

INTERLEUKIN GENETICS INC  
Form 10-Q  
November 03, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

**For the Quarterly Period Ended September 30, 2004**

**Commission File Number 0-23413**

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**INTERLEUKIN GENETICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**135 Beaver Street**  
**Waltham, Massachusetts**  
(Address of principal executive offices)

**94-3123681**  
(IRS Employer Identification No.)

**02452**  
(Zip Code)

**(781) 398-0700**  
(Registrant's telephone number, including area code)

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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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common Stock, \$0.001 Par Value,

23,557,699 shares outstanding as of October 29, 2004.

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**TABLE OF CONTENTS**

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Financial Statements of Interleukin Genetics, Inc.

Consolidated Balance Sheets as of September 30, 2004 (Unaudited) and December 31, 2003 (Audited)

Consolidated Statements of Operations (Unaudited)

Consolidated Statements of Cash Flows (Unaudited)

Notes to Interim Consolidated Financial Statements (Unaudited)

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

Item 3. Defaults Upon Senior Securities

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

Item 5. Other Information

Item 6. Exhibits and Reports on Form 8-K

Signatures

Exhibit Index

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

**INTERLEUKIN GENETICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	September 30, 2004 (Unaudited)	December 31, 2003 (Audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,506,990	\$ 4,759,453
Accounts receivable	23,191	123,436
Funded research and development costs	300,000	
Prepaid expenses and other current assets	173,198	114,519
Total current assets	6,003,379	4,997,408
Fixed assets, net	854,513	271,669
Other long-term assets	306,134	189,365
Total assets	\$ 7,164,026	\$ 5,458,442
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 562,517	\$ 69,807
Accrued expenses	639,587	538,191
Deferred revenue	872,360	653,760
Commitments for funded research and development projects	494,726	
Current portion of capital lease obligations	18,324	26,346
Total current liabilities	2,587,514	1,288,104
Long-term notes	2,595,336	2,595,336
Capital lease obligations, net of current portion	5,904	17,290
Total liabilities	5,188,754	3,900,730
Stockholders' equity:		
Preferred stock; Series A \$0.001 par value 6,000,000 shares authorized; 5,000,000 shares issued and outstanding at September 30, 2004 and December 31, 2003; aggregate liquidation preference of \$18,000,000 at September 30, 2004	5,000	5,000
Common stock; \$0.001 par value, 75,000,000 shares authorized; 23,557,699 and 23,262,588 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	23,558	23,263
Additional paid-in capital	49,160,750	46,521,470
Accumulated deficit	(47,214,036)	(44,992,021)
Total stockholders' equity	1,975,272	1,557,712
Total liabilities and stockholders' equity	\$ 7,164,026	\$ 5,458,442

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

**INTERLEUKIN GENETICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenue	\$ 1,400,066	\$ 633,785	\$ 2,708,986	\$ 1,295,432
Cost of revenue	829,188	493,573	1,775,833	892,910
Gross profit	570,878	140,212	933,153	402,522
Operating expenses:				
Research and development	256,083	374,362	991,843	1,722,676
Selling, general and administrative	667,199	481,935	2,099,333	1,778,088
Total operating expenses	923,282	856,297	3,091,176	3,500,764
Loss from operations	(352,404)	(716,085)	(2,158,023)	(3,098,242)
Other income (expense):				
Interest income	15,038	14,882	38,238	37,894
Interest expense	(35,151)	(36,072)	(102,230)	(110,572)
Amortization of note discount		(30,017)		(210,119)
Other income (expense)				2
Total other income (expense)	(20,113)	(51,207)	(63,992)	(282,795)
Net loss	\$ (372,517)	\$ (767,292)	\$ (2,222,015)	\$ (3,381,037)
Net loss per weighted average share, basic and diluted	\$ (0.02)	\$ (0.03)	\$ (0.09)	\$ (0.15)
Weighted average number of common shares, basic and diluted	23,530,154	23,236,630	23,451,930	23,172,176

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

**INTERLEUKIN GENETICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,222,015)	\$ (3,381,037)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	90,224	288,527
Amortization of funded research and development costs	265,000	
Change in value of stock options issued as compensation for services rendered		111,580
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	100,245	1,619
Prepaid expenses and other current assets	(58,679)	15,702
Accounts payable	492,710	(87,918)
Accrued expenses	101,396	(43,806)
Deferred revenue	218,600	(11,998)
Commitments for funded research and development projects	(70,274)	
Net cash used in operating activities	(1,082,793)	(3,107,331)
<b>Cash flows from investing activities:</b>		
Purchases of fixed assets	(657,407)	(52,211)
Increase in other assets	(132,430)	(31,061)
Net cash used in investing activities	(789,837)	(83,272)
<b>Cash flows from financing activities:</b>		
Net proceeds from sale of Series A preferred stock		6,850,225
Proceeds from issuance of bridge loan		1,095,336
Repayment of bridge loans		(525,000)
Proceeds from equity milestone payment	2,000,000	
Net proceeds from exercise of options to purchase common stock	639,575	133,142
Payments of capitalized lease obligations	(19,408)	(25,624)
Net cash provided by financing activities	2,620,167	7,528,079
Net increase in cash and cash equivalents	747,537	4,337,476
Cash and cash equivalents at beginning of period	4,759,453	733,848
Cash and cash equivalents at end of period, including restricted cash and cash equivalents	\$ 5,506,990	\$ 5,071,324
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>		
<i>Non-Cash Investing and Financing Activities:</i>		
Acquisition of fixed assets under capital leases	\$	\$ 32,395
<i>Interest and Income Taxes Paid:</i>		
Interest	\$ 102,230	\$ 98,049
Income taxes	\$	\$

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

**INTERLEUKIN GENETICS, INC.**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2004 AND 2003**  
**(Unaudited)**

**Note 1. Basis of Presentation**

The accompanying unaudited interim consolidated financial statements include the accounts of Interleukin Genetics, Inc. and its wholly-owned subsidiaries (collectively referred to as the Company or Interleukin ) as of September 30, 2004 and have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial reporting and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. All intercompany accounts and transactions have been eliminated. These unaudited interim consolidated financial statements, which, in the opinion of management, reflect all adjustments (including normal recurring adjustments) necessary for a fair presentation, should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003. Operating results for the three and nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for any future interim period or for the entire fiscal year.

**Note 2. Realization of Assets and Liquidity**

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplates continuation of the Company as a going concern. However, the Company has sustained substantial losses from operations since inception. In addition, the Company has used, rather than provided, cash in its operations.

At September 30, 2004, the Company had an accumulated deficit of approximately \$47.2 million including a net loss of approximately \$2.2 million for the nine months ended September 30, 2004. For the nine months ended September 30, 2004, the Company has used , rather than provided, cash in its operations of approximately \$1.1 million.

The Company believes that its cash position at September 30, 2004, along with its anticipated revenue, and, if required, additional borrowings would be sufficient to fund operations as planned through mid-2005.

The Company's future financial needs depend on many factors. The Company will need funds for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Additional financing in amounts necessary to fund the Company's needs may not be available when needed, or, if available, may not be available on favorable terms. If the Company cannot obtain additional capital on acceptable terms when needed, the Company may have to discontinue operations, or, at a minimum, curtail one or more of its research and development programs.

On March 5, 2003, the Company entered into a broad strategic alliance with several affiliates of the Alticor, Inc. family of companies to develop and market personalized nutritional and skin care products. For the purpose of clarity, in this document we will refer to Alticor and all of its wholly-owned subsidiaries, including Access Business Group, Pyxis Innovations and Quixtar as Alticor.

On June 17, 2004, the Company entered into a research agreement, valued at \$2.2 million, as amended, with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. , During the first phase of the agreement the Company is eligible to receive up to \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, the Company will be eligible to receive, during the second phase of the agreement, an additional \$0.8 million in funding over a six-month period beginning on January 1, 2005.

**Note 3. Significant Accounting Policies**

*Management Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reported periods. Actual results could differ from those estimates.

