss							(2,629)	(2,629)
Balance, September 30, 2004		$	19,230,283	$ 192	$ 157,422	$ (169)	$ (85,803)	$ 71,642

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)

	Nine Months Ended September 30,	
	2004	**2003**
	(in thousands)	
Cash flows from operating activities:		
Net loss	$ (2,629)	$(11,386)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,583	1,168
Non-cash compensation and interest expense	85	494
Bad debt expense	729	1,104
Other	12	(8)
Changes in net assets and liabilities:		
Accounts receivable, net	(7,961)	(4,489)
Inventories	(4,748)	(980)
Prepaid expenses and other current assets	(734)	(197)
Deposits and other assets	204	11
Restricted cash	550	
Cost associated with deferred revenue	1,025	
Accounts payable	2,931	1,321
Accrued expenses and other liabilities	1,048	1,191
Deferred revenue	(4,587)	
Net cash used in operating activities	(12,492)	(11,771)
Cash flows from investing activities:		
Purchases of property and equipment	(3,100)	(1,224)
Net cash used in investing activities	(3,100)	(1,224)
Cash flows from financing activities:		
Proceeds from lines of credit	12,102	2,500
Repayments on lines of credit	(14,759)	(500)
Proceeds from issuance of common stock	66,476	23
Repayments on long-term debt	(410)	(361)
Proceeds from sale of preferred stock	407	11,727
Net cash provided by financing activities	63,816	13,389

Net increase in cash and cash equivalents	48,224	394
Cash and cash equivalents at beginning of period	384	1,134
Cash and cash equivalents at end of period	$ 48,608	$ 1,528

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 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, 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.

In May 2004, the Company completed its initial public offering (IPO) in which it sold 4,887,500 shares of its common stock at $15 per share. Net proceeds to the Company were approximately $65.7 million. As of the closing date of the offering, all of the convertible preferred stock previously outstanding was converted into 9,522,604 shares of common stock. A summary of the terms of this offering can be found in the Registration Statement on Form S-1 as filed with the Securities and Exchange Commission (Commission file number 333-113008).

As of September 30, 2004, the Company had cash and cash equivalents of $48.6 million. The Company expects to have negative cash flows from operations for the remainder of 2004. The Company believes that its current cash, lines of credit, and cash anticipated to be generated from future operations, will be sufficient to meet anticipated cash needs for working capital and capital expenditures into 2005 and the foreseeable future.

(2) Summary of Significant Accounting Policies

Unaudited Interim Results. The accompanying consolidated financial statements for the three and nine months ended September 30, 2004 and 2003 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 nine months ended September 30, 2004 and 2003 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 nine months ended September 30, 2004 are not necessarily indicative of the results to be expected for the year ending December 31, 2004 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 our 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 $1,645 and $1,285 at September 30, 2004 and December 31, 2003, respectively. Bad debt expense was $287 and $729 for the three and nine months ended September 30, 2004 and $295 and $1,104 for the three and nine months ended September 30, 2003, respectively. The related write-offs of accounts receivable were $89, $369, $94 and $152 for these periods, respectively.

Table of Contents

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. Obsolete inventory is written off monthly.

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 September 30, 2004 and December 31, 2003, accrued product warranties totaled $1,607 and $1,734, respectively, and are classified as a current liability in accrued expenses ($737 and $608, respectively) and as a long-term liability in other liabilities ($870 and $1,126, 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Balance at beginning of period	$ 1,737	$ 1,529	$ 1,734	$ 1,775
Warranty expense	856	294	1,661	458
Warranty claims settled	(986)	(228)	(1,788)	(638)
Balance at end of period	$ 1,607	$ 1,595	$ 1,607	$ 1,595

Comprehensive Income (Loss). Comprehensive income (loss) represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. No separate statement of comprehensive income (loss) has been presented because comprehensive income (loss) was equal to net income (loss) in the three and nine months ended September 30, 2004 and 2003.

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 nine months ended September 30, 2004, approximately 82% 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.

