DURECT CORP
Form 10-Q
August 02, 2016
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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 EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number 000-31615

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3297098**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10260 Bubb Road

Cupertino, California 95014

(Address of principal executive offices, including zip code)

(408) 777-1417

(Registrant s telephone number, including area code)

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 ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

As of July 25, 2016, there were 137,410,381 shares of the registrant s Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	June 30, 2016 (unaudited)	December 31, 2015 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,036	$ 3,583
Short-term investments	24,523	25,457
Short-term restricted investments	100	
Accounts receivable (net of allowances of $148 at June 30, 2016 and $161 at December 31, 2015)	1,855	2,222
Inventories	4,157	3,917
Prepaid expenses and other current assets	2,602	3,142
Total current assets	41,273	38,321
Property and equipment (net of accumulated depreciation of $21,170 and $20,971 at June 30, 2016 and December 31, 2015, respectively)	1,382	1,566
Goodwill	6,399	6,399
Long-term investments	1,050	
Long-term restricted investments	150	250
Other long-term assets	236	236
Total assets	$ 50,490	$ 46,772
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,317	$ 1,286
Accrued liabilities	4,770	4,970
Contract research liabilities	569	575
Deferred revenue, current portion	1,033	616
Total current liabilities	7,689	7,447
Deferred revenue, non-current portion	2,097	2,269
Long-term debt, net	19,752	19,684
Other long-term liabilities	1,790	2,489
Commitments and contingencies		

Stockholders equity:		
Common stock	14	12
Additional paid-in capital	441,572	420,453
Accumulated other comprehensive income (loss)	10	(14)
Accumulated deficit	(422,434)	(405,568)
Stockholders equity	19,162	14,883
Total liabilities and stockholders equity	$ 50,490	$ 46,772

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Collaborative research and development and other revenue (see Note 2)	$ 371	$ 1,778	$ 790	$ 3,516
Product revenue, net	2,786	2,663	5,975	5,698
Total revenues	3,157	4,441	6,765	9,214
Operating expenses:				
Cost of product revenues	913	1,022	2,155	2,028
Research and development	7,852	5,638	14,477	11,005
Selling, general and administrative	2,888	2,724	5,950	5,544
Total operating expenses	11,653	9,384	22,582	18,577
Loss from operations	(8,496)	(4,943)	(15,817)	(9,363)
Other income (expense):				
Interest and other income	40	23	67	151
Interest expense	(558)	(558)	(1,116)	(1,119)
Net other expense	(518)	(535)	(1,049)	(968)
Net loss	$ (9,014)	$ (5,478)	$ (16,866)	$ (10,331)
Net change in unrealized gain (loss) on available-for-sale securities, net of reclassification adjustments and taxes	7	(4)	24	(89)
Total comprehensive loss	$ (9,007)	$ (5,482)	$ (16,842)	$ (10,420)
Net loss per share				
Basic	$ (0.07)	$ (0.05)	$ (0.13)	$ (0.09)
Diluted	$ (0.07)	$ (0.05)	$ (0.13)	$ (0.09)
Weighted-average shares used in computing net loss per share				
Basic	132,812	118,804	127,480	116,313

Diluted	132,812	118,804	127,480	116,313

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (16,866)	$ (10,331)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	206	260
Stock-based compensation	1,407	1,274
Amortization of debt issuance costs	68	37
Realized gain from sale of marketable equity security, net of tax		(117)
Net amortization/accretion on investment	(107)	(146)
Changes in assets and liabilities:		
Accounts receivable	367	221
Inventories	(241)	(288)
Prepaid expenses and other assets	540	(137)
Accounts payable	31	(367)
Accrued and other liabilities	257	(24)
Contract research liabilities	(6)	46
Deferred revenue	245	(31)
Total adjustments	2,767	728
Net cash used in operating activities	(14,099)	(9,603)
Cash flows from investing activities		
Purchases of property and equipment	(22)	(53)
Purchases of available-for-sale securities	(18,646)	(17,561)
Proceeds from maturities of available-for-sale securities	18,661	17,871
Proceeds from sale of marketable equity security		178
Net cash (used in) provided by investing activities	(7)	435
Cash flows from financing activities		
Payments on equipment financing obligations	(12)	(10)
Net proceeds from issuances of common stock	18,571	12,488
Net cash provided by financing activities	18,559	12,478

Net increase in cash and cash equivalents	4,453	3,310
Cash and cash equivalents, beginning of the period	3,583	2,680
Cash and cash equivalents, end of the period	$ 8,036	$ 5,990

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

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DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Nature of Operations

DURECT Corporation (the Company) was incorporated in the state of Delaware on February 6, 1998. The Company is a biopharmaceutical company with research and development programs broadly falling into two categories: (i) new chemical entities derived from our Epigenomics Regulator Program, in which we attempt to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) Drug Delivery Programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve in some manner through a new formulation. The Company has several products under development by itself and with third party collaborators. The Company also manufactures and sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, the Company conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

Basis of Presentation

The accompanying unaudited financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore do not include all the information and footnotes necessary for a complete presentation of the Company s results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at June 30, 2016, the operating results and comprehensive loss for the three and six months ended June 30, 2016 and 2015, and cash flows for the six months ended June 30, 2016 and 2015. The balance sheet as of December 31, 2015 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto, included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2015 filed with the SEC.

The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventories, in part, include certain excipients that are sold to a customer and included in products awaiting regulatory approval. These inventories are capitalized based on management s judgment of probable sale prior to their expiration date which in turn is primarily based on non-binding forecasts from our customers as well as management s internal estimates. The valuation of inventory requires management to estimate the value of inventory that may become expired prior to use. The Company may be required to expense previously capitalized inventory costs upon a change in management s judgment, due to, among other potential factors, a denial or delay of approval of a customer s product

by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable. In addition, these circumstances may cause the Company to record a liability related to minimum purchase agreements that the Company has in place for raw materials. In 2014, the Company recorded charges to cost of goods sold of approximately $1.6 million, of which approximately $1.1 million related to the write-down of the cost basis of inventory and $500,000 related to the accrual of a liability for the minimum purchase commitment for the excipients. As of June 30, 2016, the remaining carrying value of the excipients in the Company s inventory was $1.2 million. In addition, the Company has remaining unrecorded future purchase commitments totaling $1.5 million through 2018. In the event that management determines that the Company will not utilize all of these materials, there could be a potential write-off related to this inventory and a reserve for future purchase commitments.

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The Company s inventories consisted of the following (in thousands):

	June 30, 2016 (unaudited)	December 31, 2015
Raw materials	$ 1,159	$ 1,168
Work in process	1,589	1,412
Finished goods	1,409	1,337
Total inventories	$ 4,157	$ 3,917

Revenue Recognition

Revenue from the sale of products is recognized when there is persuasive evidence that an arrangement exists, the product is shipped and title transfers to customers, provided no continuing obligation on the Company s part exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. The Company enters into license and collaboration agreements under which it may receive upfront license fees, research funding and contingent milestone payments and royalties. The Company s deliverables under these arrangements typically consist of granting licenses to intellectual property rights and providing research and development services. The accounting standards contain a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated as a package and should be evaluated as a single agreement.

Comprehensive Income (Loss)

Components of other comprehensive income (loss) are comprised entirely of unrealized gains and losses on the Company s available-for-sale securities and marketable equity security for all periods presented. Total comprehensive loss has been disclosed in the Company s Condensed Statements of Comprehensive Loss.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed using the weighted-average number of common shares outstanding and common stock equivalents (i.e., options to purchase common stock) outstanding during the period, if dilutive, using the treasury stock method for options.

Options to purchase approximately 20.8 million and 20.6 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2016, respectively, as the effect would be anti-dilutive. Options to purchase approximately 11.5 million and 17.1 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2015, respectively, as the effect would be anti-dilutive.