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### *Revenue Recognition*

Contract revenue is recognized ratably as services are provided based on a fixed contract price or on negotiated hourly rates. Provisions for anticipated losses on fixed-price contracts are made in the period such losses are identified. Revenue from genetic susceptibility tests is recognized when the tests have been completed and the results reported to the doctors or patients who ordered the tests. To the extent test kits have been purchased and paid for but not yet submitted for test results recognition of all related revenue is deferred. These amounts are presented as deferred revenue in the accompanying consolidated balance sheets.

The Company has entered into agreements with outside parties for the distribution of genetic susceptibility tests, both domestically and internationally for which it receives royalty payments. Royalties are recognized when earned under the Company's royalty agreements when amounts are fixed or determinable and payment is reasonably assured. Revenue from milestone or other contingent payments is recognized when earned in accordance with the terms of the related agreement.

### *Stock-based Compensation*

The Company accounts for its stock-based compensation plans under Accounting Principles Board Opinion No. 25 ( APB No. 25 ), *Accounting for Stock Issued to Employees*. Under APB No. 25, no stock-based compensation is reflected in net loss, as all options granted under the plans had an exercise price equal to the market value of the underlying common stock on the date of grant and the related number of shares granted is fixed at that point in time. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standard ( SFAS ) No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, issued in December 2002.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2004		2003		2004		2003	
	Net Loss	Loss per Share	Net Loss	Loss per Share	Net Loss	Loss per Share	Net Loss	Loss per Share
As Reported	\$ (372,517)	\$ (0.02)	\$ (767,292)	\$ (0.03)	\$ (2,222,015)	\$ (0.09)	\$ (3,381,037)	\$ (0.15)
Stock based employee compensation expense	(125,940)	(0.00)	(229,100)	(0.01)	(497,399)	(0.03)	(625,020)	(0.02)
Pro Forma	\$ (498,457)	\$ (0.02)	\$ (996,392)	\$ (0.04)	\$ (2,719,414)	\$ (.012)	\$ (4,006,057)	\$ (0.17)

The effects of applying SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. SFAS No. 123 does not apply to awards prior to 1996 and additional awards in future years are anticipated.

The fair value of the options was estimated at the date of grant using the Black-Scholes option valuation model with the weighted average assumptions listed in the table below:

	2004	2003	
Risk free interest rate	4.0	% 4.0	%
Expected life	7 years	7 years	

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Expected volatility	80	% 80	%
Expected dividend yield	0	% 0	%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options. The Company's employee stock options have characteristics significantly different from those of traded options such as extremely limited transferability and, in most cases, vesting restrictions. In addition, the assumptions used in option valuation models are based upon historical averages that may not predict future results, particularly the expected stock price volatility of the underlying stock. Because changes in these input assumptions can materially affect the fair value estimate, in management's opinion, existing valuation models do not provide a reliable, single measure of the fair value of the Company's employee stock options.

*Recent Accounting Pronouncements*

On March 31, 2004, the Financial Accounting Standards Board ( FASB ) issued a proposed Statement, *Share-Based Payment*, which addresses the accounting for share-based awards to employees, including employee stock purchase plans. The FASB formally proposed to require companies to recognize as an expense the fair value of stock options and other stock-based compensation to employees.

The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB No. 25, *Accounting for Stock Issued to Employees*, and generally would require instead, that such transactions, be accounted for using a fair-value-based method. This Exposure Draft was open for public comment until June 30, 2004. During its deliberations to address the comment letters, the FASB has preliminarily indicated that the effective date for this statement would be for periods beginning after June 15, 2005.

The Company currently accounts for its stock-based compensation plans in accordance with APB No. 25. Therefore, the eventual adoption of this proposed statement, if issued in final form by the FASB, is likely to have a material effect on the Company's consolidated financial statements.

**Note 4. Strategic Research Arrangements**

In July 1999, the Company entered into an agreement (the Master Agreement ) with Sheffield University ( Sheffield ), whereby it will undertake the development and commercialization of certain discoveries resulting from Sheffield's research. For certain of the discoveries, the parties have reached a specific non-cancelable agreement of development and commercialization. However, for new discoveries on which the parties have not yet reached specific agreement, the agreement may be terminated with or without cause by either party upon six months' notice.

The Master Agreement was a five-year agreement with an automatic yearly renewal. In 1999, in accordance with this agreement, the Company issued 275,000 shares of common stock to Sheffield for transferring all rights and title of certain patents. The value of the common stock of \$653,125 was charged to research and development expenses in the third quarter of 1999. Additionally, each year beginning July 1, 2000, Sheffield received 25,000 fully vested options to purchase common stock at the then current market price, plus 10,000 fully vested options to purchase common stock for each new patent application filed in the previous 12 months. During the years ended December 31, 2003 and December 31, 2002, 45,000 and 35,000 fully vested options, respectively, to purchase common stock were granted under this agreement. These options have a five-year exercise period. In 1999, the Company signed another research agreement with Sheffield (the Research Agreement ) that automatically renews in one-year increments. The Research Agreement requires us to pay the cost of agreed upon research projects conducted at Sheffield. Both, the Master Agreement and the Research Agreement, expired in June 2004. The Company elected to discontinue the Master Agreement because its discovery research is being performed at its functional genomics laboratory in Waltham, Massachusetts but extended the Research Agreement through June 2005 to continue ongoing and planned research projects at Sheffield. The Research Agreement with Sheffield can be canceled if a certain key collaborator leaves Sheffield.

In September 1999, a five-year consulting agreement was entered into with a key collaborator from Sheffield. In accordance with the consulting agreement, the key collaborator received 200,000 shares of common stock for relinquishing interests in previous research agreements. The value of the common stock of \$475,000 was charged to research and development expense in the third quarter of 1999. The key collaborator will also receive 1% of the first \$4 million of net sales under the PST® Technology and 2% for sales above \$4 million. Since 2002, this collaborator received no significant royalty payments for sales of PST®. On July 1, 2002 and 2003, in consideration for future services, the key collaborator received 25,000 fully vested options to purchase common stock at the then current market price. These options have a five-year exercise period from the date of grant. This agreement expired in June 2004 but was extended until September 30, 2004. Effective October 1, 2004, the

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Company entered into a new agreement with this collaborator through September 30, 2005 with an annual automatic renewal unless sooner terminated.

For the three and nine months ended September 30, 2004 the Company expensed approximately \$50,000 and \$154,000, respectively, for research conducted at Sheffield. This includes funding to Sheffield and to collaborators at Sheffield.

### **Note 5. Strategic Alliance with Alticor Inc.**

On March 5, 2003, the Company entered into a broad strategic alliance with several affiliates of the Alticor family of companies to develop and market novel nutritional and skin care products. The alliance utilizes the Company's intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market.

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The alliance includes an equity investment, a multi-year research and development agreement, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The major elements of the alliance are:

The purchase by Alticor of \$9,000,000 of equity in the form of 5 million shares of Series A Preferred Stock for \$1.80 per share. These are convertible into approximately 28.2 million shares of common stock at a conversion price equal to \$0.3196, representing 54.5% of the Company's common stock if converted. \$7,000,000 of the total purchase price was received on March 5, 2003. The remaining \$2,000,000 was subject to the achievement of a defined milestone. This milestone was achieved in February of this year and the milestone payment was received on March 11, 2004.

The right of the Series A Preferred stockholders to nominate and elect four directors to a five person board.

A research and development agreement providing the Company with funding of \$5,000,000, payable in quarterly installments over the period between April 2003 and March 2005, to conduct certain research projects with a royalty on resulting products.

Credit facilities in favor of the Company, as follows:

\$1,500,000 working capital credit line to initiate selected research agreements with third party entities approved by the board of directors of Interleukin;

\$2,000,000 refinancing of notes previously held by Alticor, extending the maturity date and reducing the interest rate; and

\$595,336 refinancing on July 1, 2003 of bridge financing notes previously held by third parties, extending the maturity date and reducing the interest rate.

As of September 30, 2004 there was \$2,595,336 outstanding under the terms of these credit facilities. The credit facilities will mature in December 2007, bear interest at 1% over the prime rate (5.75% at September 30, 2004), are secured by a security interest in the Company's intellectual property, (except intellectual property relating to periodontal disease and sepsis) and are convertible at the election of Alticor into 4,060,288 shares of common stock at a conversion price equal to \$0.6392 per share, subject to future adjustment.