As noted above, 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 18% of the Company s products during the nine months ended September 30, 2004. 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,

Table of Contents

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 nine months ended September 30, 2004 and 2003, 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss) attributable to common stockholders, as reported	$2,819	$(2,212)	$(2,629)	$(16,449)
Add Non-cash employee compensation, as reported	8		24	464
Deduct Total stock-based employee compensation expense determined under fair value-based method	(154)	(108)	(433)	(299)
Pro forma net income (loss) attributable to common stockholders	$2,673	$(2,320)	$(3,038)	$(16,284)
Income (loss) attributable to common stockholders per share:				
Basic, as reported	$ 0.15	$ (0.57)	$ (0.23)	$ (4.25)
Basic, pro forma	$ 0.14	$ (0.60)	$ (0.27)	$ (4.21)
Diluted, as reported	$ 0.14	$ (0.57)	$ (0.23)	$ (4.25)
Diluted, pro forma	$ 0.13	$ (0.60)	$ (0.27)	$ (4.21)

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, and the warranty accrual. Actual amounts could differ from those estimates.

(3) Inventories

Inventories consist of the following as of:

	September 30, 2004	December 31, 2003
Raw Material	$ 1,569	$ 1,064
Work in process	3,396	423
Finished goods	3,118	1,848
	$ 8,083	$ 3,335

(4) Deemed Dividend Beneficial Conversion Feature of Preferred Stock

In accordance with EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments (EITF No. 00-27), the issuance costs associated with the sale of the Series C Convertible Preferred Stock (Series C) in 2003 were not offset against the proceeds in calculating the intrinsic value of the conversion option but were considered in the calculation of the amount shown on the consolidated balance sheet. After considering the allocation of the proceeds based on the relative fair values, it was determined that the Series C had a beneficial conversion feature (BCF) in accordance with EITF No. 98-5 and EITF No. 00-27. Accordingly, a BCF adjustment of $5,063 was recorded with respect to the issuance of Series C from January through April 2003 closings. The value of the BCF was recorded in a manner similar to a dividend, and since the Series C had no maturity date and was convertible at the date of issuance, the BCF was charged to the statement of operations.

Table of Contents

(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 less than 10% of net revenues, and the Company has no foreign operations.

(6) 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 nine months ended September 30, 2004 and 2003.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	Net Income (Loss)	Shares	Per Share Amount	Net Income (Loss)	Shares	Per Share Amount
2004						
Basic	$ 2,819	19,215,289	$ 0.15	$ (2,629)	11,453,535	$(0.23)
Dilutive effect of:						
Stock options		1,491,007				
Warrants		97,985				
Diluted	$ 2,819	20,804,281	$ 0.14	$ (2,629)	11,453,535	$(0.23)
2003						
Basic	$(2,212)	3,870,716	$(0.57)	$(16,449)	3,869,429	$(4.25)
Dilutive effect of:						
Stock options						
Warrants						
Diluted	$(2,212)	3,870,716	$(0.57)	$(16,449)	3,869,429	$(4.25)

For the nine months ended September 30, 2004 and the three and nine months ended September 30, 2003, 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 September 30, 2004, 2,334 common stock options were excluded from the diluted calculation because the effect would be anti-dilutive. For the nine months ended September 30, 2004, 2,513,232 common stock options and 159,693 common warrants were excluded from the diluted calculation because the effect would be anti-dilutive. For the three and nine months ended September 30, 2003, 2,584,356 common stock options, 863,762 Series C warrants and 318,135 common warrants were excluded from the diluted calculation because the effect would be anti-dilutive.

(7) Subsequent Event

On October 29, 2004, the Company announced that it entered into license and development agreements with Debiotech, SA for certain technology and intellectual property. The Company acquired the exclusive worldwide license to make, use, and sell products utilizing the intellectual property portfolio owned by Debiotech, SA relating to micro-pumps and micro-needles for use related to insulin administration and in-vivo glucose sensing. The Company paid $12.0 million in cash and issued 400,000 restricted shares of the Company s common stock. Additionally, the Company agreed to pay (i) a license fee up to $2.0 million upon the receipt of the requisite deliverables for 510(k) approval from the FDA for the micro-pump, providing receipt of such deliverables occurs prior to certain dates, and (ii) royalties on sales of products resulting from these agreements. It is expected that a portion of the upfront license fee will be taken as an operating charge in the fourth quarter of 2004, and the remainder of the upfront license fee will be capitalized, and upon project success, expensed ratably over the life of the technology.

