INTERLEUKIN GENETICS INC
Form 10-Q
November 13, 2008
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2008

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

For the transition period from to

Commission File Number: 001-32715

INTERLEUKIN GENETICS, INC.

(Exact name of registrant in its charter)

Delaware	**94-3123681**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
135 Beaver Street, Waltham, MA	**02452**
(Address of principal executive offices)	(Zip Code)

Registrant s Telephone Number: **(781) 398-0700**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-Accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

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

Class	Outstanding at September 30, 2008
Common Stock, par value $0.001 per share	**31,793,254**

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2008 (Unaudited)	December 31, 2007 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,914,848	$ 7,646,468
Accounts receivable from related party	31,259	48,147
Trade accounts receivable, net of allowance for doubtful accounts of $6,696 at September 30, 2008 and December 31, 2007	760,083	942,115
Inventory	831,189	999,392
Deferred tax asset	57,000	41,000
Prepaid expenses and other current assets	264,455	335,386
Total current assets	7,858,834	10,012,508
Fixed assets, net	466,634	578,706
Intangible assets, net	4,967,030	5,741,402
Other assets	53,333	53,333
Total Assets	**$ 13,345,831**	**$ 16,385,949**
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 638,500	$ 836,071
Accrued expenses	1,994,082	1,948,364
Deferred revenue	781,305	1,458,208
State taxes payable		32,500
Commitments for funded research and development projects	22,056	92,056
Due to seller from August 2006 acquisition		1,200,000
Convertible debt		595,336
Total current liabilities	3,435,943	6,162,535
Long Term Debt	4,000,000	
Deferred tax liability		31,000
Total liabilities	7,435,943	6,193,535
Stockholders equity:		
Convertible preferred stock $0.001 par value 6,000,000 shares authorized; 5,000,000 shares of Series A issued and outstanding at September 30, 2008 and December 31, 2007; aggregate liquidation preference of $18,000,000 at September 30, 2008	5,000	5,000
Common stock $0.001 par value 100,000,000 shares authorized; 31,793,254 and 30,832,102 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	31,793	30,832
Additional paid-in capital	85,417,712	84,517,903
Accumulated deficit	(79,544,617)	(74,361,321)
Total stockholders equity	5,909,888	10,192,414
Total liabilities and stockholders equity	**$ 13,345,831**	**$ 16,385,949**

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

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INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Revenue:				
Revenue from related party	$ 533,310	$ 757,904	$ 1,666,949	$ 2,191,228
Revenue from others	1,638,285	1,803,381	5,635,403	5,197,802
Total revenue	2,171,595	2,561,285	7,302,352	7,389,030
Cost of Revenue	1,000,265	1,207,722	3,642,712	3,603,162
Gross Profit	1,171,330	1,353,563	3,659,640	3,785,868
Operating expenses:				
Research and development	933,004	785,942	2,455,230	2,246,340
Selling, general and administrative	1,562,400	1,163,531	5,451,136	4,821,032
Amortization of intangibles	334,955	413,209	996,669	1,236,074
Total operating expenses	2,830,359	2,362,682	8,903,035	8,303,446
Loss from operations	(1,659,029)	(1,009,119)	(5,243,395)	(4,517,578)
Other income (expense):				
Interest income	38,591	108,116	130,498	340,762
Interest expense	(50,411)	(61,187)	(80,899)	(183,036)
Amortization of note discount		(115,469)		(346,406)
Total other income (expense)	(11,820)	(68,540)	49,599	(188,680)
Net loss before income taxes	**(1,670,849)**	**(1,077,659)**	**(5,193,796)**	**(4,706,258)**
Provision for income taxes	29,000	(4,000)	10,500	(12,000)
Net loss	**$ (1,641,849)**	**$ (1,081,659)**	**$ (5,183,296)**	**$ (4,718,258)**
Basic and diluted net loss per common share	**$ (0.05)**	**$ (0.04)**	**$ (0.17)**	**$ (0.17)**
Weighted average common shares outstanding	**31,792,999**	**27,637,303**	**31,204,196**	**27,576,940**

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

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INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