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On February 26, 2004, the Company signed an agreement with Alticor for a firm minimum order of DNA-based risk assessment tests to be delivered in the first year of product launch. A soft launch is expected for the first half of 2005 with a full product launch in the following quarter.

On June 17, 2004, the Company entered into a research agreement valued at \$2.2 million, as amended, with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. , During the first phase of the agreement the Company is eligible to receive up to \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, the Company will be eligible to receive, during the second phase of the agreement, an additional \$0.8 million in funding over a six-month period beginning on January 1, 2005.

### **Note 6. Capital Stock**

#### *Authorized Common and Preferred Stock*

At September 30, 2004, the Company had authorized 6,000,000 shares of Series A Preferred stock of which 5,000,000 shares were issued and outstanding. At September 30, 2004, the Company had authorized 75,000,000 shares of \$0.001 par value common stock of which 61,259,974 shares were outstanding or reserved for issuance. Of those, 23,557,699 shares were outstanding, 28,160,200 were reserved for the conversion of the Series A Preferred to common stock, 4,060,288 shares were reserved for the conversion of approximately \$2.6 million of debt, 4,490,045 shares were reserved for the exercise of authorized and outstanding stock options, 525,000 shares were reserved for the exercise of authorized and outstanding warrants to purchase common stock and 466,742 shares were reserved for the exercise of rights held under the Employee Stock Purchase Plan.

#### *Series A Preferred Stock*

On March 5, 2003, the Company entered into a Purchase Agreement with Alticor, pursuant to which Alticor purchased Series A Preferred Stock for \$7,000,000 in cash on that date, and an additional \$2,000,000 in cash that was paid, as a result of the Company

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achieving a certain milestone, on March 11, 2004. The offering was made to Alticor by way of a private placement exempt from registration under the Securities Act.

The Series A Preferred Stock issued in the private placement is convertible into 28,160,200 shares of common stock reflecting a conversion price of \$0.3196 per share after being adjusted for the milestone payment and is subject to weighted average antidilution adjustments. Assuming the conversion of all shares of Series A Preferred Stock as of September 30, 2004, such shares represent 54.5% of the outstanding shares of the Company's common stock.

The Series A Preferred Stock accrues dividends at the rate of 8% of the original purchase price per year, payable only, as and if declared by the Board of Directors and are non-cumulative. To date, no dividends have been declared on these shares. If the Company declares a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by the Company or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of its Common Stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of its Common Stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of its assets or surplus funds to the holders of its common stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such share for each share of Series A Preferred Stock then held by them. After receiving this amount, the holders of Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of the remaining assets.

Each share of Series A Preferred Stock is convertible at any time at the option of the holder into a number of shares of the Company's common stock determined by dividing the then-effective purchase price (currently \$1.80 since the milestone payment was received, and subject to further adjustment) by the conversion price in effect on the date the certificate is surrendered for conversion (currently \$0.3196). The liquidation preference at September 30, 2004 was \$18,000,000.

Each holder of Series A Preferred Stock is entitled to vote its shares of Series A Preferred Stock on an as-converted basis with the holders of common stock as a single class on all matters submitted to a vote of the stockholders, except as otherwise required by applicable law. This means that each share of Series A Preferred Stock will be entitled to a number of votes equal to the number of shares of common stock into which it is convertible on the applicable record date.

### **Note 7. Debt**

On March 5, 2003 as part of the Company's strategic alliance with Alticor the Company was granted credit facilities as follows:

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\$1,500,000 working capital credit line to initiate selected research agreements with third party entities approved by the board of directors of Interleukin;

\$2,000,000 refinancing of notes previously held by Alticor, extending the maturity date and reducing the interest rate; and

\$595,336 refinancing on July 1, 2003 of bridge financing notes previously held by third parties, extending the maturity date and reducing the interest rate.

As of September 30, 2004 there was \$2,595,336 outstanding under the terms of these credit facilities. The credit facilities will mature in December 2007, bear interest at 1% over the prime rate (5.75% at September 30, 2004), are secured by a security interest in the Company's intellectual property (except intellectual property related to periodontal disease and sepsis), and are convertible at the election of Alticor into shares of common stock at a conversion price equal to \$0.6392 per share.

**Note 8. Loss per Share**

The following is the reconciliation of the numerators and denominators of the basic and diluted per share computations of net loss:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss	\$ (372,517)	\$ (767,292)	\$ (2,222,015)	\$ (3,381,037)
<b>Basic and diluted:</b>				
Common shares outstanding, beginning of period	23,512,904	23,233,088	23,262,588	23,118,249
Weighted average common shares issued during the period	17,250	3,542	189,342	53,927
Weighted average shares outstanding basic and diluted	23,530,154	23,236,630	23,451,930	23,172,176
Net loss per weighted average share, basic and diluted	\$ (0.02)	\$ (0.03)	\$ (0.09)	\$ (0.15)

SFAS No. 128, *Earnings per Share*, outlines methods for computing and presenting earnings per share. SFAS No. 128 requires a calculation of basic and diluted earnings per share for all periods presented. The Company reported losses for the three and nine months ended September 30, 2004 and 2003 and accordingly any potential common stock equivalents are anti-dilutive due to the loss in each period. Potential common stock excluded from the calculation of diluted net loss per share consists of stock options, warrants, preferred stock and convertible debt as described in the table below.

	September 30,	
	2004	2003
Options outstanding	2,855,167	2,580,133
Warrants outstanding	525,000	525,000
Preferred stock	28,160,200	28,157,683
Convertible debt	4,060,288	4,060,288
Total	35,600,655	35,323,104

The table reflects the change in the number of potential shares of common stock available to the holders of the convertible debt resulting from the milestone payment from Alticor that was received on March 11, 2004 for both the 2004 and 2003 periods. See Note 5 entitled "Strategic Alliance with Alticor Inc." for details of this transaction.

**Note 9. Segment Disclosures**

The Company follows the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 establishes standards for reporting information about operating segments in annual and interim financial statements, requiring that public business enterprises report financial and descriptive information about reportable segments based on a management approach. SFAS No. 131 also establishes standards for related disclosures about products and services, geographic areas and major customers. In applying the requirements of this statement, the Company continues to have one reportable segment, which is the development of genetic susceptibility tests and therapeutic targets for common diseases.

**Note 10. Commitments and Contingencies**

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In connection with the research agreement with Alticor dated March 5, 2003, the Company is obligated to purchase two clinical databases. As of June 30, 2004, the Company determined that this obligation met the criteria of SFAS No. 5, *Accounting for Contingencies*, and estimated the cost of these two databases at \$450,000. Accordingly, the Company recorded a liability and a current asset of \$450,000 at that time. The Company is amortizing the cost of the two databases ratably over the remaining nine months of the research contract. As of September 30, 2004, the Company had negotiated the acquisition of the first of the two databases. The Company believes that the acquisition of the databases, will not exceed the amount that the Company has estimated, however actual amounts could differ.

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

This report on Form 10-Q and the documents incorporated by reference within this document contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Words or phrases such as "will likely result", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "project", "outlook", or similar expressions are intended to identify forward-looking statements. Forward-looking statements address or may address the following subjects:

The sufficiency of our current cash resources, additional anticipated financings and anticipated revenue to fund operations through mid-2005;

Our expectation that we will receive at least an additional \$1,250,000 in revenue over the six-month period ending March 2005 from Alticor under the terms of the Strategic Alliance Research Agreement;

Our expectation that we will receive at least an additional \$1,510,000 in revenue over the nine-month period ending June 2005 from Alticor under the terms of the Weight Management Research Agreement;

Any expectation we may have of raising additional capital through equity financings;

Our expectation that we will receive royalty payments and/or genetic test processing revenue under the terms of a License Agreement and a Distribution Agreement with Alticor;

Our expectation that we will receive royalty payments and/or genetic test processing revenue from customers other than Alticor;

Our expectation that we may sign additional research agreements with Alticor or other third parties;

Our expectation of the benefits that will result from the ongoing research programs that outside parties are conducting on our behalf;

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Any expectation we may have regarding the success of developing products, the timing of releasing products for sale or the success of these products when they are released;

Any expectation we may have of attracting business partners to assist in developing, marketing or distribution of our products;

Any expectation that certain health-care related trends will emerge or continue that will support our business model;

Our expectation that our total research and development costs, including clinical costs, but excluding contract research and development, will be between approximately \$1.5 and \$2.0 million for the year ended December 31, 2004;

Our expectation that our capital expenditures will be between \$0.9 million and \$1.1 million for the year ended December 31, 2004;

Our expectation that we might derive benefit from our patented intellectual property; and

Our expectation that we will continue to experience losses until our genetic testing revenue grows substantially from current levels.