Recent Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross share compensation

expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. Some of the areas of simplification apply only to nonpublic entities. For public business entities, the amendments in ASU 2016-09 are effective for annual periods beginning after 15 December 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 2017, and interim periods within annual periods beginning after 15 December 2018. Early adoption is permitted for any entity in any interim or annual period for which financial statements haven t been issued or made available for issuance. If an entity early adopts the amendments in an interim period, any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the impact that ASU 2016-09 will have on its financial statements.

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, *Leases* (Topic 842), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). For lessees, leases will continue to be classified as either operating or financing in the income statement. This ASU becomes effective for the Company in the first quarter of

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fiscal year 2019 and early adoption is permitted. This ASU is required to be applied with a modified retrospective approach and requires application of the new standard at the beginning of the earliest comparative period presented. The Company is currently evaluating the impact that ASU 2016-02 will have on its financial statements.

In May 2014, the FASB issued guidance codified in ASC 606, Revenue Recognition Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition. The core principle of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The guidance provides companies with two implementation methods. Companies can choose to apply the standard retrospectively to each prior reporting period presented (full retrospective application) o 19,390 Prepaid expenses and other current assets (47,974) (26,209)Accounts payable 386,543 (10,198)Accrued expenses 43,058 12,184 Deferred revenue 329,613 146,098 Net cash used in operating activities (1,525,190) (2,216,662)CASH FLOWS FROM INVESTING ACTIVITIES: Capital additions (10,247) (5,000)Net cash used in investing activities (10,247) (5,000)CASH FLOWS FROM FINANCING ACTIVITIES: Proceeds from issuance of notes payable — 1,316,255 Proceeds from private placement of preferred stock — 3,000,000 Proceeds from private placement of common stock 12,000,000 — Private placement offering costs (859,206) — Proceeds from exercises of employee stock options 520 — Proceeds from employee stock purchase plan 12,839 8,810 Net cash provided by financing activities 11,154,153 4,325,065 Net increase in cash and cash equivalents 9,618,716 2,103,403 Cash and cash equivalents, beginning of period 1,225,426 1,728,222 Cash and cash equivalents, end of period $10,844,142 $3,831,625 Supplemental disclosures of cash flow information: Cash paid for interest $291,914 $204,884 Supplemental disclosures of non-cash financing activities: Warrants issued in connection with private placements $— $104,907 Conversion of debt to common stock $14,316,255 $—

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

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INTERLEUKIN GENETICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2013

(UNAUDITED)

Note 1—Basis of Presentation

Interleukin Genetics, Inc. (“the Company”) develops genetic tests for sale into the emerging personalized health market and performs testing services that can help individuals improve and maintain their health through preventive or therapeutic measures. The Company’s principal operations and markets are located in the United States.

The accompanying condensed financial statements include the accounts of the Company as of June 30, 2013 and December 31, 2012 and for the six months ended June 30, 2013 and 2012.

The financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial reporting. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. These unaudited condensed 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, 2012. Operating results are not necessarily indicative of the results that may be expected for any future interim period or for the entire fiscal year.

For information regarding our critical accounting policies and estimates, please refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates” contained in our Annual Report on Form 10-K for the year ended December 31, 2012 and Note 3 to our condensed financial statements contained herein.

Note 2—Operating Matters and Liquidity

The Company has experienced net operating losses since its inception through June 30, 2013. The Company had net losses of $5.1 million and $5.0 million for the years ended December 31, 2012 and 2011, respectively, and $3.0 million for the six months ended June 30, 2013, contributing to an accumulated deficit of $110.7 million as of June 30, 2013.

The Company continues to take steps to reduce operating costs, including genetic test processing costs as well as general and administrative expenses. Cost savings are achieved through test process improvements, reductions in personnel and the subleasing of underutilized rental space. Management believes that the current laboratory space is adequate to process high volumes of genetic tests.

As more fully discussed in Note 8 herein, on May 17, 2013, the Company entered into a Common Stock Purchase Agreement with various accredited investors, pursuant to which the Company sold an aggregate of 43,715,847 shares of its common stock in a private placement transaction, at a price of $0.2745 per share for gross proceeds of $12,000,000. The investors also received warrants to purchase up to an aggregate of 32,786,885 shares of common stock at an exercise price of $0.2745 per share. The warrants are exercisable as to 63% of the shares immediately and as to 37% of the shares following receipt of shareholder approval of an increase in the number of authorized shares of common stock from 150,000,000 to 300,000,000, and have a term of seven years from the date they become exercisable.

The Company’s financial statements have been prepared assuming that it will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company expects to incur additional losses in 2013 and, accordingly, is dependent on the recent financing and potential revenue to fund its operations in the commercial launch of the PST® test with Renaissance Health Services Corporation (“RHSC”), the parent corporation of eight Delta Dental member companies operating in their eight respective states. The Company currently believes RHSC may begin offering dental plans that incorporate our genetic PST® test for plan years beginning January 1, 2014. The timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of such plans, which timing is very uncertain at this time, and is contingent upon a number of factors, including RHSC’s affiliates’ ability to develop such plans and to develop a viable market for such plans. The Company expects to have the cash resources necessary, for at least the next twelve months, to support the launch of the PST genetic test in dental offices in collaboration with RHSC in 2014.

Note 3—Significant Accounting Policies

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 collectability 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 June 30, 2013 and December 31, 2012, the Company had deferred genetic test revenue of $2.0 million and $1.6 million, respectively. Included in deferred revenue at June 30, 2013 are $694,000 in customer payments in excess of one year old. Management continues to evaluate steps it may take in resolving these older payments.

Sales Commission

The Company accounts for sales commissions due to Amway Global under the Merchant Channel and Partner Agreement in accordance with SEC Staff Accounting Bulletin (“SAB”) 104. Commissions are recorded as an expense at the time they become due which is at the point of sale. The cost of commissions was $237,000 and $452,000 for the six months ended June 30, 2013 and 2012, respectively.

Accounts Receivable

Accounts receivable is stated at estimated net realizable value, which is generally the invoiced amount less any estimated discount related to payment terms. The Company offers its commercial genetic test customers a 2% cash discount if payment is made by bank wire transfer within 10 days of the invoice date. No accounts receivable reserve is required at June 30, 2013 as all accounts receivable are expected to be collected.

Inventory

Inventory is carried at lower of cost (first-in, first-out method) or market and no inventory reserve is deemed necessary at June 30, 2013. As the Company does not manufacture any products, no overhead costs are included in inventory. When a kit is sold, the corresponding cost of the kit is recorded as cost of goods sold and removed from inventory.

Inventory consisted of the following at June 30, 2013 and December 31, 2012:

	June 30, 2013	December 31, 2012
Raw materials	$ 98,487	$ 154,485
Finished goods	10,549	3,753
Total inventory, net	$ 109,036	$ 158,238

Income Taxes

The Company accounts for income taxes in accordance with FASB ASC 740, *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 (benefit) for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. The Company has recorded a full valuation allowance against its deferred tax assets of approximately $27.6 million as of June 30, 2013, 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.

Due to changes in Massachusetts corporate income tax regulations enacted in 2009, the Company began filing a combined tax return with certain Alticor affiliated entities, referred to herein as “the unitary group”. The law requires corporations with net operating loss carryforwards to go back to each year in which the loss was generated and recompute the loss as if it occurred on a consolidated basis. The Company was required to include data from the newly formed unitary group as if the unitary group was in place during the loss years. As a result, the losses generated by the Company were significantly reduced through this required computation. Due to a change in common ownership, the Company is no longer qualified to join in a combined filing of the unitary group as of June 29, 2012. Accordingly, the Company will cease filing combined Massachusetts tax returns with the unitary group. The Company estimates that the combined and separate filings will have no impact on the Company's financial condition, results of operations and cash flows.

On January 2, 2013, President Obama signed The American Taxpayer Relief Act of 2012 (H.R. 8) legislation which extended many of the tax provisions that expired in 2011 or 2012. For financial reporting purposes, the tax impact of this legislation is taken into account in the quarter in which the legislation is enacted by Congress and signed into law by the President. Since President Obama signed the bill on January 2, 2013, the financial reporting for these legislative changes occurred in the 1st quarter, 2013. Therefore, for 2012, no deferred tax asset with respect to the federal R&D tax credit was recorded. In the 1st quarter 2013, the full deferred tax asset for the 2012 federal R&D tax credit has been recorded as a discrete item. The total impact to 2013 is a deferred tax asset of approximately $60,000 which is fully reserved.