For the Nine Months Ended September 30, 2008
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional		
	Shares	$0.001 par value	Shares	$0.001 par value	Paid-in Capital	Accumulated Deficit	Total
Balance as of December 31, 2007 (Audited)	**5,000,000**	**$ 5,000**	**30,832,102**	**$ 30,832**	**$ 84,517,903**	**$ (74,361,321)**	**$ 10,192,414**
Net loss						(5,183,296)	(5,183,296)
Investment by Alticor:							
Research Funding					168,254		168,254
Common stock issued:							
Employee stock purchase plan			5,620	6	5,572		5,578
Restricted stock awards			12,500	12	(12)		
Conversion of Long-term Debt to Equity			943,032	943	601,843		602,786
Stock-based compensation expense					124,152		124,152
Balance as of September 30, 2008	**5,000,000**	**$ 5,000**	**31,793,254**	**$ 31,793**	**$ 85,417,712**	**$ (79,544,617)**	**$ 5,909,888**

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

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INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	For the Nine Months Ended September 30,	
	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,183,296)	$ (4,718,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,215,884	1,467,625
Amortization of note discount		346,406
Stock-based and other compensation expense	124,152	156,193
Changes in operating assets and liabilities, excluding the effects of the acquisition:		
Accounts receivable, net	198,919	(166,440)
Inventory	168,203	533,233
Prepaid expenses and other current assets	(8,887)	114,411
Accounts payable	(197,571)	179,163
Accrued expenses	(554,283)	(166,563)
State taxes payable	(32,500)	
Deferred revenue	(508,649)	(1,857)
Commitments for funded R&D	(70,000)	(73,500)
Deferred tax provision	32,819	12,000
Net cash used in operating activities	(4,815,209)	(2,317,587)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital additions	(107,143)	(25,137)
Increase in other assets	(222,297)	(114,617)
Settlement of claims relating to the acquisition of the assets and business of the Alan James Group, LLC	(600,000)	17,740
Net cash used in investing activities	(929,440)	(122,014)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of notes payable	4,000,000	
Proceeds from exercises of rights offering, stock warrants, options and employee stock purchase plan	13,029	414,958
Net cash provided by financing activities	4,013,029	414,958
Net decrease in cash and cash equivalents	(1,731,620)	(2,024,643)
Cash and cash equivalents, beginning of period	7,646,468	10,082,919
Cash and cash equivalents, end of period	**$ 5,914,848**	**$ 8,058,276**
Supplemental disclosures of cash flow information:		
Cash paid for income taxes		
Cash paid for interest	$ 30,488	$ 183,036

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

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INTERLEUKIN GENETICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1 Basis of Presentation

The condensed consolidated financial statements include the accounts of Interleukin Genetics, Inc. (the Company), and its wholly-owned subsidiary, as of September 30, 2008 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 condensed 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, 2007. Operating results for the nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for any future interim period or for the entire fiscal year.

Note 2 Settlement of acquisition contingency and issues

On March 25, 2008, pursuant to the terms of a settlement agreement between the Company and former owners of the Alan James Group regarding the acquisition of its assets and business, the Company agreed to pay a total of $1,200,000. This agreement resolved all remaining issues associated with the Company s August 2006 acquisition of that business including contingent consideration and compensation arrangements with the sellers/former management. The $1,200,000 due to sellers is recorded as a current liability at December 31, 2007. The Company applied $600,000 of the settlement cost against the previously accrued separation expense that was recorded on September 30, 2007 and the remaining $600,000 was applied against the $2,130,374 aggregate total of contingent liabilities and amounts due under escrow recorded as part of the original acquisition. The remaining contingent liabilities and amounts due under escrow balance of $1,530,374 was eliminated as no longer due and applied as a reduction in the balances on a pro rata basis of the intangible assets recorded as part of the original acquisition, including the effect of term reduction on the non-compete agreements.

Note 3 Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Interleukin Genetics, Inc., and its wholly owned subsidiary, Interleukin Genetics Laboratory Services, Inc. and AJG Brands, Inc. doing business as the Alan James Group. All intercompany accounts and transactions have been eliminated. Results of AJG Brands, Inc. are included in operations since August 17, 2006, the date of acquisition.

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 disclosures 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. The Company s most critical accounting policies are in areas of its strategic alliance with Alticor, revenue recognition, allowance for sales returns, trade promotions, accounts receivable, inventory, stock-based compensation, income taxes and long-lived assets. These critical accounting policies are more fully discussed in these notes to the consolidated financial statements.

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Revenue Recognition

Revenue from genetic testing services is recognized when there is persuasive evidence of an arrangement, service has been rendered, the sales price is determinable and collectibility is reasonably assured. Service is deemed to be rendered when the results have been reported to the individual who ordered the test. To the extent that tests have been prepaid but results have not yet been reported, recognition of all related revenue is deferred. As of September 30, 2008 and December 31, 2007, the Company has deferred receipts of $0 and $12,250, respectively, for tests that have been prepaid but results have not yet been reported.