Actual results may vary materially from those expressed in forward-looking statements. Factors that could cause actual results to differ from expectations include but are not limited to; risks related to market acceptance of genetic risk assessment tests in general and our products in particular, risks related to technology and product obsolescence, delays in development of products, dependence on third parties, our ability to fund operations through mid-2005, competitive risks and those risks set forth within the section titled "Factors That May Affect Our Future Performance" beginning on page 17 within this report. We cannot be certain that our results will not be adversely affected by one or more of these factors or by other factors not currently anticipated. All information set forth in this Form 10-Q is as of the date of this Form 10-Q. Unless required by law we accept no responsibility to update this information.

## Overview

We are in the business of personalized health. In essence, personalized health is a new and growing field that includes the development and marketing of: 1) genetic risk assessment products, 2) pharmacogenetic tests, 3) personalized nutrition supplements and skincare products, and 4) personalized therapeutics. We will use our intellectual property and expertise to develop products or acquire additional intellectual property that can be leveraged, through collaboration with partners, to address market needs with any or all of these product categories listed above.

Our current commercial strategy is to partner with companies that have sales and marketing capabilities and products or services that complement our own products. We currently have no plans to develop our own sales force; we plan to rely on our strategic partners to promote and distribute our products. The essence of these strategic partnerships is that the selling partner will benefit because its product or service sales will be spurred by our products. The first of these strategic partnerships is the partnership we have with Alticor.

Currently, we will generate cash flow by: 1) charging a fee for generating a personalized risk assessment 2) receiving a royalty from products sold as a result of the risk assessment report and 3) receiving a license fee and royalty from licensing our core technology out to others. Furthermore, we plan to collaborate with other companies in the research and development of products. In these collaborations, we expect to receive a certain amount of research funding from the partner covering labor, material, overhead and a small amount of profit.

On March 5, 2003, we entered into a broad strategic alliance with Alticor to develop and market personalized nutritional and skin care products ( Strategic Alliance Research Agreement ). The alliance will utilize our intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market.

On June 17, 2004, we entered into a research agreement valued at \$2.2 million, as amended, with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight ( Weight Management Research Agreement ). During the first phase of the agreement we are eligible to receive up to \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, we will be eligible to receive, during the second phase of the agreement, an additional \$0.8 million in funding over a six-month period beginning on January 1, 2005.

We are devoting most of our resources to the support of the Strategic Alliance with Alticor which includes the development of our own products to be sold in combination with Alticor's products. A portion of our resources is also devoted to the development of a new product for the periodontal market. Our revenue has consisted primarily of research payments from Alticor and minimal royalties from PST®. Additionally, we expect to continue incurring losses as we continue research and development efforts in the development of new tests and new products.

The Strategic Alliance with Alticor includes an equity investment, a multi-year research and development agreement, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The financial elements of the alliance are described in greater detail within the Liquidity and Capital Resources beginning on page 16. During the three and nine months ended September 30, 2004 we recognized \$1,392,000 (99.4% of our total revenue) and \$2,682,000 (99.0% of our total revenue), respectively, from research services provided to Alticor under the terms of this and other related agreements.

PST® is a genetic test predictive of risk for periodontal disease and is currently marketed in the United States and Europe. We use third parties to market and distribute PST® and we earn royalties based upon their sales. In December 2000, we entered into an exclusive seven-year license agreement with Hain Diagnostika/ADS GmbH ( Hain ) for the marketing, distribution and processing of PST® in all countries outside of North America and Japan. In May 2003, we amended the agreement with Hain to a non-exclusive license limited to the European Territory and added LabOral International as another distributor in Europe. Since December 2001, Kimball Genetics has been our sole marketing partner within the United States. We are currently assessing the commercial viability of this product.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of our operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported revenue

and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The significant accounting policies that management believes are most critical to aid in fully understanding and evaluating our reported financial results include the following:

### ***Revenue Recognition***

Contract revenue is recognized ratably as services are provided based on a fixed contract price or on negotiated hourly rates. Provisions for anticipated losses on fixed-price contracts are made in the period such losses are identified. Revenue from genetic susceptibility tests is recognized when the tests have been completed and the results reported to the doctors or patients who ordered the test. To the extent test kits have been purchased and paid for but not yet submitted for test results, we defer recognition of all related revenue. These amounts are presented as deferred revenue in the accompanying consolidated balance sheets.

We have entered into agreements with outside parties for the distribution of genetic susceptibility tests, both domestically and internationally for which we receive royalty payments. Royalties are recognized when earned under our royalty agreements when amounts are fixed or determinable and payment is reasonably assured. Revenue from milestone or other contingent payments is recognized when earned in accordance with the terms of the related agreement.

### ***Income Taxes***

The preparation of our consolidated financial statements requires us to estimate our income taxes in each of the jurisdictions in which we operate, including those outside the United States, which may be subject to certain risks that ordinarily would not be expected in the United States. The income tax accounting process involves estimating our actual current exposure together with assessing temporary differences resulting from differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences result in the recognition of deferred tax assets and liabilities. We must then record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. We have recorded a full valuation allowance against our deferred tax assets of \$14.8 million as of September 30, 2004, due to uncertainties related to our ability to utilize these assets. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods we may need to adjust our valuation allowance which could materially impact our financial position and results of operations.

### ***Stock-based Compensation***

We account for our stock-based compensation plans under Accounting Principles Board Opinion No. 25 ( APB No. 25 ), *Accounting for Stock Issued to Employees*. Under APB No. 25, no stock-based compensation is reflected in net loss, as all options granted under the plans had an exercise price equal to the market value of the underlying common stock on the date of grant and the related number of shares granted is fixed at that point in time. The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of Statement of Financial Accounting Standard ( SFAS ) No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, issued in December 2002.

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	Three Months Ended September 30, 2004				Three Months Ended September 30, 2003			
	Net Loss	Loss per Share	Net Loss	Loss per Share	Net Loss	Loss per Share	Net Loss	Loss per Share
As Reported	\$ (372,517)	\$ (0.02)	\$ (767,292)	\$ (0.03)	\$ (2,222,015)	\$ (0.09)	\$ (3,381,037)	\$ (0.15)
Stock-based employee compensation expense	(125,940)	(0.00)	(229,100)	(0.01)	(497,399)	(0.03)	(625,020)	(0.02)
Pro Forma	\$ (498,457)	\$ (0.02)	\$ (996,392)	\$ (0.04)	\$ (2,719,414)	\$ (0.12)	\$ (4,006,057)	\$ (0.17)

The effects of applying SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. SFAS No. 123 does not apply to awards prior to 1996 and additional awards in future years are anticipated.

The fair value of the options was estimated at the date of grant using the Black-Scholes option valuation model with the weighted average assumptions listed in the table below:

	2003	2004	
Risk free interest rate	4.0	% 4.0	%
Expected life	7 years	7 years	
Expected volatility	80	% 80	%
Expected dividend yield	0	% 0	%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options. Our employee stock options have characteristics significantly different from those of traded options such as extremely limited transferability and, in most cases, vesting restrictions. In addition, the assumptions used in option valuation models are based upon historical averages that may not predict future results, particularly the expected stock price volatility of the underlying stock. Because changes in these input assumptions can materially affect the fair value estimate, in management's opinion, existing valuation models do not provide a reliable, single measure of the fair value of its employee stock options.