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:

technical issues relating to the IR 1200 or any of the Company s ancillary supplies;

failure to capture recurring purchases of ancillary supplies by patients using our pumps;

any significant disruption with vendors;

the failure to successfully develop and commercialize the technologies licensed from Debiotech, SA;

any failure to achieve and then maintain profitability;

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 comply with any FDA or foreign regulations;

an inability to attract and retain personnel;

competition;

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 in our Registration Statement on Form S-1 which went effective on May 19, 2004. 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 introduced our first generation pump in July 2000. We began shipping our third generation pump, the IR 1200, in April 2004. We also provide ancillary supplies necessary for pump therapy, including insulin cartridges, infusion sets, batteries, and various accessories.

Our approximately 50-person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximately 65 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. In the nine months ended September 30, 2004, approximately 82% our products were sold directly to patients. 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, and as of September 30, 2004, the shipment of upgrade pumps under this program was completed; we are however awaiting the return of $577,000 of pumps from patients participating in the program. We do not anticipate the need for additional product upgrade programs in the foreseeable future where we exchange an older generation pump for a newer generation pump.

In accordance with 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 between November 1, 2003 and March 31, 2004 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.

As a result of this program, our net revenues for the three and nine months ended September 30, 2004 increased by the recognition of net revenues deferred from previous quarters.

Cost of Products Sold. Cost of products sold include 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 southeastern 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 expensed 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 our 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.

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 nine months ended September 30, 2004, approximately 82% 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 payor payments.

Consistent with SAB 104, 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

Table of Contents

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.

Table of Contents

Three Months Ended September 30, 2004 and 2003

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 September 30,					
	2004		2003		Change, 2004/2003	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$22,654	100.0%	$11,291	100.0%	$11,363	100.6%
Operating expenses:						
Cost of products sold	8,805	38.9	4,602	40.8	4,203	91.3
Research and development expenses	1,723	7.6	1,244	11.0	479	38.5
Selling, general and administrative expenses	9,403	41.5	7,612	67.4	1,791	23.5
Total operating expenses	19,931	88.0	13,458	119.2	6,473	48.1
Income (loss) from operations	2,723	12.0	(2,167)	(19.2)	4,890	225.7
Interest income	155	0.7	4		151	3775.0
Interest expense	(59)	(0.3)	(49)	(0.4)	(10)	(20.4)
Net income (loss)	2,819	12.4	(2,212)	(19.6)	5,031	227.4
Deemed dividend						
Net income (loss) attributable to common stockholders	$ 2,819	12.4%	$ (2,212)	(19.6)%	$ 5,031	227.4%
Net Revenues, Cost of Products Sold and Gross Margin						
Net Revenues (dollars and as a percent of total)						
Insulin pumps	$17,278	76.3%	$ 8,063	71.4%	$ 9,215	114.3%
Ancillary supplies	5,376	23.7	3,228	28.6	2,148	66.5
Total	$22,654	100.0%	$11,291	100.0%	$11,363	100.6%

Cost of Products Sold (dollars and as a percent of total)						
Insulin pumps	$ 5,638	64.0%	$ 2,484	54.0%	$ 3,154	127.0%
Ancillary supplies	3,167	36.0	2,118	46.0	1,049	49.5
Total	$ 8,805	100.0%	$ 4,602	100.0%	$ 4,203	91.3%
Gross Margin (dollars and as a percent of total)						
Insulin pumps	$11,640	84.0%	$ 5,579	83.4%	$ 6,061	108.6%
Ancillary supplies	2,209	16.0	1,110	16.6	1,099	99.0
Total	$13,849	100.0%	$ 6,689	100.0%	$ 7,160	107.0%
Gross Margin % (as a percent of net revenues)						
Insulin pumps		67.4%		69.2%		
Ancillary supplies		41.1%		34.4%		
Total		61.1%		59.2%		

Net Revenues. In the three months ended September 30, 2004, net revenues increased by $11.4 million, or 100.6%, to $22.7 million from $11.3 million in the comparable period in 2003. The increase in net revenues was a result of $3.8 million primarily from increased demand, $2.1 million in increased shipments of ancillary supplies and the recognition of $5.5 million of revenue deferred in prior periods under the pump upgrade program. Net revenues from domestic and foreign sales were $21.9 million and $0.8 million, respectively, in the three months ended September 30, 2004 and $10.9 million and $0.4 million, respectively, in the comparable period in 2003. Our average selling price of pumps remained relatively stable over this period.

Table of Contents

Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges and other ancillary supplies increased by $2.1 million, or 66.5%, in the three months ended September 30, 2004 versus the same period in 2003. The increase in net revenues for ancillary supplies was due to increased unit sales, while prices remained near prior period levels. The growth in net revenues from sales of ancillary supplies reflected our growth in the number of patients using our pumps in the comparable three month periods of 2004 and 2003 and our retention of patients from prior years.