Revenue from product sales is recognized when there is persuasive evidence of an arrangement, delivery has occurred and title and risk of loss have transferred to the customer, the sales price is determinable and collectibility is reasonably assured. The Company has no consignment sales. Product revenue is reduced for allowances and adjustments, including returns, discontinued items, discounts, trade promotions and slotting fees.

Revenue from contract research and development is recognized over the term of the contract as the Company performs its obligations under that contract (including revenue from Alticor, a related party).

Allowance for Sales Returns:

The Company s revenue is affected by retailers right to return damaged and outdated products. For product sales for which the Company believes it can reasonably and reliably estimate future returns, it recognizes revenue at the time of sale. For product sales for which the Company cannot reasonably and reliably estimate future returns, such as new products, the Company defers revenue recognition until the return privilege has substantially expired or the amount of future returns can be reasonably and reliably estimated. As of September 30, 2008 and December 31, 2007, the Company has deferred revenue of $77,441 and $93,080, respectively, of revenue for product sales for which it cannot reasonably and reliably estimate future returns.

The Company analyzes sales returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists.* The Company is able to make reasonable and reliable estimates based on its history. The Company also monitors the buying patterns of the end-users of its products based on sales data received. The Company reviews its estimated product returns based on data communicated by its customers. The Company also monitors the levels of inventory at its largest customers to avoid excessive customer stocking of merchandise. The Company believes it has sufficient interaction and knowledge of its customers, industry trends and industry conditions to adjust the accrual for returns when necessary. If the Company loses a major account, it may agree to accept a substantial amount of returns.

Trade Promotions:

The Company uses objective procedures for estimating its allowance for trade promotions. The allowance for trade promotions offered to customers is based on contracted terms or other arrangements agreed in advance.

Accounts Receivable

Trade accounts receivable are stated at their estimated net realizable value, which is generally the invoiced amount less any estimated discount related to payment terms. The Company offers its customers a 2% cash discount if payment is made within 30 days of the invoice date, however, most customers take the discount regardless of when payment occurs. As of September 30, 2008 and December 31, 2007, the Company has reduced trade accounts receivable by $15,286 and $17,851, respectively, for discounts anticipated to have been taken. The Company provides for an allowance for estimated bad debts based on management s estimate of the amount of possible credit losses in the Company s existing accounts receivable. As of September 30, 2008 and December 31, 2007, the Company has provided an allowance for uncollectible accounts of $6,696.

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Inventory

Inventory is stated at the lower of cost or market. Cost is determined using the specific identification method. Management periodically evaluates inventory to identify items that are slow moving or have excess quantities. Management also considers whether certain items are carried at values that exceed the ultimate sales price less selling costs. Where such items are identified, management adjusts the carrying value to the lower of cost or market.

Inventory on hand primarily consisted of the following at September 30, 2008 and December 31, 2007:

	September 30, 2008	December 31, 2007
Raw materials	$ 130,108	$ 93,022
Finished goods	701,081	906,370
Total	$ 831,189	$ 999,392

Stock-Based Compensation

The Company accounts for its stock-based compensation expense in accordance with SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS No. 123R), which requires companies to recognize compensation expense for all share-based payments to employees at fair value. SFAS No. 123R addresses all forms of share-based payment (SBP) awards, including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. SFAS No. 123R requires the Company to expense SBP awards with compensation cost for SBP transactions measured at fair value. SFAS No. 123R applies to new equity awards and to equity awards modified, repurchased or canceled after the effective date, January 1, 2006. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date shall be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated from the pro forma disclosures under SFAS No. 123R. Additionally, the Company records an expense for the amount that the fair market value exceeds the purchase cost for common stock purchased pursuant to its employee stock purchase plan.

Income Taxes

The preparation of its consolidated financial statements requires the Company to estimate its income taxes in each of the jurisdictions in which it operates, including those outside the United States, which may be subject to income tax risks that ordinarily would not be expected in the United States. The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*, which requires the recognition of taxes payable or refundable for the current year and deferred tax liabilities and assets for the future tax consequences of events that have been recognized in the financial statements or tax returns. The measurement of current and deferred tax liabilities and assets is based on provisions of the enacted tax law; the effects of future changes in tax laws or rates are not anticipated. The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining the Company s provision for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. The Company has recorded a valuation allowance against its deferred tax assets of $23.0 million as of September 30, 2008, due to uncertainties related to its ability to utilize these assets. The valuation allowance is based on management s estimates of taxable income by jurisdiction in which the Company operates and the period over which the deferred tax assets will be recoverable. In the event that actual results differ from these estimates or management adjusts these estimates in future periods, the Company may need to adjust its valuation allowance, which could materially impact its financial position and results of operations.