As a result of the Company’s change in its capital structure during the quarter ending June 30, 2013, the Company may have undergone an IRC section 382 ownership change which would limit its ability to realize the benefit of its tax attributes (i.e., federal/state net operating losses and research and development credits) during their respective carry forward periods. Furthermore, pursuant to the change in capital structure, the Company realized cancellation of indebtedness income under IRC section 108(e)(8), which reduced the Company’s federal net operating loss carry-forward pursuant to IRC section 108(b)(2)(A), due to the fact that the Company’s liabilities exceeded the fair market value of its assets. Accordingly, the Company had a reduction in its deferred tax asset and a corresponding reduction in its valuation allowance for the quarter ending June 30, 2013. The cancellation of indebtedness income resulted from a shareholder’s conversion of debt of approximately $14.3 million into common stock of the Company prior to an additional investment by an unrelated investor.

The Company reviews its recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. The Company reviews all material tax positions for all years open to statute to determine whether it is more likely than not that the positions taken would be sustained based on the technical merits of those positions. The Company did not recognize any adjustments for uncertain tax positions as of and during the six months ended June 30, 2013. However, if the Company incurred interest and penalties they would be recorded in general and administrative expenses.

Research and Development

Research and development costs are expensed as incurred.

Basic and Diluted Net Loss per Common Share

The Company applies the provisions of FASB ASC 260, *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 are as follows:

	As of June 30,	
	2013	2012
Options outstanding	2,417,250	2,100,267
Warrants outstanding	22,842,891	2,587,158
Convertible preferred stock	—	39,089,161
Convertible debt	—	2,521,222
Total	25,260,141	46,297,808

Warrants outstanding does not include 12,131,152 shares. See Notes 8 and 11 for additional information related to these shares.

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 fair value of warrants is calculated using the Black-Scholes pricing model.

Cash and Cash Equivalents

The Company maintains its cash and cash equivalents with domestic financial institutions that the Company believes to be of high credit standing. Cash and cash equivalents are available on demand and are generally in excess of FDIC insurance limits.

Recent Accounting Pronouncements

No recently issued updates or other guidance issued by the FASB through the issuance of these financial statements are expected to have a material impact on the Company’s financial reporting.

Note 4—Related Party Transactions

Since March 2003, the Company has maintained a broad strategic alliance with several affiliates of the Alticor Inc. family of companies, a related party, to develop and market novel nutritional and skin care products. The alliance initially included 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.

On October 20, 2009, the Company entered into a Merchant Network and Channel Partner Agreement with Amway Corp., d/b/a/ Amway Global ("Amway Global"), a subsidiary of Alticor Inc. Pursuant to this Agreement, Amway Global sells the Company's Inherent Health® brand of genetic tests through its e-commerce website via a hyperlink to our e-commerce site. We paid Amway Global $237,000 and $452,000 in commissions for the six months ended June 30, 2013 and 2012, respectively, representing a percentage of net sales to their customers. The Company expenses commissions owed to Amway Global at the point of sale with the customer.

On September 14, 2012, the Company received a purchase order from Access Business Group, LLC ("ABG"), an affiliate of Pyxis Innovations, Inc. ("Pyxis"), the Company's largest stockholder and a subsidiary of Alticor. The order consists of kits of the Company's Weight Management genetic test to be included in a promotional product bundle to be offered by ABG to the Amway sales channel in 2013. The total amount of the order was $1.0 million. The Company shipped $0.5 million in December 2012 and the balance in the first quarter of 2013. ABG placed an additional order for $327,000 which is reflected in accounts receivable from related party at June 30, 2013. All other amounts have been paid on this order. During the six months ended June 30, 2013, approximately 49% of our revenue came from tests processed through this program.

On September 21, 2012, the Company entered into a License Agreement with Access Business Group International LLC ("ABGI"), an affiliate of Pyxis. Pursuant to the License Agreement, the Company has granted ABGI and its affiliates a non-exclusive license to use the technology related to Interleukin's Weight Management genetic test and to sell the Weight Management test in Europe, Russia and South Africa (the "Territories"). ABGI, or a laboratory designated by ABGI, will be responsible for processing the tests, and the Company will receive a royalty for each test sold, which royalty will increase if certain pending patent applications are issued. The License Agreement has an initial term of five years from the date of first commercial sale of the Weight Management test under the agreement. Thereafter, the term will automatically renew for additional one-year periods unless at least 60 days prior notice is delivered by either party. To date, no license fees have been earned from this agreement.

In connection with the execution of the License Agreement, the Company and ABGI also entered into a Professional Services Agreement (the "PSA") pursuant to which the Company has agreed to provide services to ABGI in connection with its sale and processing of the tests within the Territories. Services will be provided pursuant to a statement of work to be entered into from time to time between the parties. Such statements of work will also specify the fees to be paid by ABGI to Interleukin for such services. The PSA has no set term and may be terminated by either party, subject to certain conditions. To date, the Company has earned $5,250 in fees from this agreement.

During the six months ended June 30, 2013 and 2012, approximately 38% and 64%, respectively, of our revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor.

On February 25, 2013, the Company entered into a Preferred Participation Agreement with RHSC, for itself and on behalf of certain of its affiliates and subsidiaries. RHSC is a related party through its affiliation with Delta Dental of Michigan, Inc. (“DDMI”), a stockholder of the Company. Pursuant to this agreement, affiliates of RHSC have agreed to reimburse the Company a fixed price for each PST® genetic test that the Company may process for a customer of affiliates of RHSC. In addition, if during the term of the agreement the Company offers the PST® test to any other person or party for a lower price, such lower price shall then be applicable to tests processed for a customer of such affiliates of RHSC for the remainder of the term of the agreement. The pricing arrangement is subject to the satisfaction of certain milestones, including that (1) within a specified timeframe, RHSC affiliates must develop and offer dental benefit plans for which a significant portion of such affiliate's clients are eligible that provides for use of the PST® test and reimbursement of the test at the agreed upon price (each such plan, hereinafter referred to as a “Reimbursed Dental Plan”) and (2) prior to a specified date, RHSC affiliates shall have sold policies for Reimbursed Dental Plans for the year beginning January 1, 2014. The Company agreed that for a one year period beginning on the date on which RHSC affiliates first offer a Reimbursed Dental Plan, it will make the PST® test available solely to RHSC affiliates and not to any other third party or person. This agreement has a term of three years beginning on February 25, 2013, but may be terminated earlier (1) upon the mutual written agreement of the Company and RHSC, (2) if either party becomes the subject of bankruptcy, insolvency, liquidation or other similar proceedings, or (3) in the event of an uncured breach of the Agreement by either party.

The timing of any revenues that the Company may receive under this agreement is dependent upon the timing of the offering of Reimbursed Dental Plans, which timing is very uncertain at this time. The Company does not expect to receive any significant revenues under this agreement until the first quarter of 2014 at the earliest, and the timing of any such revenues may be substantially later.

Note 5—Convertible Debt

On August 17, 2006, our credit facility with Pyxis was amended to provide the Company with access to approximately $14.3 million of additional working capital borrowings. Any amounts borrowed thereunder accrued interest at the prime rate and required quarterly interest payments. The principal amount of any borrowing under this credit facility was convertible at Pyxis’ election into a maximum of 2,521,222 shares of common stock, reflecting a conversion price of $5.6783 per share.

This credit facility had been modified several times, including on November 29, 2012, to extend the due date to March 31, 2014.

Immediately prior to the closing of the private placement of common stock on May 17, 2013, Pyxis, converted all of the principal amount of debt outstanding into 2,521,222 shares of common stock. Accordingly, there is no convertible debt outstanding at June 30, 2013.