Cost of Products Sold. Cost of products sold increased $4.2 million, or 91.3%, to $8.8 million in the three months ended September 30, 2004 from $4.6 million in the comparable period of 2003. This increase reflected the increase in net revenues in the three months ended September 30, 2004 from the comparable period of 2003. However, as a percentage of net revenues, cost of products sold decreased to 38.9% in 2004 from 40.8% in 2003. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by $3.2 million, or 127%, in the three months ended September 30, 2004 as compared to the comparable period of 2003. This increase was comprised of increased costs due to the growth of sales volumes. Additional costs of approximately $439,000 were incurred during the quarter due to production ramp-up of the IR 1200. Costs associated with pumps shipped under the pump upgrade program were $1.3 million in the quarter.

Gross Margin. Gross margin increased to 61.1% in the three months ended September 30, 2004 from 59.2% in the comparable period of 2003. Gross margin for pumps decreased to 67.4% in 2004 due to the additional costs associated with production ramp-up of the IR 1200. The pump upgrade program contributed 4.9% to the gross margin for pumps through the better absorption of overhead. Gross margin for ancillary supplies increased to 41.1% in the three months ended September 30, 2004 from 34.4% in the comparable period of 2003. Gross margin improved for ancillary supplies due to lower cost sources of supply.

It is anticipated that the gross margin and gross margin percentage will decline slightly in the fourth quarter due to the decline in units produced due to the fulfillment of all pumps associated with the pump upgrade program. Additionally, it is anticipated the decline will be partially offset by the expected increase in net revenues from sales of ancillary supplies, as the patient base expands.

Research and Development. Research and development expenses increased $479,000, or 38.5%, to $1.7 million for the three months ended September 30, 2004 from $1.2 million in the comparable period of 2003 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 7.6% for the three months ended September 30, 2004 from 11.0% in the comparable period of 2003. The percentage decrease in research and development expenses resulted primarily from the growth of our net revenues. In future quarters, we expect research and development expenditures as a percentage of net revenues to decline due to the growth of our net revenues.

Selling, General and Administrative Expenses. Selling, general and administrative (SG&A) expenses increased by $1.8 million, or 23.5%, to $9.4 million in the three months ended September 30, 2004 from $7.6 million in the comparable period of 2003. However, as a percentage of net revenues, SG&A expenses decreased to 41.5% for the three months ended September 30, 2004 from 67.4% in the comparable period of 2003.

Of the absolute dollar increase, $911,000 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. In addition, higher professional fees of $236,000 and expenses of $145,000 to correct the IR 1200 software bug in September 2004 contributed to higher SG&A costs. The remaining increase was primarily related to increased insurance expense and increased administrative personnel costs.

We expect SG&A expenses to continue to increase for the remainder of 2004 as compared to 2003 in absolute dollars as we expand our sales, clinical, and marketing efforts to support the anticipated growth of our business. Also, we expect to incur additional costs as we operate as a public company. However, we expect that SG&A expenses should continue to decline as a percentage of net revenues as we continue to leverage our SG&A infrastructure.

Interest Income. Interest income increased to $155,000 in the three months ended September 30, 2004 from $4,000 in the comparable period of 2003. 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 increased to $59,000 in the three months ended September 30, 2004 from $49,000 in the comparable period of 2003. The increase reflects higher financing costs associated with increased insurance premiums.

Table of Contents

Net Income (Loss) Attributable to Common Stockholders. We reported net income of $2.8 million in the three months ended September 30, 2004 as compared to a net loss of $2.2 million in the comparable period of 2003. The effect of the pump upgrade program contributed $4.2 million of income during the three months ended September 30, 2004.

Table of Contents

Nine Months Ended September 30, 2004 and 2003

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.