In January 2007, the Company adopted FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (an interpretation of FASB Statement No. 109) (FIN 48). FIN 48 prescribes how a company should recognize, measure,

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present and disclose in its financial statements uncertain tax positions that a company has taken or expects to take on a tax return. At December 31, 2007, the Company reviewed all material tax positions for all years open to statute and for all tax jurisdictions open to statute to determine whether it was more likely than not that the positions taken would be sustained based upon the technical merits of those positions. The implementation of FIN 48 had no impact on the Company s financial statements.

Research and Development

Research and development costs are expensed as incurred.

Basic and Diluted Net Loss per Common Share

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is the same as basic net loss per share for all the periods presented, as the effect of the potential common stock equivalents is anti-dilutive due to the loss in each period. Potential common stock equivalents excluded from the calculation of diluted net loss per share consists of stock options, warrants, convertible preferred stock and convertible debt as described in the table below:

	As of September 30,	
	2008	**2007**
Options outstanding	2,014,073	1,459,475
Warrants outstanding	400,000	400,000
Convertible preferred stock	28,160,200	28,160,200
Convertible debt	704,436	4,060,288
Total	31,278,709	34,079,963

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. During the nine months ended September 30, 2008 and 2007, there were no items other than net loss included in the comprehensive loss.

Fair Value of Financial Instruments

The Company, using available market information, has determined the estimated fair values of financial instruments. The stated values of cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to the short-term nature of these instruments. The

carrying amounts of the Company s capital lease obligations also approximate fair value. The carrying amounts of borrowing agreements approximate their fair value as the rates applicable to the financial instruments reflect changes in overall market interest rates.

Cash Equivalents

Cash equivalents consist of money market funds at a financial institution. These funds are not federally insured.

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over estimated useful lives of three to five years. Leasehold improvements are amortized over the estimated useful life of the asset, or the remaining term of the lease, whichever is shorter.

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Long-Lived Assets

The Company applies the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). SFAS No. 144 requires that the Company evaluate its long-lived assets for impairment whenever events or changes in circumstances indicate that carrying amounts of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. Any write-downs, based on fair value, are to be treated as permanent reductions in the carrying amount of the assets. The Company believes that no impairment exists related to the Company s long-lived assets at September 30, 2008.

Intangible Assets

Purchase accounting requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair market value of the assets purchased and liabilities assumed. The Company accounted for its acquisitions using the purchase method of accounting. Values were assigned to goodwill and intangible assets based on third-party independent valuations, as well as management s forecasts and projections that include assumptions related to future revenue and cash flows generated from the acquired assets.

The Company applies the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires impairment tests be periodically repeated and on an interim basis, if certain conditions exist, with impaired assets written down to fair value. An analysis performed by management on December 31, 2007, determined that the indefinite lived trademarks had a current fair market value of $764,000. Management adjusted the book value of the indefinite lived trademarks to reflect this $236,000 impairment in value at December 31, 2007.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 was issued to provide consistency and comparability in determining fair value measurements and to provide for expanded disclosures about fair value measurements. The definition of fair value maintains the exchange price notion in earlier definitions of fair value but focuses on the exit price of the asset or liability. The exit price is the price that would be received to sell the asset or paid to transfer the liability adjusted for certain inherent risks and restrictions. Expanded disclosures are also required about the use of fair value to measure assets and liabilities. This statement is effective for fiscal years beginning after November 15, 2007 and interim periods with in those fiscal years. FSP No. 157-2 defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008 for non-financial assets and liabilities. The Company adopted this statement for its financial assets and liabilities on January 1, 2008. The adoption of SFAS 157 had no material impact on the Company s financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 115*, which is effective for fiscal years beginning after November 15, 2007. The statement permits entities to choose to measure many financial instruments and certain other items at fair value. The Company adopted SFAS 159 on January 1, 2008. The Company has not elected to account for any of its assets or liabilities using the fair value option under SFAS 159 and accordingly, the adoption of SFAS 159 did not have a impact on the Company s financial position or results of operations.

In July 2007, the Emerging Issues Task Force (EITF) issued EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The Company adopted EITF 07-3 on January 1, 2008. The adoption of EITF 07-3 did not have a material effect on the Company s financial position or results of operations.