Note 6—Intangible Assets

Intangible assets at June 30, 2013 and December 31, 2012 consisted of the following:

	June 30, 2013	December 31, 2012
Patent costs	$ 1,154,523	$ 1,154,523
Less — Accumulated amortization	(810,025)	(697,666)
Total	$ 344,498	$ 456,857

Patent amortization expense was $54,633 and $57,726 for the six months ended June 30, 2013 and 2012, respectively.

Patent costs which are amortized on a straight-line basis over a 10-year life, are scheduled to amortize as follows:

Year ending December 31,

2013 (remaining six months)	$54,633
2014.	94,100
2015.	77,656
2016.	61,119
Thereafter.	56,990
	$344,498

Note 7—Commitments and Contingencies

Operating Lease

The Company leases its office and laboratory space under a non-cancelable operating lease expiring on March 31, 2014. In May 2010, the Company completed a sublease of approximately 6,000 square feet of underutilized office and laboratory space which successfully reduced our total space operating costs. The sublease also expires on March 31, 2014. Rent expense, net of the benefit of the sublease, was $161,000 and $167,000 for the six months ended June 30, 2013 and 2012, respectively. The Company has not executed its renewal option and plans to negotiate for an extension of its current office and laboratory space.

Note 8—Capital Stock

Authorized Preferred and Common Stock

At June 30, 2013, the Company had authorized 6,000,000 shares of $0.001 par value preferred stock. The Company had authorized 150,000,000 shares of $0.001 par value common stock of which 149,960,265 shares were outstanding or reserved for issuance. Of those, 122,140,718 shares were outstanding; 4,277,280 shares were reserved for the potential exercise of outstanding stock options and for shares of common stock available for future grants under our stock plan; 699,376 shares were reserved for the potential exercise of rights held under the Employee Stock Purchase Plan; 1,750,000 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of $1.30 per share which are exercisable currently until March 5, 2015; 437,158 shares were reserved

for the exercise of outstanding warrants to purchase common stock at an exercise price of $0.2745 per share which are exercisable currently until June 29, 2017; and 20,655,733 shares were reserved for the exercise of outstanding warrants to purchase common stock at an exercise price of $0.2745 per share which are exercisable currently until May 17, 2020.

On June 29, 2012, the Company entered into an agreement with Pyxis to exchange the 5,000,000 shares of Series A Convertible Preferred Stock held by Pyxis for 5,000,000 shares of Series A-1 Convertible Preferred Stock (the "Series A-1 Preferred Stock") and filed a new Certificate of Designation, Preferences and Rights of Preferred Stock with the State of Delaware for the Series A-1 Preferred Stock and Series B Convertible Preferred Stock (the "Series B Preferred Stock" and, with the Series A-1 Preferred Stock, the "Preferred Stock"). Concurrently therewith, the Company completed a financing with Delta Dental of Michigan, Inc. ("DDMI") pursuant to which DDMI purchased 500,000 shares of Series B Preferred Stock for gross proceeds of $3,000,000. Net proceeds to the Company after fees and expenses were approximately $2.7 million. In addition, fully vested warrants to purchase 437,158 shares of common stock at an exercise price of $0.2745 per share were issued to the placement agent in the transaction. These warrants expire in five years. For purposes of determining the fair value of these warrants, the Black-Scholes pricing model was used with the following assumptions:

Risk-free interest rate	1	%
Expected life	5 years	
Expected volatility	142.36	%
Dividend yield	0	%

Using these assumptions, the fair value of the warrants is $104,907.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Preferred Stock were entitled to receive on a *pari passu* basis, prior and in preference to any distribution of any of the Company's 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 shares for each share of Preferred Stock then held by them. The liquidation preference for the Preferred Stock at May 17, 2013, prior to the financing, was $24,000,000 in the aggregate, reflecting a liquidation preference of $18,000,000 for the Series A-1 Preferred Stock and $6,000,000 for the Series B Preferred Stock. After receiving this amount, the holders of the Preferred Stock were entitled to participate on an as-converted basis with the holders of common stock in any of the remaining assets.

Each share of Series A-1 Preferred Stock was 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 ($1.80, and subject to adjustment) by the conversion price in effect on the date the certificate was surrendered for conversion. The Series A-1 Preferred Stock was convertible into 28,160,200 shares of common stock reflecting a conversion price of $0.3196 per share. Each share of Series B Preferred Stock was 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 ($6.00, and subject to adjustment) by the conversion price in effect on the date the certificate was surrendered for conversion. The Series B Preferred Stock was convertible into 10,928,961 shares of common stock reflecting a conversion price of $0.2745 per share.

Each holder of Preferred Stock was entitled to vote its shares of 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 Preferred Stock was entitled to a number of votes equal to the number of shares of common stock into which was convertible on the applicable record date.

On May 17, 2013, the Company entered into a Common Stock Purchase Agreement with various accredited investors ("the "Purchasers"), pursuant to which the Company sold securities to the Purchasers in a private placement transaction. The Company sold an aggregate of 43,715,847 shares of its common stock, at a price of $0.2745 per share for gross proceeds of $12,000,000. The Purchasers also received warrants to purchase up to an aggregate of 32,786,885 shares of Common Stock at an exercise price of $0.2745 per share (the "Warrants"). The Warrants were exercisable as to 63% of the shares immediately and as to 37% of the shares following receipt of shareholder approval of a share authorization increase and have a term of seven years from the date they become exercisable.

For warrants that are exercisable upon shareholder approval of an increase in the Company's authorized shares of common stock, the Company recorded a non-current liability at June 30, 2013 based on the allocation of the relative fair values of the common stock and warrants issued in the private placement. In addition, the Company recognized non-cash interest expense of $286,579 representing the increase in the fair value of the warrant liability from the date of issuance to June 30, 2013. For its services in this transaction, the placement agent received cash compensation in the amount of approximately $780,000 and the placement agent and an affiliate received warrants to purchase an

aggregate of 2,295,082 shares of common stock, at an exercise price of $0.2745 per share (the “Placement Agent Warrants”). The Placement Agent Warrants become exercisable following the shareholder approval of an increase in the Company’s authorized shares of common stock and expire seven years from the date they becomes exercisable. The cash compensation and the initial fair value of the warrants were recorded as issuance costs resulting in a reduction to Shareholders’ Equity.

For purposes of determining the fair value of the warrants exercisable upon shareholder approval of an increase in the Company’s authorized shares, the Black-Scholes pricing model was used with the following assumptions:

	May 17, 2013		June 30, 2013	
Risk-free interest rate	1.35	%	1.58	%
Expected life	4 years		4 years	
Expected volatility	144.63	%	145.62	%
Dividend Yield	0	%	0	%

Using these assumptions, the fair value of the warrants is $5,072,129 on May 17, 2013 and $5,358,708 on June 30, 2013.

In connection with this private placement, all preferred stockholders converted their shares of Preferred Stock to common stock in accordance with the terms noted above resulting in the issuance of 39,089,161 shares of common stock.

Under the terms of the Common Stock Purchase Agreement, the Company is required, within 30 days, to file a preliminary proxy statement for its 2013 Annual Meeting of Shareholders, which proxy statement shall include a proposal to amend the Company’s Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 shares to 300,000,000 shares. The definitive proxy statement was filed on June 24, 2013. See Note 11 Subsequent Events for disclosure of the results of the shareholder voting on this proposal.

In addition, pursuant to the Common Stock Purchase Agreement, each Purchaser has the right, at any time and from time to time following the date of shareholder approval of the increase in the number of authorized shares of common stock from 150,000,000 shares to 300,000,000 shares and on or before June 30, 2014, to purchase at one or more subsequent closings its pro rata share of up to an aggregate of $5,000,000 of additional shares of common stock and warrants on the same terms and conditions as those set forth above. If, prior to the June 30, 2014, investors have not purchased their entire pro rata share of such additional investment of $5,000,000, those who have purchased their entire pro rata share of the additional investment, will be entitled to purchase the unsold portion of the additional investment.