	Nine Months Ended September 30,					
	2004		2003		Change, 2004/2003	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$47,911	100.0%	$ 27,876	100.0%	$20,035	71.9%
Operating expenses:						
Cost of products sold	19,338	40.3	12,934	46.4	6,404	49.5
Research and development expenses	4,395	9.2	3,732	13.4	663	17.8
Selling, general and administrative expenses	26,715	55.8	22,472	80.6	4,243	18.9
Total operating expenses	50,448	105.3	39,138	140.4	11,310	28.9
Loss from operations	(2,537)	(5.3)	(11,262)	(40.4)	8,725	77.5
Interest income	209	0.4	19	0.1	190	1,000.0
Interest expense	(301)	(0.6)	(143)	(0.5)	(158)	(110.5)
Net loss	(2,629)	(5.5)	(11,386)	(40.8)	8,757	76.9
Deemed dividend			(5,063)	(18.2)	5,063	100.0
Net loss attributable to common stockholders	$ (2,629)	(5.5)%	$(16,449)	(59.0)%	$13,820	84.0%
Net Revenues, Cost of Products Sold and Gross Margin						
Net Revenues						
Insulin pumps	$34,247	71.5%	$ 18,971	68.1%	$15,276	80.5%
Ancillary supplies	13,664	28.5	8,905	31.9	4,759	53.4
Total	$47,911	100.0%	$ 27,876	100.0%	$20,035	71.9%

Cost of Products Sold						
Insulin pumps	$11,373	58.8%	$ 6,852	53.0%	$ 4,521	66.0%
Ancillary supplies	7,965	41.2	6,082	47.0	1,883	31.0
Total	$19,338	100.0%	$ 12,934	100.0%	$ 6,404	49.5%
Gross Margin						
Insulin pumps	$22,874	80.1%	$ 12,119	81.1%	$10,755	88.7%
Ancillary supplies	5,699	19.9	2,823	18.9	2,876	101.9
Total	$28,573	100.0%	$ 14,942	100.0%	$13,631	91.2%
Gross Margin %						
Insulin pumps		66.8%		63.9%		
Ancillary supplies		41.7%		31.7%		
Total		59.6%		53.6%		

Net Revenues. In the nine months ended September 30, 2004, net revenues increased by $20.0 million, or 71.9%, to $47.9 million from $27.9 million in the comparable period in 2003. The increase in net revenues was a result of the recognition of $4.7 million of revenue deferred in prior periods associated with the pump upgrade program, $10.5 million primarily from increased demand and $4.8 million of increased shipments of ancillary supplies. Net revenues from domestic and foreign sales were $45.3 million and $2.6 million, respectively, in the nine months ended September 30, 2004 and $26.3 million and $1.6 million, respectively, in the comparable period in 2003. Pump net revenues increased by $15.3 million due to an increase in unit shipments. Our average selling price of pumps remained relatively stable over this period.

Table of Contents

Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges and other ancillary supplies increased by 53.4% in the nine months ended September 30, 2004 versus the comparable period of 2003. 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 the comparable nine month period of 2004 and 2003 and our retention of patients from prior years.

Cost of Products Sold. Cost of products sold increased by $6.4 million, or 49.5%, to $19.3 million in the nine months ended September 30, 2004 from $12.9 million in the comparable period of 2003 reflecting the increase in net revenues in the nine months ended September 30, 2004 from the comparable period of 2003. However, as a percentage of net revenues, cost of products sold decreased to 40.3% in 2004 from 46.4% in 2003. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, better manufacturing yields of our pumps, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by $4.5 million, or 66.0% in the nine months ended September 30, 2004 as compared to the comparable period of 2003. The rate of this increase was lower than the rate of increase of pump sales due to the economies and efficiencies described above, which offset the additional costs associated with the production ramp-up of the IR 1200 incurred during the third quarter of 2004. Costs associated with the additional pumps shipped under the pump upgrade program were $1.0 million in the nine month period.

Gross Margin. Gross margin increased to 59.6% in the nine months ended September 30, 2004 from 53.6% in the comparable period of 2003. Gross margin for pumps increased to 66.8% in 2004 due to increases in sales volume, better absorption of overhead, improved yields and lower cost of raw materials. The pump upgrade program contributed to the improvement of the gross margin through the better absorption of overhead. The effect of the shipment of pumps under the pump upgrade program contributed 2.0% to the improvement of the gross margin for pumps. Ancillary supplies gross margin increased to 41.7% in the nine months ended September 30, 2004 from 31.7% in the comparable period of 2003. Gross margin improvement for ancillary supplies was due to lower cost sources of supply.

Research and Development. Research and development expenses increased $663,000, or 17.8%, to $4.4 million for the nine months ended September 30, 2004 from $3.7 million in the comparable period of 2003 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 9.2% for the nine months ended September 30, 2004 from 13.4% in the comparable period of 2003. The percentage decrease in research and development expenses resulted primarily from the growth in our net revenues. In future periods, we expect research and development expenditures as a percentage of net revenues to decline due to the growth of our net revenues.