## Results of Operations

### *Three Months Ended September 30, 2004 Compared to Three Months Ended September 30, 2003*

Revenue for the three months ended September 30, 2004 was \$1.4 million compared to \$634,000 for the three months ended September 30, 2003, an increase of 121%. This increase is primarily the result of \$690,000 of revenue from a new research project with Alticor. In June 2004, we entered into a research agreement valued at \$2.2 million, as amended, with Alticor, to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. With the execution of this agreement we are eligible to receive, during the first phase of the agreement, up to \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, we will be eligible to receive, during the second phase of the agreement, an additional \$0.8 million in funding over a six-month period beginning on January 1, 2005. Both periods include \$625,000 in revenue from our Strategic Alliance Research Agreement with Alticor.

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Cost of revenue was \$829,000 for the three months ended September 30, 2004, compared to \$494,000 for the same period in 2003. Gross profit margin was 41% for the three months ended September 30, 2004 compared to 22% for the same period in 2003. The increase in cost of revenue is a direct result of the increase in revenue. The improvement in gross profit margin is primarily the result of the timing of recognizing revenue and expenses on research contracts. Revenue is generally recognized ratably over the research contract period whereas the expenses are recognized as incurred. In some instances, research expenses being performed by third parties are not deemed to have been incurred until the attainment of certain milestones. The Company expects that the gross profit margin will return to historical levels over the term of the research contracts.

**Strategic Alliance:** Pursuant to the terms of our Strategic Alliance Research Agreement with Alticor, we are collaborating in the development of personalized nutrigenomic products for sale in the United States and Canada. Our primary responsibility is to develop genetic tests to assess personalized risk and to develop and use screening technologies to validate the effectiveness of nutrigenomic consumables Alticor is developing. Additionally, we play a key role in enhancing and maintaining scientific credibility in academic and medical communities. After our initial focus in developing products for sale in the United States and Canada, we

expect that we will expand our focus to include developing nutrigenomic products for sale overseas and developing other products in the United States and overseas in other areas of wellness and skin care.

**Weight Management:** Pursuant to the terms of our Weight Management Research Agreement with Alticor, we are conducting research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight.

For the three months ended September 30, 2004, we had internally-funded research and development expenses of \$256,000 as compared to \$374,000 for the same quarter of 2003, a decrease of 32%. The decrease in R&D expenses reflects a re-allocation of internal resources from internally funded projects to the research projects funded by Alticor that are now reported as cost of revenue. During the remainder of 2004 we are not planning new research and clinical projects. The most significant ongoing projects are the following:

**General Research:** We are continuing the development of our basic understanding of genetic variations, specifically as it relates to inflammation. We expect to identify and study new single nucleotide polymorphisms (SNPs) that cause functional changes on inflammatory responses to stimuli. We anticipate expanding our SNP discovery work in order to begin development work on genetic tests and to assist in the development of products in the areas of weight management, maintenance of mental acuity, skincare, exercise performance and the prevention of complications among pre-diabetics.

**Rheumatoid Arthritis:** In collaboration with United Health Group, we conducted a study to determine whether analysis of genotype will be useful to predict responses to anti-cytokine therapy for individuals with rheumatoid arthritis. The anti-cytokine therapies currently on the market act very differently on human biology. Three of the four anti-cytokine therapies used to treat rheumatoid arthritis are anti TNF drugs; the other acts upon the IL-1 gene. We believe that depending upon the specific genetics of individuals, we might be able to predict which class of drugs would be most effective. We have concluded the genotyping in this project and are currently analyzing the data.

In collaboration with the University of Sheffield School of Health and Related Research (SchARR), we conducted a study to determine if it is cost effective to analyze patients' genotypes prior to the use of a specific biologic in the treatment of Rheumatoid Arthritis. The results of the economic modeling indicated that use of a pharmacogenetic test prior to prescribing that specific biologic could potentially be cost-effective by producing higher response rates.

**Therapeutic Product:** We continue to assess opportunities to develop off-patent drugs or drugs that have been shown to be safe but do not have FDA approval for anti-inflammatory indications in individuals with a specific genotype. Our plan is to attempt to validate these drugs for pharmacogenomic applications. We hope to use our knowledge of genetic variations in the area of inflammation to find new applications for some of these drugs. We commenced animal/pre-clinical studies in June 2004.

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We expect total research and development expenses, including clinical costs but excluding contract research and development costs, to be between approximately \$1.5 and \$2.0 million for the calendar year 2004. Actual costs may vary from this estimate as a result of our ability to raise additional new capital, changes in technology, the success of current and future research projects, the success or failure of our current or future strategic alliances and collaborations and the identification of new business opportunities. We have not made an attempt to finalize an estimate of our research and development expenses beyond 2004 due to the factors listed above.

Selling, general and administrative expenses were \$667,000 during the three months ended September 2004 compared to \$482,000 during the same quarter last year, an increase of 38%. This increase is primarily the result of adding the appropriate infrastructure in our efforts to develop other markets for our products and building our CLIA laboratory. We believe that building our own laboratory will be the best way to both offer flexibility in the services and products we are able to provide to our customers and control costs.

Interest income remained flat at \$15,000 for the three months ended September 30, 2004 compared to the same period in 2003. Interest expense of \$35,000 was incurred during the quarter ended September 30, 2004, compared to \$36,000 in the same period in 2003.

### *Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003*

Revenue for the nine months ended September 30, 2004 was \$2.7 million compared to \$1.3 million for the nine months ended September 30, 2003, a 109% increase. The increase was primarily the result of \$2.6 million of revenue in 2004 from our research agreements with Alticor as compared to \$1.3 million in 2003.

Cost of revenue was \$1.8 million for the nine months ended September 30, 2004, compared to \$893,000 for the same period in 2003. Gross profit margin was 34% for the nine months ended September 30, 2004 compared to 31% for the same period in 2003. The

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increase in cost of revenue is a direct result of the increase in revenue. The improvement in gross profit margin is primarily the result of the timing of recognizing revenue and expenses on research contracts. Revenue is generally recognized ratably over the research contract period whereas the expenses are recognized as incurred. In some instances, research expenses being performed by third parties are not deemed to have been incurred until the attainment of certain milestones. The Company expects that the gross profit margin will return to historical levels over the term of the research contracts.

For the nine months ended September 30, 2004, we had internally-funded research and development expenses of \$1.0 million as compared to \$1.7 million for the same period in 2003, a decrease of 42%. The decrease in R&D expenses reflects a re-allocation of internal resources from internally funded projects to the research projects funded by Alticor that are now reported as cost of revenue.

Selling, general and administrative expenses were \$2.1 million for the nine months ended September 2004 compared to \$1.8 million for the same period last year, an increase of 18%. This increase is primarily the result of adding the appropriate infrastructure in our efforts to develop other markets for our products and building our CLIA laboratory.

Interest income remained flat at \$38,000 for the nine months ended September 30, 2004 compared to the same period in 2003. Interest expense of \$102,000 was incurred during the nine months ended September 30, 2004, compared to \$111,000 for the same period in 2003. The decrease is primarily due to the lower interest rate of the refinancing transaction with Alticor completed in July 2003 offset by a slight increase in the Bank's prime rate over the two periods. We also had an expense of \$210,000 for the nine months ended September 30, 2003 related to the amortization of the value of the warrants issued in connection with promissory notes, which were retired in July 2003.

### **Liquidity and Capital Resources**

As of September 30, 2004, we had cash and cash equivalents of \$5.5 million. Net cash used in operating activities during the nine months ended September 30, 2004 was \$1.1 million as compared to \$3.1 million used during the same period in 2003. Cash was used primarily to fund operations. The reduction in cash used in operations in the 2004 period was primarily due to the increase of \$1.4 million in revenue for the nine months ended September 30, 2004 compared to the same period in 2003. In addition, as of September 30, 2004, our accounts payable amounted to \$563,000, a significant increase over historical balances. This was largely due to amounts of payables related to the commercial lab construction which are expected to be paid during the fourth quarter of 2004. We expect the accounts payable balance to return to historical levels.