Registration Rights Agreement

On May 17, 2013, the Company also entered into a Registration Rights Agreement with the Purchasers, Pyxis, DDMI and the placement agent, pursuant to which the Company is required to file a registration statement on Form S-1 within 45 days to cover the resale of (i) the shares sold to the Purchasers and the shares of common stock underlying the Warrants, (ii) the shares of common stock issued to Pyxis upon conversion of the Series A-1 Preferred Stock and the convertible debt, (iii) the shares of common stock issued to DDMI upon the conversion of the Series B Preferred Stock, and (iv) the shares of common stock underlying the Placement Agent Warrants. The Company filed the registration statement on July 1, 2013, and it was declared effective on August 9, 2013.

In addition, within 45 days following June 30, 2014, the Company will be required to file a registration statement to cover the resale of (i) any shares of common stock sold to the Purchasers pursuant to the additional investment and the shares of common stock underlying any warrants issued to Purchasers pursuant to such additional investment, and (ii) shares of common stock underlying any additional warrants issued to the placement agent in connection with the additional investment.

Note 9—Stock-Based Compensation Arrangements

Total stock-based compensation is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Stock option grants beginning of period	$ 25,243	$ 48,185	$ 51,965	$ 94,796
Stock-based arrangements during the period:				
Stock option grants	3,061	3	6,110	3
Restricted stock issued:				
Employee stock purchase plan	1,291	169	2,208	1,332

$ 29,595	$ 48,357	$ 60,284	$ 96,131

Stock option and restricted stock grants

The following table details stock option and restricted stock activity for the six months ended June 30, 2013 and 2012:

	Six Months Ended June 30, 2013		Six Months Ended June 30, 2012	
	Shares	Weighted Avg Exercise Price	Shares	Weighted Avg Exercise Price
Outstanding, beginning of period	2,302,000	$ 1.06	2,228,067	$ 1.14
Stock options granted	200,000	0.29	500	0.34
Stock options exercised	(2,000)	0.12	—	—
Restricted stock exercised	(2,500)	0.00	(2,500)	0.00
Canceled/Expired	(80,250)	1.58	(125,800)	0.59
Outstanding, end of period	2,417,250	$ .98	2,100,267	$ 1.17
Exercisable, end of period	1,443,075	$ 1.40	1,393,217	$ 1.50

During the six month period ended June 30, 2013, the Company granted 200,000 stock options under the 2004 Employee, Director & Consultant Stock Plan. At June 30, 2013, the Company had an aggregate of 1,860,030 shares of common stock available for grant under this plan.

It is the Company's policy to grant stock options with an exercise price equal to the fair market value of the Company's common stock at the grant date, and stock options to employees generally vest over four years based upon continuous service. Historically, the majority of the Company's stock options have been granted in connection with the employee's start date with the Company. In addition, the Company may grant stock options in recognition of promotion and/or performance.

Employee Stock Purchase Plan

Purchases made under the Company's Employee Stock Purchase Plan are deemed to be compensatory because employees may purchase stock at a price equal to 85% of the fair market value of the Company's common stock on either the first day or the last day of a calendar quarter, whichever is lower. During the six months ended June 30, 2013 and 2012, employees purchased 50,624 and 52,158 shares, respectively, of common stock at a weighted-average purchase price of $0.26 and $0.17, respectively, while the weighted-average market value was $0.30 and $0.20 per share, respectively, resulting in compensation expense of $2,208 and $1,332, respectively.

Restricted Stock Awards

Holders of restricted stock awards participate fully in the rewards of stock ownership of the Company, including voting and dividend rights. Recipients of restricted stock awards are generally not required to pay any consideration to the Company for these restricted stock awards. The Company measures the fair value of the shares based on the last reported price at which the Company's common stock traded on the date of the grant and compensation cost is recognized over the remaining service period. During each of the six months ended June 30, 2013 and 2012, the Company granted no restricted stock awards.

At June 30, 2013, there was approximately $252,000 of total unrecognized compensation related to non-vested share-based compensation arrangements granted under the Company's stock plans.

Note 10—Industry Risk and Concentration

The Company develops genetic risk assessment tests and performs research for its own benefit. As of June 30, 2013, the Company has introduced four genetic risk assessment tests commercially. Commercial success of the Company's genetic risk assessment tests will depend on their success as being deemed to be scientifically credible and cost-effective by consumers and the marketing success of the Company and its collaborative partner.

Research in the field of disease predisposing genes and genetic markers is intense and highly competitive. The Company has many competitors in the United States and abroad that have considerably greater financial, technical, marketing, and other resources available. If the Company does not discover disease predisposing genes or genetic markers and develop risk assessment tests and launch such services or products before its competitors, then the potential for significant revenues may be reduced or eliminated.

During the six months ended June 30, 2013 and 2012, approximately 38% and 64%, respectively, of our revenue came from sales through our Merchant Network and Channel Partner Agreement with Amway Global, a subsidiary of Alticor.

Note 11—Subsequent Events

On August 9, 2013, the Company's shareholders' approved, among other things, (i) an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000 shares; (ii) an amendment to the Company's Certificate of Incorporation to effect a reverse stock split by combining outstanding shares of the Company's common stock into a lesser number of outstanding shares by a ratio of not less than 1-for-5 and not more than 1-for-20 at any time prior to the earlier of August 1, 2014 and the 2014 annual meeting of stockholders, the exact ratio to be set within this range by the Company's board of directors in its sole discretion; and (iii) the 2013 Employee, Director and Consultant Equity Incentive Plan.

Following the shareholder approval of the increase in authorized shares on August 9, 2013 the Company filed a certificate of amendment with the Delaware Secretary of State, which provided for adequate authorized shares for all potential common stock equivalents issued as of June 30, 2013. As a result, the warrant liability reflected as a non-current liability in the accompanying balance sheet will be reclassified to shareholders' equity at its fair value as of August 9, 2013. As the fair value of the warrant liability increased from June 30, 2013 to August 9, 2013, the Company will record an increase in interest expense of $11,000 equal to this increase in its statement of operations for the three months ended September 30, 2013.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed financial statements and the notes thereto included elsewhere in this document.

General Overview and Trends

Interleukin Genetics, Inc. is a personalized health company that develops specific, health area focused, unique genetic tests. Our overall mission is to provide test products that can help individuals improve or maintain their health through preventive measures or lifestyle changes. Our vision is to use the science of applied genetics to empower individuals and physicians to better understand the set of actions and steps necessary to guide the best lifestyle and treatment options. We believe that the science of applied genetics can help companies provide improved services to their consumers, and assist in improving outcomes in drug development and use.

During the six months ended June 30, 2013, we continued to focus our resources on commercializing our PST® test following completion of the large validation study with the University of Michigan and Renaissance Health Services Corporation ("RHSC") and on the sales of our Inherent Health® brand of genetic tests and related programs. The objective of this study is to improve dental care by identifying and using certain risk factors to set preventative treatment regimens.

On February 25, 2013, we entered into a Preferred Participation Agreement with RHSC, for itself and on behalf of certain of its affiliates and subsidiaries. Pursuant to this agreement, affiliates of RHSC have agreed to reimburse us a fixed price for each PST® genetic test that we process for a customer of affiliates of RHSC. In addition, if during the term of the agreement we offer the PST® test to any other person or party for a lower price, such lower price shall then be applicable to tests processed for a customer of such affiliates of RHSC for the remainder of the term of the agreement. The pricing arrangement is subject to the satisfaction of certain milestones, including that (1) within a specified timeframe, RHSC affiliates must develop and offer dental benefit plans for which a significant portion of such affiliate's clients are eligible that provides for use of the PST® test and reimbursement of the test at the agreed

upon price (each such plan, hereinafter referred to as a "Reimbursed Dental Plan") and (2) prior to a specified date, RHSC affiliates shall have sold policies for Reimbursed Dental Plans for the year beginning January 1, 2014. We have agreed that for a one year period beginning on the date on which RHSC affiliates first offer a Reimbursed Dental Plan, we will make the PST® test available solely to RHSC affiliates and not to any other third party or person. This agreement has a term of three years beginning on February 25, 2013, but may be terminated earlier (1) upon the mutual written agreement of us and RHSC, (2) if either party becomes the subject of bankruptcy, insolvency, liquidation or other similar proceedings, or (3) in the event of an uncured breach of the Agreement by either party.