Selling, General and Administrative Expenses. SG&A expenses increased by $4.2 million, or 18.9%, to $26.7 million in the nine months ended September 30, 2004 from $22.5 million in the comparable period of 2003. However, as a percentage of net revenues, SG&A expenses decreased to 55.8% for the nine months ended September 30, 2004 from 80.6% in the comparable period of 2003.

Of the absolute dollar increase, $2.1 million 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. In addition, higher administrative personnel costs of $440,000 and professional fees of $316,000 contributed to higher SG&A costs in the nine months ended September 30, 2004. The remaining increase is primarily attributable to increased general and administrative expenses associated with operating as a public company.

Interest Income. Interest income increased to $209,000 in the nine months ended September 30, 2004 from $19,000 in the comparable period of 2003. 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 increased to $301,000 in the nine months ended September 30, 2004 from $143,000 in the comparable period of 2003. This reflects a higher outstanding debt balance than in the comparable period. The increase in average debt was primarily the result of higher borrowing under our credit lines during the first half of 2004.

Deemed Dividend Beneficial Conversion Feature of Preferred Stock. In connection with issuances of preferred stock in the nine months ended September 30, 2003, we recorded a non-cash charge of $5.1 million that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. There was no similar item in the nine months ended September 30, 2004.

Net Income (Loss) Attributable to Common Stockholders. We reported a net loss of $2.6 million in the nine months ended September 30, 2004 as compared to a net loss of $16.4 million in the comparable period of 2003. The effect of the pump upgrade program contributed

Table of Contents

$3.7 million of income during the nine months ended September 30, 2004.

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

	2003				2004		
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr
Net revenues	$ 7,380	$ 9,205	$11,291	$ 6,244	$ 4,837	$20,420	$22,654
Gross margin	3,751	4,502	6,689	1,786	1,750	12,974	13,849
Net income (loss)	(4,470)	(4,704)	(2,212)	(6,418)	(8,084)	2,636	2,819
Deemed dividend	(4,911)	(152)		(2,815)			
Net income (loss) attributable to common stockholders	$(9,381)	$(4,856)	$ (2,212)	$(9,233)	$(8,084)	$ 2,636	$ 2,819
Basic net income (loss) attributable to common stockholders per share	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)	$ (2.01)*	$ 0.24	$ 0.15
Diluted net income (loss) attributable to common stockholders per share	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)	$ (2.01)*	$ 0.14	$ 0.14

*Basic and diluted net loss per share has been revised from ($2.07).

Net revenues increased from $7.4 million in the first quarter of 2003 to $11.3 million in the third quarter of 2003. In the fourth quarter of 2003 and the first quarter of 2004, our net revenues decreased due to our deferral of $5.2 million and $4.5 million of net revenues, respectively, 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.

Gross margin improved from 50.8% in the first quarter of 2003 to 59.2% in the third quarter of 2003. The gross margin for the fourth quarter of 2003 and the first quarter of 2004 dropped to 28.6% and 36.2%, respectively, 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 63.5% as a result of the increased absorption of overhead due to the increased volume of pumps from the pump upgrade program, the shipment in the second quarter of the unfulfilled orders from the first quarter and the increased demand and improvements in the cost of the ancillary supplies. Gross margin in the third quarter of 2004 decreased to 61.1% as a result of additional costs of approximately $439,000 due to increased costs associated with production ramp-up of the IR 1200.

Net loss before deemed dividend declined from $4.5 million in the first quarter of 2003 to $2.2 million in the third quarter of 2003. Net loss increased in the fourth quarter of 2003 and the first quarter of 2004 to $6.4 million and $8.1 million, respectively, due to the pump upgrade program and the resulting deferral of net revenues and associated costs. Additionally, the net loss was increased due to 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

Table of Contents

demand for both pumps and ancillary supplies.

The deemed dividend was caused by the sale of preferred stock and warrants from January through April and in November 2003. The deemed dividend in 2003 increased the net loss attributable to common stockholders for the year ended December 31, 2003. Additional losses due to deemed dividends in 2004 are not anticipated.