Investing activities used cash of \$790,000 during the nine months ended September 30, 2004 compared to \$83,000 during the same period in 2003. During 2004, we used cash to purchase fixed assets and to fund the development of intellectual property. Specifically, we are in the process of building a commercial clinical laboratory to process the samples from the product launches that we anticipate in 2005. As of September 30, 2004, we have spent approximately \$557,000 and have commitments to spend an additional \$301,000. However, we anticipate that we may spend between \$0.9 million and \$1.1 million in total on the laboratory.

Financing activities provided cash of \$2.6 million during the nine months ended September 30, 2004 compared to \$7.5 million during the nine months ended September 30, 2003. During 2004 we received \$2.0 million from an equity milestone payment from Alticor and approximately \$640,000 from the exercise of employee stock options and stock purchases through the employee stock purchase plan. During 2003 we received \$6.9 million in net proceeds from our Stock Purchase Agreement with Alticor and \$570,000 from the issuance of term promissory notes, net of repayments.

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We currently do not have any commitments for any material capital expenditures other than that which has been mentioned above. Our obligations at September 30, 2004 for capital lease payments totaled \$24,000, of which \$6,000 is classified as long-term and \$18,000 is classified as current. These capital lease obligations mature through March 2006 at various interest rates.

On March 5, 2003, we entered into a Stock Purchase Agreement with Alticor pursuant to which Alticor purchased 5,000,000 shares of our Series A Preferred Stock for an aggregate of \$7.0 million in cash. In March 2004, Alticor paid us an additional \$2.0 million without issuing additional shares of Series A Preferred Stock when we achieved the milestones set forth in the Stock Purchase Agreement. The offering was made to Alticor by way of a private placement exempt from registration under the Securities Act. As of September 30, 2004, the Series A Preferred Stock is convertible into an aggregate of 28,160,200 shares of our common stock (reflecting a conversion price of \$0.3196 per share), subject to weighted average anti-dilution adjustments. If all the shares of Series A Preferred Stock had been converted to common stock as of September 30, 2004, the shares issued would represent approximately 54.5% of our outstanding common stock.

Pursuant to the terms of the Stock Purchase Agreement, in March 2003 Alticor also refinanced \$2.0 million of debt we had incurred to Alticor from October 2002 through January 2003. In September 2003, Alticor advanced an additional \$595,000 that we used to repay bridge financing notes issued in August 2002. All of our indebtedness to Alticor carries a variable interest rate equal to 1% above the

prime rate, payable quarterly in cash, matures on December 31, 2007 and is convertible at the option of Alticor into shares of our common stock at a conversion price of two times the then applicable conversion price of the Series A Preferred Stock. As of September 30, 2004, outstanding indebtedness to Alticor would be convertible into 4,060,288 shares of our common stock. Alticor also has agreed to provide a working capital credit line of up to \$1.5 million to initiate selected research agreements with third party entities approved by our board of directors. We have not accessed the credit line as of this date.

Concurrent with the closing of the Stock Purchase Agreement, we entered into a Strategic Alliance Research Agreement with Alticor, governing the terms of developing and validating nutrigenomic and dermagenomic tests and products. Alticor agreed to provide us with a total of \$5.0 million beginning in April 2003 and continuing until March 2005, to conduct certain research projects. Through September 30, 2004, Alticor had paid us approximately \$4.4 million under this research agreement. We will also receive a royalty payment based upon sales of the resulting products. We also entered into a License Agreement with Alticor, granting an exclusive, world-wide license of all of our current and future intellectual property, limited to the field of nutrigenomics and dermagenomics in exchange for royalty payments based upon the sales of these products.

In June 2004, we entered into a research agreement with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. During the first phase of the agreement we are eligible to receive up to \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, we will be eligible to receive, during the second phase of the agreement, an additional \$820,000 in funding over a six-month period beginning on January 1, 2005. As of September 30, 2004, Alticor had paid us approximately \$0.9 million under this research agreement. We will also receive a royalty payment based upon sales of the resulting products.

We anticipate that our existing cash and cash equivalents, together with anticipated revenue and interest income, will be sufficient to conduct operations as planned through mid-2005. Our future cash requirements are anticipated to be substantial. Our cash requirements are expected to arise from the commercial launch of our products, continued research and development efforts, the protection of the intellectual property rights (including preparing and filing of patent applications), as well as operational, administrative, legal and accounting expenses. There is no assurance that we will be able to raise additional capital on terms acceptable to us, if at all. If additional amounts cannot be raised and we are unable to substantially reduce our expenses, or increase our revenue, we would suffer material adverse consequences to our business, financial condition and results of operations and would likely be required to seek other alternatives.

#### **Contractual Obligations**

Contractual Obligations	Total	Payments Due By Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-Term Debt Obligations	\$ 2,595,336	\$	\$	\$ 2,595,336	\$
Capital Lease Obligations	24,228	18,324	5,904		
Operating Lease Obligations	1,529,502	437,000	874,000	218,502	
Total	\$ 4,149,066	\$ 455,324	\$ 879,904	\$ 2,813,838	\$

### Factors That May Affect Our Future Performance

*We have a history of operating losses and expect these losses to continue in the future.*

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from operations of \$5.1 million in 2002, \$3.9 million in 2003 and \$2.2 million through the first nine months of 2004. As of September 30, 2004, our accumulated deficit was \$47.2 million. Our losses result primarily from research and development, general and administrative expenses. We have not generated significant revenue from product sales, and we do not know if we will ever generate sufficient revenue from product sales to cover our operating expenses. We will need to generate significant revenue to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

*The market for genetic susceptibility tests is unproven.*

The market for genetic susceptibility tests is at an early stage of development and may not continue to grow. The general scientific community, including us, has only a limited understanding of the role of genes in predicting disease. When we identify a gene or genetic marker that may predict disease, we conduct clinical trials to confirm the initial scientific discovery and to establish the scientific discovery's clinical utility in the marketplace. The results of these clinical trials could limit or delay our ability to bring the

test to market, reduce the test's acceptance by our customers or cause us to cancel the program, any of which limit or delay sales and cause additional losses. The only genetic susceptibility test we currently market is PST®, and it has produced only minimal revenue to date. The marketplace may never accept our products, and we may never be able to sell our products at a profit. We may not complete development of or commercialize our other genetic susceptibility tests.

The success of our genetic susceptibility tests will depend upon their acceptance as medically useful and cost-effective by patients, physicians, dentists, other members of the medical and dental community and by third-party payors, such as insurance companies and the government. We can achieve broad market acceptance only with substantial education about the benefits and limitations of genetic susceptibility tests. Our tests may not gain market acceptance on a timely basis, if at all. If patients, dentists and physicians do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

***The market for personalized healthcare is unproven.***

The competition in the field of Personalized Health is not well defined due to a lack of an established market and customer base. The concept is new and requires consumers to do things differently, hence may be considered a disruptive technology. Adoption of such technology requires substantial market development and customer prospecting. There are a few companies offering predisposition tests or health risk assessments and product recommendations based upon these assessments. Activities in these areas remain small and the overall market is unproven. While both Alticor and we have done some initial market research regarding the marketability of these products there can be no assurance that these products will be successful upon launch or that they can be sold at sufficient margins to make them profitable to our partners or us. If customers do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

***We rely heavily on third parties to perform sales, marketing and distribution functions on our behalf, which could limit our efforts to successfully market products.***

We have limited experience and capabilities with respect to distributing, marketing and selling genetic susceptibility tests. We have relied and plan to continue to rely significantly on sales, marketing and distribution arrangements with third parties, over which we have limited influence. If these third parties do not successfully market our products, it will reduce our anticipated sales and increase our losses. If we are unable to negotiate acceptable marketing and distribution agreements with future third parties, or if in the future we elect to perform sales, marketing and distribution functions ourselves, we will incur significant costs and face a number of additional risks, including the need to recruit experienced marketing and sales personnel. On March 5, 2003, we signed a strategic alliance with Alticor. As part of this alliance, Alticor will conduct sales, marketing and distribution functions on our behalf. On February 26, 2004, we signed a purchase order agreement with Alticor for a firm minimum order of DNA-based risk assessment tests to be delivered during the first year of product launch. While Alticor has far more experience and success in marketing, selling and distributing products than we do, we could become very dependent upon their success and their failure to successfully market our products could reduce our anticipated sales and increase our losses.