On June 10, 2013 we announced the online publication of the research study "Patient Stratification for Preventive Dental Care" in *Journal of Dental Research.* The study provides new insights into the prevention of periodontitis (gum disease) and the opportunity for significant advancement in the delivery of personalized, preventive dental care. Periodontitis affects an estimated 47% of the adult population.

Periodontitis initiation and progression is driven by two factors: bacterial plaque that initiates the disease and the body's inflammatory response to bacteria which, when overly aggressive, causes breakdown of the bone and tissue that support the teeth. This inflammatory response varies greatly within the population and is significantly impacted by individual genetic make-up. Genetic testing can identify patients who have an increased inflammatory response to oral bacteria which significantly increases risk of periodontitis and tooth loss. Smoking and diabetes also contribute significantly to the risk of periodontal disease. The study explored the influence of three key risk factors for periodontal disease—smoking, diabetes and genetics—on tooth loss given varied frequencies of preventive dental visits that included cleanings. By examining claims data from 5,117 patients without periodontitis throughout a 16 year period and conducting genetic testing, researchers determined that patients with genetic variations of the IL-1 genotype, or one or more other risk factors examined, were at significantly increased risk for tooth loss and therefore require more preventive dental care. The IL-1 genetic variation was the single most prevalent risk factor—nearly one in three Americans carry this genetic variation. This study demonstrates the important opportunity to provide more effective preventive oral care through the use of risk-based patient assessment that includes genetic testing.

Research was conducted under the direction of Dr. William Giannobile, Najjar endowed Professor of Dentistry and Biomedical Engineering, and Chair of the Department of Periodontics and Oral Medicine at the University of Michigan.

The timing of any revenues that we may receive under our agreement with RHSC is dependent upon the timing of the offering of Reimbursed Dental Plans, which timing is very uncertain at this time, and is contingent upon a number of factors, including RHSC's affiliates ability to develop Reimbursed Dental Plans and to develop a viable market for such plans. We do not expect to receive any significant revenues under this agreement until the first quarter of 2014 at the earliest, and the timing of any such revenues may be substantially later, and we may never receive significant revenues under this agreement.

Our Inherent Health® brand of genetic tests includes the first-of-its-kind test for weight management that identifies an individual's genetic tendencies for weight gain related to either fat or carbohydrates in the diet. The Inherent Health® brand also offers customers a full suite of affordable, easy-to-use and meaningful genetic tests in heart health, bone health and nutritional needs. In addition, we launched additional products under the name Wellness Select that allows our e-commerce customers to purchase any combination of our Inherent Health® genetic tests at a discounted price.

In September 2012, Access Business Group LLC ("ABG"), an affiliate of Alticor, a related party, placed a purchase order totaling $1.0 million consisting of weight management kits. The kits are included as part of a promotional bundle of products that Amway is now selling to their Individual Business Owners (IBOs). The total order has been shipped and $327,000 remains in accounts receivable from related party at June 30, 2013. Cash received from the order will remain in deferred revenue until the earlier of the tests being returned or being processed. We are now processing tests from the program in our laboratory. The program has an end date of December 31, 2013, and we expect to recognize revenue from the program throughout 2013.

Our research and development expenses are focused on our own development and commercialization efforts related primarily to our PST® and Osteoarthritis genetic tests. We are also focusing on seeking potential commercial partners to validate our technology within their specific business model as a collaboration with little or no cost to us. This is different than in prior years when our development focus was concentrated in research and development to bring new test configurations to market.

On May 17, 2013, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with various accredited investors (the "Purchasers"), pursuant to which we sold securities to the Purchasers in a private placement transaction (the "Private Placement"). In the Private Placement, we sold an aggregate of 43,715,847 shares of our common stock at a price of $0.2745 per share for gross proceeds of $12,000,000. The Purchasers also received warrants to purchase up to an aggregate of 32,786,885 shares of common stock an exercise price of $0.2745 per share (the "Warrants"). The Warrants have a term of seven years from the date they become exercisable. Sixty-three percent of the shares issuable pursuant to the Warrants were exercisable immediately upon issuance, and the remaining 37%

became exercisable following the Share Authorization Increase (as defined below), which occurred on August 9, 2013.

In addition, pursuant to the Purchase Agreement, each Purchaser has the right, at any time and from time to time following the date of shareholder approval of an amendment to our Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 shares to 300,000,000 shares, which occured on August 9, 2013 (the "Share Authorization Increase"), and on or before June 30, 2014 (the "Expiration Date"), to purchase at one or more subsequent closings its pro rata share of up to an aggregate of 18,214,936 additional shares of common stock at a purchase price of $0.2745 per share and warrants to purchase up to an aggregate of 13,661,201 shares of common stock at an exercise price of $0.2745 per share (the "Additional Investment"). If, prior to the Expiration Date, Purchasers have not purchased their entire pro rata share of the Additional Investment, Purchasers who have purchased their entire pro rata share of the Additional Investment, will be entitled to purchase the unsold portion of the Additional Investment.

Immediately prior to the closing of the Private Placement, and in accordance with the terms of the Purchase Agreement: (i) Pyxis Innovations Inc. ("Pyxis"), the sole holder of our outstanding Series A-1 Convertible Preferred Stock converted all 5,000,000 shares of outstanding Series A-1 stock into 28,160,200 shares of our common stock; (ii) Pyxis, the sole holder of our outstanding convertible debt, converted all of the principal amount of debt outstanding ($14,316,255) into 2,521,222 shares of our common stock; and (iii) Delta Dental Plan of Michigan, Inc. ("DDMI"), the sole holder of our outstanding Series B Convertible Preferred Stock converted all 500,000 outstanding shares of Series B stock into 10,928,961 shares of common stock.

In the genetic test business, competition is in flux and the markets and customer base are not well established. Adoption of new technologies by consumers requires substantial market development and customer education. Historically, we have focused on our relationship with our primary customer, Alticor, a significant direct marketing company, in order to assist us in developing the market for our products and educating our potential customers. Our challenge in 2013 and beyond will be to develop the market for our other personalized health products, in particular our PST® test. We continue to allocate considerable resources to commercialization of our PST® and Inherent Health® brands of genetic tests. Due to the early stage of these initiatives, we cannot predict with certainty fluctuations we may experience in our genetic test revenues or whether revenues derived from the Preferred Participation Agreement with RHSC and its affiliates and the Merchant Network and Channel Partner Agreement with Amway Global will ever be material or if material, will be sustained in future periods.

Three Months Ended June 30, 2013 and June 30, 2012

Total revenue for the three months ended June 30, 2013 was $852,000, compared to $799,000 for the three months ended June 30, 2012. The increase of $53,000, or 6.6%, is primarily attributable to increased testing revenue from genetic tests processed as a result of sales of our Inherent Health® Weight Management genetic test through the promotional product bundle program of ABG, an affiliate of Pyxis. Genetic testing revenue is derived from tests sold and processed, which is driven by consumer demand. Deferred revenue, which consists of genetic tests sold and not yet processed, increased $330,000 to $2.0 million at June 30, 2013 as compared to $1.6 million on December 31, 2012.

During the three months ended June 30, 2013, 24% of our sales revenue came through our Merchant Network and Channel Partner Agreement with Amway Global, compared to 63% during the three months ended June 30, 2012. Pursuant to this agreement, Amway Global sells our genetic tests through its e-commerce web site via a hyperlink to our e-commerce site.

Cost of revenue for the three months ended June 30, 2013 was $496,000 or 58.2% of revenue, compared to $393,000, or 49.2% of revenue, for the three months ended June 30, 2012. The increase in the cost of revenue as a percentage of revenue is primarily attributable to the higher laboratory costs associated with processing tests associated with the Amway product promotion bundle which have a lower selling price than those purchased through the Amway partner

store.