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In December 2007, the FASB completed the second phase of its business combination project and issued the following two accounting standards:

i. Statement No. 141(R), Business Combinations; and

ii. Statement No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51.

These statements dramatically change the way companies account for business combinations and noncontrolling interests. Compared with their predecessors, Statements 141(R) and 160 will require:

- More assets acquired and liabilities assumed to be measured at fair value as of the acquisition date;
- Liabilities related to contingent consideration to be remeasured at fair value in each subsequent reporting period;
- An acquirer in preacquisition periods to expense all acquisition related costs; and
- Noncontrolling interests in subsidiaries initially to be measured at fair value and classified as a separate component of equity.

Statements 141(R) and 160 should both be applied prospectively for fiscal years beginning on or after December 15, 2008. However, Statement 160 requires entities to apply the presentation and disclosure requirements retrospectively to comparative financial statements if presented. Both standards prohibit early adoption. The Company is currently assessing the impact these new standards will have on its consolidated financial statements.

In December 2007, the FASB ratified a consensus opinion reached by the EITF on EITF Issue 07-1, Accounting for Collaborative Arrangements (EITF 07-1). The guidance in EITF 07-1 defines collaborative arrangements and establishes presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement). The consensus in EITF 07-1 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. The consensus requires retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective application is impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. The Company intends to adopt EITF 07-1 effective January 1, 2009 and retrospectively apply the requirements of this consensus to its collaborative arrangements in existence on that date. The Company is evaluating the impact of EITF 07-1 will have on its financial statements. The Company currently does not believe that the adoption of EITF 07-1 will have a significant effect on its financial statements.

In December 2007, the SEC staff issued Staff Accounting Bulletin (SAB) 110, Share-Based Payment (SAB 110) which amends SAB 107 to permit public companies, under certain circumstances, to use the simplified method in SAB 107 for employee option grants after December 31, 2007. Use of the simplified method after December 2007 is permitted only for companies whose historical data about their employees exercise behavior does not provide a reasonable basis for estimating the expected term of the options. The Company currently uses the simplified method to estimate the expected term for employee option grants as adequate historical experience is not available to provide a reasonable estimate. SAB 110 is effective for employee options granted after December 31, 2007. The Company adopted SAB 110 effective January 1, 2008 and will continue applying the simplified method until enough historical experience is readily available to provide a reasonable estimate of the expected term for employee option grants.

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In April 2008, the FASB issued FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets (SFAS 142). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We are currently evaluating the potential impact that the adoption of FSP 142-3 may have on our consolidated financial statements.

Note 4 Strategic Alliance with Alticor Inc.

On February 25, 2008, the Company entered into research agreement (RA8), effective January 1, 2008, to expand the research being performed under its current agreements with Alticor through 2008. The Company will receive $1,200,000 during 2008 under the research agreement, on a time and materials basis. Additionally, in 2008 the Company will recognize as revenue approximately $800,000 of previously deferred revenue. In addition to the $800,000 of deferred revenue that will be recognized under RA8, $168,254 of funds previously paid to the Company by Alticor under research agreement 3 (RA3) and research agreement 4 (RA4), for which no work has been performed, will not need to be repaid to Alticor by the Company. Since the Company performed no prior services relating to the $168,254 received from Alticor, and the Company is not required to perform any future services relating to these funds, the Company has determined that the funds should be classified as additional paid-in capital and are recorded as such on the Company s balance sheet as of September 30, 2008.

Note 5 Debt

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

- $2,000,000 refinancing of notes previously held by Alticor, extending the maturity date to December 31, 2007 and reducing the interest rate;

- $595,336 refinancing on July 1, 2003 of bridge financing notes previously held by third parties, extending the maturity date to September 30, 2008 and reducing the interest rate; and

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

The credit facilities bore interest at 1% over the prime rate (5.0% at September 30, 2008), were collateralized by a security interest in the Company s intellectual property (except intellectual property related to periodontal disease and sepsis), and were convertible at the election of Alticor into shares of common stock at a stated conversion price equal to $0.6392 per share. At September 30, 2008 there was no outstanding borrowing under these three credit facilities and the credit facilities had all expired.