***If we fail to obtain additional capital, or obtain it on unfavorable terms, then we may have to end our research and development programs and other operations.***

We anticipate that our current and anticipated financial resources are adequate to maintain our current and planned operations through mid-2005. If we are not generating sufficient cash or cannot raise additional capital prior to that date, we will be unable to fund our business operations and will be required to seek other strategic alternatives.

Our future capital needs depend on many factors. We will need capital for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Additional financing may not be available when needed, or, if available, it may not be available on favorable terms. If we cannot obtain additional funding on acceptable terms when needed, we may have to discontinue operations, or, at a minimum, curtail one or more of our research and development programs.

***Because a single shareholder has a controlling percentage of our voting power, other stockholders' voting power is limited.***

As of September 30, 2004 a single stockholder owned, or had rights to own approximately 57.8% of our outstanding common stock. Accordingly, this stockholder will be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders' or warrant holders' interests. This ownership concentration may also adversely affect the market price of our common stock. Four of our five directors are individuals chosen by this single stockholder. These directors might pursue

policies in the interest of this single stockholder to the detriment of our other stockholders.

***The Series A Preferred Stock has certain rights which are senior to common shareholder rights and this may reduce the value of the common stock.***

The Series A Preferred Stock, which was issued to Alticor on March 5, 2003, accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. If we declare a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by us or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our common stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our common stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of our assets or surplus funds to the holders of our common stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such share for each share of Series A Preferred Stock then held by them. After receiving this amount, the holders of the Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of our remaining assets.

The preferential treatment accorded the Series A Preferred Stock might reduce the value of the common stock.

***If we are unsuccessful in establishing additional strategic alliances, our ability to develop and market products and services will be damaged.***

Entering into strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We anticipate entering into additional collaborative arrangements with Alticor and other parties in the future. We face significant competition in seeking appropriate collaborators. In addition, these alliance arrangements are complex to negotiate and time-consuming to document. If we fail to maintain existing alliances or establish additional strategic alliances or other alternative arrangements, then our ability to develop and market products and services will be damaged. In addition, the terms of any future strategic alliances may be unfavorable to us or these strategic alliances may be unsuccessful.

***If we fail to obtain an adequate level of reimbursement for our products or services by third-party payors, then our products and services will not be commercially viable.***

The availability and levels of reimbursement by governmental and other third-party payors affect the market for any healthcare service. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. To the extent that our products are sold through the medical channel, our ability to successfully commercialize our existing genetic

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susceptibility test and others that we may develop depends on obtaining adequate reimbursement from third-party payors. The extent of third-party payor reimbursement will likely heavily influence physicians' and dentists' decisions to recommend genetic susceptibility tests, as well as patients' elections to pursue testing. If reimbursement is unavailable or limited in scope or amount, then we cannot sell our products and services profitably. In particular, third-party payors tend to deny reimbursement for services which they determine to be investigational in nature or which are not considered reasonable and necessary for diagnosis or treatment. To date, few third-party payors have agreed to reimburse patients for genetic susceptibility tests, and we do not know if third-party payors will, in the future, provide full reimbursement coverage for these genetic tests. If third-party payors do not provide adequate reimbursement coverage, then individuals may choose to directly pay for the test. If both third-party payors and individuals are unwilling to pay for the tests, then the number of tests we can sell will be significantly decreased, resulting in reduced revenue and additional losses.

***If we fail to obtain patent protection for our products and preserve our trade secrets, then competitors may develop competing products and services, which will decrease our sales and market share.***

Our success will partly depend on our ability to obtain patent protection, in the United States and in other countries, for our products and services. In addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties.

We own exclusive rights in sixteen issued U.S. patents and have a number of additional U.S. patent applications pending. We have also been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent

applications pending. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

Obtain patents;

Obtain licenses to the proprietary rights of others;

Prevent others from infringing on our proprietary rights; and

Protect trade secrets.

Our pending patent applications may not result in issued patents or any issued patents may never afford meaningful protection for our technology or products. Further, others may develop competing products which avoid legally infringing upon, or conflicting with, our patents. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements. The third parties we contract with may breach these agreements, and we might not have adequate remedies for any breach. Additionally, our competitors may discover or independently develop our trade secrets.

***Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our costs or prevent us from developing or marketing our products or services.***

We may not have rights under patents or patent applications that are related to our current or proposed products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop or sell any proposed products or services, with patent rights controlled by third parties, our collaborators or we may seek, or may be required to seek, licenses under third-party patents and patent applications. If this occurs, we will pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may be prohibited from developing or selling our products or services.

If third parties believe our products or services infringe upon their patents, they could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products or services. Any litigation could result in substantial expenses to us and significant diversion of attention by our technical and management personnel. Even if we prevail, the time, cost and diversion of resources of patent litigation would likely damage our business. If the other parties in any patent litigation brought against us are successful, in addition to any liability for damages, we may have to cease the infringing activity or obtain a license.

*Technological changes may cause our products and services to become obsolete.*

Our competitors may develop susceptibility tests that are more effective than our technologies or that make our technologies obsolete. Innovations in the treatment of the diseases in which we have products or product candidates could make our products obsolete. These innovations could prevent us from selling, and significantly reduce or eliminate the markets for, our products.

*We may be prohibited from fully using our net operating loss carryforwards, which could affect our financial performance.*

As a result of the losses incurred since inception, we have not recorded a federal income tax provision and have recorded a valuation allowance against all future tax benefits. As of December 31, 2003, we had net operating loss carryforwards of approximately \$12.8 million for federal and state income tax purposes, expiring in varying amounts through the year 2023. We also had a research tax credit of approximately \$621,000 at December 31, 2003 that expires in varying amounts through the year 2023. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We have experienced two such ownership changes. One change arose in March 2003 and the other was in June 1999. As a result, all of our net operating loss carryforwards will be limited in utilization. The annual limitation may result in the expiration of the carryforwards prior to utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable income, of which there is no assurance.

*We are subject to intense competition from other companies, which may damage our business.*

Our industry is highly competitive. Our competitors in the United States and abroad are numerous and include major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions, including those receiving funding from the Human Genome Project. Many of our competitors have considerably greater financial resources, research and development staffs, facilities, technical personnel, marketing and other resources than we do. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers before we do. If we do not discover disease predisposing genes and commercialize these discoveries before our competitors, then our ability to generate sales and revenue will be reduced or eliminated, and could make our products obsolete. We expect competition to intensify in our industry as technical advances are made and become more widely known.

***We are subject to government regulation which may significantly increase our costs and delay introduction of future products.***

The sale, performance or analyses of our genetic tests do not currently require FDA or other federal regulatory authority approval. Changes in existing regulations could require advance regulatory approval of genetic susceptibility tests, resulting in a substantial curtailment or even prohibition of our activities without regulatory approval. If our genetic tests ever require regulatory approval, on either a state or federal level, then the costs of introduction will increase and marketing and sales of products may be significantly delayed. We anticipate that the testing procedure itself will be performed primarily in our own DNA testing laboratory which will need to be certified under the auspices of the Clinical Laboratory Improvement Act of 1988 ( CLIA ), administered by the Health Care Financing Administration. We anticipate there will also be additional state and local regulations governing the operation of this laboratory. A delay in receiving CLIA certification or any applicable state or local certification would reduce our revenue and increase our net losses.

***We may be subject to product liability claims that are costly to defend and that could limit our ability to use some technologies in the future.***

The design, development, manufacture and use of our genetic susceptibility tests involve an inherent risk of product liability claims and associated adverse publicity. Producers of medical products face substantial liability for damages in the event of product failure or allegations that the product caused harm. We currently maintain product liability insurance, but it is expensive and difficult to obtain, may not be available in the future on economically acceptable terms and may not be adequate to fully protect us against all claims. We may become subject to product liability claims that, even if they are without merit, could result in significant legal defense costs. We could be held liable for damages in excess of the limits of our insurance coverage, and any claim or resulting product recall could create significant adverse publicity.