Research and development expenses were $188,000 for the three months ended June 30, 2013, compared to $317,000 for the three months ended June 30, 2012. The decrease of $130,000, or 40.8% is primarily attributable to decreases in compensation, consulting and clinical trial costs. In the first quarter of 2013, our Chief Scientific Officer had fully transitioned to his role as Chief Executive Officer and, accordingly, related compensation costs were classified as part of selling, general and administrative expenses in the 2013 period whereas such costs had previously been classified as research and development expenses.

Selling, general and administrative expenses were $1.6 million for the three months ended June 30, 2013, compared to $1.2 million for the three months ended June 30, 2012. The increase of $0.4 million, or 33.8% is primarily attributable to increased consulting and compensation expenses related to marketing activities for our PST periodontal test, partially offset by lower corporate legal fees as well as lower sales commissions paid to Amway Global as part of our Merchant Channel and Partner Store Agreement.

Interest expense was $346,000 for the three months ended June 30, 2013, as compared to $115,000 for the three months ended June 30, 2012. The increase in interest expense of $232,000 is attributable to non cash interest associated with the fair value of the warrant liability partially offset by lower interest expense due to the conversion of all outstanding convertible debt to common stock on May 17, 2013.

Six Months Ended June 30, 2013 and June 30, 2012

Total revenue was $1.3 million for the six months ended June 30, 2013, as compared to $1.5 million for the six months ended June 30, 2012. The decrease of $0.2 million, or 9.3%, is primarily attributable to increased testing revenue from genetic tests processed as a result of sales of our Inherent Health® Weight Management genetic test through the promotional product bundle program of Access Business Group, LLC, an affiliate of Pyxis, offset by lower revenue recognized from sales through our Merchant Network and Channel Partner Agreement with Amway Global and, to a lesser extent in 2012 only, revenue recognized in 2012 as part of our PST validation study with the University of Michigan and RHSC.

During the six months ended June 30, 2013, 38% of our sales revenue came through our Merchant Network and Channel Partner Agreement with Amway Global compared to 64% during the six months ended June 30, 2012.

Cost of revenue for the six months ended June 30, 2013 was $880,000 or 65.7% of revenue, compared to $769,000, or 52.1% of revenue, for the six months ended June 30, 2012. The increase in the cost of revenue as a percentage of revenue is primarily attributable to the higher laboratory costs associated with processing tests associated with the Amway product promotion bundle which have a lower selling price than those purchased through the Amway partner store.

Research and development expenses were $348,000 for the six months ended June 30, 2013, compared to $764,000 for the six months ended June 30, 2012. The decrease of $416,000 or 54.4%, in research and development expenses is primarily attributable to decreased compensation, consulting and clinical study costs. In the first quarter of 2013, our Chief Scientific Officer had fully transitioned to his role as Chief Executive Officer and, accordingly, related compensation costs were classified as part of selling, general and administrative expenses in the 2013 period whereas such costs had previously been classified as research and development expenses.

Selling, general and administrative expenses were $2.6 million for the six months ended June 30, 2013, compared to $2.3 million for the six months ended June 30, 2012. The increase of $263,000, or 11.4%, is primarily attributable to increased consulting and compensation expenses related to marketing activities for our PST periodontal test, partially offset by lower corporate legal fees as well as lower sales commissions paid to Amway Global as part of our Merchant Channel and Partner Store Agreement.

Interest expense was $461,000 for the six months ended June 30, 2013, as compared to $220,000 for the six months ended June 30, 2012. The increase in interest expense of $242,000 is attributable to non cash interest associated with the fair value of the warrant liability partially offset by lower interest expense due to the conversion of all outstanding convertible debt to common stock on May 17, 2013.

Liquidity and Capital Resources

As of June 30, 2013, we had cash and cash equivalents of $10.8 million and no outstanding debt.

Cash used in operations was $1.5 million for the six months ended June 30, 2013, as compared to $2.2 million for the six months ended June 30, 2012. Cash used in operations is primarily impacted by operating results and changes in working capital, particularly the timing of the collection of related party receivables, inventory levels, receipt of orders and the timing of payments to suppliers. In the six months ended June 30, 2013, approximately $1.1 million was received as payment for weight management kits ordered as part of Amway's promotional product bundle incorporating our weight management genetic test. Deferred revenue, which consists of cash received from genetic test sales increased by $330,000 to $2.0 million during the six months ended June 30, 2013.

Cash used in investing activities was $10,247 for the six months ended June 30, 2013, compared to $5,000 for the six months ended June 30, 2012. These amounts represent capital additions. We believe that based on current and projected volumes, our laboratory equipment is sufficient to process genetic tests. We expect additional capital purchases may be needed in the foreseeable future to automate some of our laboratory process as we start to process samples related to our PST® test.

Cash provided by financing activities was $11.1 million for the six months ended June 30, 2013, compared to $4.3 million for the six months ended June 30, 2012. On May 17, 2013, we entered into a Common Stock Purchase Agreement with various accredited investors, pursuant to which we sold an aggregate of 43,715,847 shares of our common stock, at a price of $0.2745 per share for net cash proceeds of $11.1 million. On April 13, 2012, we received $1.3 million in proceeds from the issuance of a note payable under our credit facility with Pyxis. On June 29, 2012, we completed a financing with DDMI, pursuant to which DDMI purchased 500,000 shares of Series B Convertible Preferred Stock for gross proceeds of $3,000,000. All costs associated with this transaction were paid in the third quarter of 2012. We received $12,839 from stock purchases through the employee stock purchase plan during the six months ending June 30, 2013 compared to $8,810 for the six months ended June 30, 2012.

The amount of cash we generate from operations is currently not sufficient to continue to fund operations and grow our business. We expect that our current and anticipated financial resources, including the proceeds from the May 2013 private placement will be adequate to maintain our current and planned operations at least through the next twelve months. We may need significant additional capital to fund our continued operations, to facilitate the commercial launch of our PST® genetic test, continued research and development efforts, obtaining and protecting patents and administrative expenses. We believe our success depends on our ability to have sufficient capital and liquidity to fund operations at least until we begin to receive significant revenues under the Preferred Participation Agreement with RHSC and its affiliates. The timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of Reimbursed Dental Plans by RHSC affiliates, which timing is uncertain at this time, and is contingent upon a number of factors, including RHSC's affiliates' ability to develop reimbursed Dental Plans and to develop a viable market for such plans. We do not expect to receive any significant revenues under this agreement until the first quarter of 2014 at the earliest, and the timing of such revenues may be substantially later, and we may never receive significant revenues under this agreement.

Until such time, if ever, that we generate revenues sufficient to fund operations, we may fund our operations by issuing common stock, debt or other securities in one or more public or private offerings, as market conditions permit, or through the incurrence of debt from commercial lenders. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or cease activities or operations or enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our products, technologies or intellectual property.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements. The preparation of these financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires us to (i) make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenue and expenses; and (ii) disclose contingent assets and liabilities. A critical accounting estimate is an assumption that could have a material effect on our financial statements if another, also reasonable, amount were used or a change in the estimates is reasonably likely from period to period. We base our accounting estimates on historical experience and other factors that we consider reasonable under the circumstances. However, actual results may differ from these estimates. To the extent there are material differences between our estimates and the actual results, our future financial condition and results of operations will be affected. Our most critical accounting policies and estimates upon which our financial condition depends, and which involve the most complex or subjective decisions or assessments are set forth in Note 4 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no significant changes in our accounting policies or changes from the methodology applied by management for critical accounting estimates previously disclosed in our most recent Annual Report on Form 10-K.

Recent Accounting Pronouncements

Please see the discussion of "Recent Accounting Pronouncements" in Note 4, Significant Accounting Policies contained in the Notes to Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2012. No new updates or other guidance issued to date by the FASB in 2013 are expected to have a material impact on our financial statements.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk***

As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore are not required to provide the information required by this Item 3.