On August 17, 2006, a new credit facility with Alticor was extended to provide the Company with access to an additional $14,400,000 of working capital borrowings at any time prior to August 17, 2008. Any amounts borrowed will bear interest at prime, require quarterly interest payments and will mature on August 16, 2011. The principal amount of any borrowing under this credit facility is convertible at Alticor s election into a maximum of 2,533,234 shares of common stock, reflecting a conversion price of $5.6783 per share. As a condition of this financing, the Company initiated a rights offering of 2,533,234 shares of its common stock to existing stockholders (other than Alticor) at a per share price of $5.6783. The proceeds received from the rights offering reduced the availability under the credit facility. As a result of the rights offering, the availability under the credit facility has been reduced by $68,208, leaving approximately $14,300,000 available. On

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June 10, 2008, the Company borrowed $4,000,000 under the credit facility which is the amount outstanding at September 30, 2008 leaving $10,300,000 of available credit. On August 12, 2008, this credit facility was extended to permit borrowing at any time prior to March 31, 2009.

On December 17, 2007, pursuant to the terms of the notes, Pyxis Innovations Inc., an affiliate of Alticor, converted the indebtedness due on December 31, 2007, representing an aggregate principal amount of $2,000,000 and accrued interest of $39,679, into 3,190,987 shares of the Company s common stock.

On June 11, 2008, pursuant to the terms of the notes, Pyxis Innovations Inc., an affiliate of Alticor, converted the indebtedness due on June 30, 2008, representing an aggregate principal amount of $595,336 and accrued interest of $7,450, into 943,032 shares of the Company s common stock.

Note 6 Commitments and Contingencies

Operating Leases

The Company leases its offices and laboratory space under non-cancelable operating leases that expire at various dates through September 2009. The Company also leases certain office equipment under lease obligations, all of which are classified as operating leases. Future minimum lease commitments under lease agreements with initial or remaining terms of one year or more at September 30, 2008, are as follows:

Year Ending December 31,		
2008	$	143,499
2009		181,997
2010		9,090
2011		5,945
2012		
	$	340,531

Rent expense was $149,070 and $147,633 for the quarter ended September 30, 2008 and 2007, respectively.

Acquisition of Databases

In connection with the research agreement with Alticor dated March 5, 2003, the Company is obligated to purchase two clinical databases. As of September 30, 2004, the Company determined that this obligation met the criteria for accrual 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 charged research and development expenses of $450,000 at that time. As of September 30, 2008 and 2007, the Company had cumulative expenditures of $427,944 and $357,944, respectively, associated with the acquisition of these 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.

Sponsored Research Agreements

In connection with the research agreement with Alticor dated March 5, 2005, the Company entered into a sponsored research agreement with Yonsei University to conduct a clinical study. The sponsored research agreement was originally for an amount of $499,882. This amount has been renegotiated to $412,288 and is payable upon achievement of certain milestones. As of September 30, 2008, Yonsei University had achieved milestones valued at $316,000. The remaining commitment on this agreement is $96,288. At September 30, 2008, Yonsei University had completed the other milestones associated with this sponsored research agreement , resulting in the balance of $96,288 being paid on October 20, 2008. This amount will be reflected as research and development expense in the fourth quarter of 2008.

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In connection with the research agreements with Alticor dated March 5, 2005 and March 29, 2007, the Company entered into a sponsored research agreement with SOGO Clinical Pharmacology Co., LTD (SOGO) to conduct a clinical study. The sponsored research agreement is for an amount of ¥26,346,600, or approximately $224,000 (based on the exchange rate on March 30, 2007 of 117.56 ¥ to 1 US$) and was payable upon achievement of certain milestones. As of December 31, 2007, SOGO had achieved milestones valued at ¥26,346,600 or $232,131 based on actual payment in U.S. dollars.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on its financial condition, results of operations or cash flows.

Note 7 Capital Stock

Authorized Preferred and Common Stock

At September 30, 2008, the Company had authorized 6,000,000 shares of $0.001 par value Series A Preferred Stock, of which 5,000,000 were issued and outstanding. At September 30, 2008, the Company had authorized 100,000,000 shares of $0.001 par value common stock of which 66,835,988 shares were outstanding or reserved for issuance. Of those, 31,793,254 shares were outstanding; 28,160,200 shares were reserved for the conversion of Series A Preferred to common stock; 704,436 shares were reserved for the conversion of $4M of debt, 3,533,001 shares were reserved for the exercise of authorized and outstanding stock options; 400,000 shares were reserved for the exercise of outstanding warrants to purchase common stock; 428,311 shares were reserved for the exercise of rights held under the Employee Stock Purchase Plan; 1,816,786 shares were reserved for the issuance upon the conversion of convertible notes which may be issued under our remaining credit facility with Alticor.

Series A Preferred