***Ethical, legal and social issues related to genetic testing may reduce demand for our products.***

Genetic testing has raised issues regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic assessment medical information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios would decrease demand for our products and result in substantial losses.

***Our dependence on key executives and scientists could adversely impact the development and management of our business.***

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Our success substantially depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our development programs and our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and health care companies, as well as universities and nonprofit research organizations in the highly competitive Boston Massachusetts business area. Loss of the services of Dr. Philip R. Reilly, our Chief Executive Officer, Dr. Kenneth Kornman, our President and Chief Scientific Officer, or Mr. Fenel M. Eloi, our Chief Operating Officer and Chief Financial Officer, could delay our research and development programs or otherwise damage our business. We have entered into employment agreements with three-year terms with Dr. Reilly, Dr. Kornman and Mr. Eloi. Each of these employees can terminate his employment upon 30 days notice. We do not maintain key man life insurance on any of our personnel.

*In a circumstance in which Alticor enters a business in competition with our own, our Directors might have a conflict of interest.*

In conjunction with our strategic alliance with Alticor, we have agreed to certain terms for allocating opportunities as permitted under

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Section 122(17) of the Delaware General Corporation Law. This agreement, as set forth in the Purchase Agreement, regulates and defines the conduct of certain of our affairs as they may involve Alticor as our majority stockholder and its affiliates, and the powers, rights, duties and liabilities of us and our officers and directors in connection with corporate opportunities.

Except under certain circumstances, Alticor and its affiliates have the right to engage in the same or similar activities or lines of business or have an interest in the same classes or categories of corporate opportunities as we do. If Alticor or one of our directors appointed by Alticor, and its affiliates acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both Alticor and its affiliates and us, to the fullest extent permitted by law, Alticor and its affiliates will not have a duty to inform us about the corporate opportunity or be liable to us or to you for breach of any fiduciary duty as a stockholder of ours for not informing us of the corporate opportunity, keeping it for its own account, or referring it to another person.

Additionally, except under limited circumstances, if an officer or employee of Alticor who is also one of our directors is offered a corporate opportunity, such opportunity shall not belong to us. In addition, we agreed that such director will have satisfied his duties to us and not be liable to us or to you in connection with such opportunity.

The terms of this agreement will terminate on the date that no person who is a director, officer or employee of ours is also a director, officer, or employee of Alticor or an affiliate.

***We do not expect to pay dividends for the foreseeable future and you should not expect to receive any funds without selling your shares of common stock, which you may only be able to do at a loss.***

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, you should not expect to receive any funds without selling your shares, which you may only be able to do at a loss.

***Our former use of Arthur Andersen LLP as our independent auditors may pose risk to us and will limit your ability to seek potential recoveries from them related to their work.***

On June 15, 2002, Arthur Andersen LLP, our former independent auditor, was convicted on a federal obstruction of justice charge. Some investors, including institutional investors, may choose not to invest in or hold securities of a company whose financial statements were audited by Arthur Andersen, which may serve to, among other things, depress the price of our common stock. In July and August 2002, our board of directors decided to no longer engage Arthur Andersen and engaged Grant Thornton LLP to serve as our independent auditors.

SEC rules require us to present our audited financial statements in various SEC filings, along with Arthur Andersen's consent to our inclusion of its audit report in those filings. The SEC recently has provided regulatory relief designed to allow companies that file reports with the SEC to dispense with the requirement to file a consent of Arthur Andersen in certain circumstances. Notwithstanding the SEC's regulatory relief, the inability of Arthur Andersen to provide its consent or to provide assurance services to us could negatively affect our ability to, among other things, access the public capital markets. Any delay or inability to access the public markets as a result of this situation could have a material adverse impact on our business. Also an investor's ability to seek potential recoveries from Arthur Andersen related to any claims that an

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investor may assert as a result of the work performed by Arthur Andersen will be limited significantly in the absence of a consent and may be further limited by the diminished amount of assets of Arthur Andersen that are or may in the future be available for claims.

### **Effects of Inflation**

We believe that inflation and changing prices over the past three years have not had a significant impact on our net revenue or on our income from continuing operations.

### **Recent Accounting Pronouncements**

On March 31, 2004, the Financial Accounting Standards Board ( FASB ) issued a proposed Statement, *Share-Based Payment*, which addresses the accounting for share-based awards to employees, including employee stock purchase plans. The FASB formally proposed to require companies to recognize the fair value of stock options and other stock-based compensation to employees.

The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB No. 25, *Accounting for Stock Issued to Employees*, and generally would require instead, that such transactions, be accounted for using a fair-value-based method. This Exposure Draft was open for public comment until June 30, 2004. During its deliberations to address the

comment letters, the FASB has preliminarily indicated that the effective date for this statement would be for periods beginning after June 15, 2005.

We currently account for our stock-based compensation plans in accordance with APB No. 25. Therefore, the eventual adoption of this proposed statement, if issued in final form by the FASB, is likely to have a material effect on our consolidated financial statements.

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

We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

#### *Interest Rate Risk*

We are exposed to market risk from changes in interest rates primarily through our financing activities. Interest on our notes payable accrues at a rate equal to the Bank's prime rate of interest plus 1% per annum. Our ability to carry out our business plan or our ability to finance future working capital requirements may be impacted if the cost of carrying debt fluctuates to the point where it becomes a burden on our resources.

#### *Foreign Currency Risk*

Some of our sales occur outside the United States and are transacted in foreign currencies. Accordingly, we are subject to exposure from adverse movements in foreign currency exchange rates. At this time we do not believe this risk is material and we do not currently use derivative financial instruments to manage foreign currency fluctuation risk. However, if foreign sales increase and the risk of foreign currency exchange rate fluctuation increases, we may in the future consider utilizing derivative instruments to mitigate these risks.

### **Item 4. Controls and Procedures**

(a) *Evaluation of Disclosure Controls and Procedures.*

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of September 30, 2004, the Company carried out an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of such date to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act 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 Control Over Financial Reporting.*

There was no change in our internal control over financial reporting that occurred during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings:**

We are not aware of any current or pending litigation to which we are or may be a party that we believe could materially adversely affect our results of operations or financial condition or net cash flows.

**Item 2. Changes in Securities, Use of Proceeds and Issuer of Purchases of Equity Securities:**

Not applicable.

**Item 3. Defaults Upon Senior Securities:**

Not applicable.

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

Not applicable.

**Item 5. Other Information:**

Not applicable.

**Item 6. Exhibits and Reports on Form 8-K:**

(a) Exhibits

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The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Quarterly Report on Form 10-Q.

### **(b) Reports on Form 8-K**

On July 2, 2004, we furnished a Current Report on Form 8-K, dated July 1, 2004, to report under Item 5 that we issued a press release announcing we had signed a Research Agreement with Access Business Group LLC, a subsidiary of Alticor Inc., to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight.

On August 10, 2004, we furnished a Current Report on Form 8-K, dated August 10, 2004, to report under Item 12 that we issued a press release announcing our financial results for our quarter ended June 30, 2004.

**On September 20, 2004, we filed a Current Report on Form 8-K, dated September 14, 2004, to report under Item 5.02 the departure of two directors and the appointment of one director.**

On September 20, 2004, we filed a Current Report on Form 8-K, dated September 14, 2004, to report under Item 5



**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.

INTERLEUKIN GENETICS, INC.

Date: November 3, 2004

By:

/s/ PHILIP R. REILLY  
Philip R. Reilly  
Chairman of the Board and Chief Executive Officer  
(Principal Executive Officer)

Date: November 3, 2004

By:

/s/ FENEL M. ELOI  
Fenel M. Eloi  
Chief Financial Officer, Secretary & Treasurer  
(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

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**Exhibit  
Number**

**Exhibit**

- 
- 10.1\*+ Amendment #1 to Research Agreement by and between the Company and Access Business Group LLC dated June 17, 2004
  - 31.1\* Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
  - 31.2\* Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
  - 32.1\* Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Filed herewith.

+ Confidential treatment requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.