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

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Control Over Financial Reporting.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f)) occurred during the quarter ended June 30, 2013 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

Not applicable.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012. which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks that we face. In addition, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. There have been no material changes in or additions to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2012, except as follows:

The following risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2012 are deleted in their entirety:

· *"If we fail to obtain additional capital by the end of April 2013, then we may have to end our operations and seek protection under bankruptcy laws."*

· *"There is substantial doubt concerning our ability to continue as a going concern."*

· *"Our Preferred Stock has certain rights that are senior to common stockholder rights and this may reduce the value of our common stock."*

The risk factor entitled "*The timing and amount of revenues, if any, that we may receive pursuant to our Preferred Participation Agreement with RHSC and its affiliates is uncertain*" included in our Annual Report on Form 10-K for the year ended December 31, 2012 is deleted in its entirety and replaced with the following risk factor:

"The timing and amount of revenues, if any, that we may receive pursuant to our Preferred Participation Agreement with RHSC and its affiliates is uncertain.

Although we have entered into a Preferred Participation Agreement with RHSC, for itself and on behalf of certain of its affiliates and subsidiaries, pursuant to which RHSC affiliates are expected to develop and offer dental benefit plans that provide for use of the PST® test and reimbursement of the test at an agreed upon price (each such plan, hereinafter referred to as a "Reimbursed Dental Plan"), the timing of any revenues that we may receive under this agreement is dependent upon the timing of the offering of such Reimbursed Dental Plans, which timing is very uncertain at this time. Although we currently believe that RHSC's affiliates may begin to offer Reimbursed Dental Plans to employer groups for plan years starting in January 2014, this timing is contingent on a number of factors, including RHSC's affiliates' ability to develop Reimbursed Dental Plans and to develop a viable market for such plans. Accordingly, the earliest that we may receive any significant revenues under this agreement is in the first quarter of 2014, and the timing of any such revenues may be substantially later, and we may never receive significant revenues under this agreement. The failure to begin receiving significant revenues under this agreement in 2014 would require us to obtain additional funding and would have a material adverse effect on our business."

The risk factor entitled "*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 likely decrease our sales and market share.*" included in our Annual Report on Form 10-K for the year ended December 31, 2012 is deleted in its entirety and replaced with the following risk factor:

"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 likely decrease our sales and market share.

Our success will 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 rights to 11 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 and any issued patents may never afford meaningful protection for our technology or products or provide us with a competitive advantage. Further, others may develop competing products, which avoid legally infringing upon, or conflicting with, our patents. There is no assurance that another company will not replicate one or more of our products, and this may harm our ability to do business. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. There have been several cases involving "gene patents" and diagnostic claims that have been considered by the U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad's U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad's composition claims to "isolated" DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or Prometheus, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus' claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted *certiorari* in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a *writ of certiorari* asking the Supreme Court to review the Federal Circuit's decision with respect to the composition of matter claims. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. On June 13, 2013, the Supreme Court issued a decision in the Myriad case. According to the decision, claims directed to genomic DNA cover unpatentable subject matter. However, claims directed to cDNA are patent eligible subject matter.

On July 3, 2012, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in Prometheus. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: “Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.” The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and March 2013. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our present or future patent portfolio.

There can be no assurance that the Supreme Court’s decision in either the Myriad or Promethes case will not have a negative impact gene or diagnostic patents generally or the ability of biotechnology and diagnostic companies to obtain or enforce their patents in the future. Such negative decisions by the Supreme Court could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, with confidentiality agreements. The third parties we contract with may breach these agreements, and we may not have adequate remedies for any breach. If they do not protect our rights, third parties could use our technology, and our ability to compete in the market would be reduced. We also realize that our trade secrets may become known through other means not currently foreseen by us. Our competitors may discover or independently develop our trade secrets.”

The risk factor entitled “*Because a single stockholder has a controlling percentage of our voting power, other stockholders’ voting power is limited*” included in our Annual Report on Form 10-K for the year ended December 31, 2012 is deleted in its entirety and replaced with the following risk factor:

"Our management and their affiliates own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of July 1, 2013, our executive officers, directors and their respective affiliates, beneficially owned approximately 62.4% of our outstanding common stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock."

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and, in particular, our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Part I – Item 2, contains or incorporates a number of forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in our discussion in this Quarterly Report on Form 10-Q will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially.

Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. There are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements, many of which are beyond our control, including the factors set forth under "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2012 and under "Item 1A. Risk Factors" above in this Quarterly Report on Form 10-Q. In addition, the forward-looking statements contained herein represent our estimates and expectations only as of the date of this filing and should not be relied upon as representing our estimates and expectations as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of the Company, as filed with the Delaware Secretary of State on March 28, 2000 (incorporated herein by reference to Exhibit 3.1 of the Quarterly Report on Form 10-Q filed August 14, 2000 (File No. 001-32715)).
3.1.2	Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Delaware Secretary of State on March 5, 2003 (incorporated herein by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on March 5, 2003(File No. 001-32715).
3.1.3	Certificate of Amendment to Certificate of Incorporation, as filed with the Delaware Secretary of State on August 5, 2003 (incorporated herein by reference to Exhibit 3.1 of the Quarterly Report on Form 10-Q filed on November 12, 2003 (File No. 001-32715)).
3.1.4	Certificate of Amendment to Certificate of Incorporation, as filed with the Delaware Secretary of State on June 21, 2007 (incorporated herein by reference to Exhibit 3.1 of the Quarterly Report on Form 10-Q filed on August 9, 2007 (File No. 001-32715)).

3.1.5	Corrected Certificate of Amendment filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on July 2, 2012 (File No. 001-32715)).
3.1.6	Certificate of Elimination of the Series A Preferred Stock filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.2 of the Current Report on Form 8-K filed on July 2, 2012 (File No. 001-32715)).
3.1.7	Certificate of Designations, Preferences, and Rights of Series A-1 Preferred Stock and Series B Preferred Stock filed with the Delaware Secretary of State on June 29, 2012 (incorporated by reference to Exhibit 3.3 of the Current Report on Form 8-K filed on July 2, 2012 (File No. 001-32715)).
3.1.8	Certificate of Elimination of the Series A-1 Preferred Stock and Series B Preferred Stock of Interleukin Genetics, Inc., dated May 31, 2013 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on June 5, 2013 (File No. 001-32715)).
3..1.9	Certificate of Amendment filed with the Delaware Secretary of State on August 9, 2012 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed on August 13, 2012 (File No. 001-32715)).
4.1	Form of Warrant issued to the Purchasers in the May 2013 Private Placement (incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K filed on May 20, 2013 (File No. 001-32715)).
4.2	Form of Warrant issued to BTIG, LLC as Placement Agent in the May 2013 Private Placement (incorporated by reference to Exhibit 4.2 of the Current Report on Form 8-K filed on May 20, 2013 (File No. 001-32715)).
10.1	Common Stock Purchase Agreement, dated May 17, 2013, by and among Interleukin and the Purchasers in the May 2013 Private Placement (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed on May 20, 2013 (File No. 001-32715)).
10.2	Registration Rights Agreement, dated May 17, 2013, by and among Interleukin and the Purchasers in the May 2013 Private Placement, Pyxis Innovations Inc., Delta Dental Plan of Michigan, Inc. and BTIG, LLC (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed on May 20, 2013 (File No. 001-32715)).
10.3	Voting Agreement and Irrevocable Proxy, dated May 17, 2013, between Interleukin and Pyxis Innovations Inc. (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K filed on May 20, 2013 (File No. 001-32715)).
31.1*	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from Interleukin Genetics Inc.’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Stockholders’ Deficit, (iv) the Condensed Statements of Cash Flows, and (v) Notes to Condensed Financial Statements.

* Filed herewith.

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: August 14, 2013 By: /s/ Kenneth S. Kornman
Kenneth S. Kornman
Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2013 By: /s/ Eliot M. Lurier
Eliot M. Lurier
Chief Financial Officer
(Principal Financial Officer)