Liquidity and Capital Resources

Historically, we have funded our operations primarily through the sale of equity securities yielding net proceeds of $79.9 million through the quarter ended March 31, 2004. On May 25, 2004, we closed our IPO of 4,250,000 shares of our common stock at $15 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. 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 two lines of credit with banks, totaling $6.3 million, of which no amounts were outstanding at September 30, 2004. We also have an equipment lease financing loan of $335,000 outstanding at September 30, 2004.

Cash Used in Operating Activities. Cash used in operating activities was $12.5 million and $11.8 million in the nine months ended September 30, 2004 and 2003, respectively. The major use of cash for the nine months ended September 30, 2004 was primarily for working capital and the funding of the loss of $2.6 million. The major use of cash for the nine months ended September 30, 2003 was to fund the loss of $11.4 million. Accounts receivable increased by $8.0 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 $4.7 million during the nine months ended September 30, 2004 due primarily to the growth of our business and the introduction of the IR 1200. Additionally, there were proportional increases in other current assets, although these were offset by increases in accounts payable and accrued expense and other liabilities.

During the three months ended March 31, 2004, the pump upgrade program did not have a negative effect on liquidity as we billed upon the shipment of all pumps subject to the upgrade program. However, as we shipped the IR 1200 replacement pumps during the second and third quarters of 2004, we did not generate any additional cash due to these upgrade shipments and had to ship the upgrade pumps to customers. As a result, in 2004, we believe our cash flows from operating activities were negatively affected by the replacement activity.

Cash Used in Investing Activities. Cash used in investing activities consisted of the purchase of approximately $3.1 million and $1.2 million of capital expenditures for the nine months ended September 30, 2004 and 2003, respectively. The capital expenditures were primarily for manufacturing equipment and computer equipment to support the significant growth in our business during that period and to position us for expected growth in 2004 and beyond.

Cash Provided by Financing Activities. Net cash provided by financing activities was $63.8 million and $13.4 million for the nine months ended September 30, 2004 and 2003, respectively. The net cash provided by financing activities during the nine months ended September 30, 2004 was primarily due to our IPO which raised net proceeds of $65.7 million. These amounts were partially offset by the repayment of debt. The net cash provided by financing activities during the nine months ended September 30, 2003 was primarily due to proceeds of $11.7 million from the sale of preferred stock.

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 September 30, 2004. 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. Borrowings are secured by a pledge of substantially all of our assets. As of September 30, 2004, there was no amount outstanding on this line of credit. We also have a $250,000 line of credit with another bank, which is secured by our accounts at such bank. The interest rate on borrowings under this line of credit is at 1.5% above the bank s prime rate. As of September 30, 2004, there was no amount outstanding on this line of credit.

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 September 30, 2004, the principal amount outstanding was $335,000.

Table of Contents

Operating Leases. At September 30, 2004, commitments related to future lease payments under operating leases, including the lease for our new facility, are $283,000 in 2004, $1.1 million in 2005, $1.2 million in 2006, $1.2 million in 2007, $1.2 million in 2008, and $6.9 million beyond 2008. There were no material commitments related to future capital expenditures on approved projects at September 30, 2004. At September 30, 2004, we had $550,000 outstanding on a letter of credit for a security deposit on the lease for our new facility.

As of September 30, 2004, we had cash and cash equivalents of $48.6 million. We expect to have negative cash flows from operations for the remainder of 2004. We expect increased selling and administrative expenses as well as increased spending for personnel and infrastructure improvement. We believe that our current cash, lines of credit, and cash generated from our operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into 2005 and the foreseeable future. If existing cash and 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 September 30, 2004, cash equivalents of $47.6 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 September 30, 2004, we had no amounts outstanding under our credit facilities.

Although approximately 3.7% and 5.5% of our net revenues for the three and nine months ended September 30, 2004, respectively 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 September 30, 2004, 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 September 30, 2004 which materially affected, or are reasonable likely to materially affect,

our internal control over financial reporting.

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

Table of Contents

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	
Acquisition of other businesses	
Repayment of indebtedness	4,767,234
Working capital	13,410,013
Cash equivalents	47,568,114
	$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.

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 September 30, 2004.

Item 5. Other Information

None.

Item 6. Exhibits

(10.1)	2004 Equity Incentive Plan Incentive Stock Option Grant
(10.2)	2004 Equity Incentive Plan Non-Qualified Stock Option Agreement
(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).

Table of Contents

(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.

SIGNATURE

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: November 15, 2004

Animas Corporation
(Registrant)