EXACT SCIENCES CORP
Form 10-Q
May 02, 2014
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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 March 31, 2014

OR

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

Commission File Number:
001-35092

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation or organization)	**02-0478229** (I.R.S. Employer Identification Number)
441 Charmany Drive, Madison WI (Address of principal executive offices)	**53719** (Zip Code)

(608) 284-5700 (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 o

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 o

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

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

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

As of May 1, 2014, the registrant had 82,814,518 shares of common stock outstanding.

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Part I Financial Information

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EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	March 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,806	$ 12,851
Marketable securities	98,204	120,408
Prepaid expenses and other current assets	2,842	2,199
Total current assets	118,852	135,458
Property and Equipment, at cost:		
Laboratory equipment	7,508	5,087
Assets under construction	4,926	2,592
Office and computer equipment	1,218	1,217
Leasehold improvements	5,050	5,043
Furniture and fixtures	268	268
	18,970	14,207
Less Accumulated depreciation	(3,694)	(3,038)
	15,276	11,169
	$ 134,128	$ 146,627
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,331	$ 761
Accrued expenses	6,806	5,806
Capital lease obligation, current portion	356	351
Lease incentive obligation, current portion	540	540
Deferred license fees, current portion		294
Total current liabilities	9,033	7,752
Long-term debt	1,000	1,000
Long-term accrued interest	90	84
Capital lease obligation, less current portion	269	360
Lease incentive obligation, less current portion	1,980	2,115
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.01 par value Authorized 5,000,000 shares Issued and outstanding no shares at March 31, 2014 and December 31, 2013		
Common stock, $0.01 par value Authorized 100,000,000 shares Issued and outstanding 71,262,715 and 71,071,838 shares at March 31, 2014 and December 31, 2013	713	711
Additional paid-in capital	457,776	455,239
Accumulated other comprehensive income	133	125
Accumulated deficit	(336,866)	(320,759)
Total stockholders equity	121,756	135,316
	$ 134,128	$ 146,627

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data - unaudited)

	Three Months Ended March 31,	
	2014	**2013**
License fees	294	1,036
Operating expenses:		

Company Background

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on the development of novel oral immediate-release and controlled-release products for the pharmaceutical market. Our business strategy is to develop pharmaceutical products based on our proprietary drug delivery technologies and, once the viability of a product has been demonstrated, to license the commercial rights to partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund development of the licensed products, complete the regulatory approval process with the U.S. Food and Drug Administration (“FDA”) or other regulatory agencies relating to the licensed products, and assume responsibility for marketing and distributing such products.

In addition, we may choose to pursue the development of certain products until the project reaches the marketing and distribution stage. We will assess the potential for successful development of a product and associated costs, and then determine at which stage it is most prudent to seek a partner, balancing such costs against the potential for additional returns earned by partnering later in the development process.

We have also undertaken a strategy under which we will work with pharmaceutical companies in order to develop new dosage forms for pharmaceutical products for which patent protection is nearing expiration. Under §(505)(b)(2) of the Food, Drug, and Cosmetics Act, the FDA may grant market exclusivity for a term of up to three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials, other than bioavailability studies, conducted by or for the sponsor.

We are currently continuing to develop the existing products in our pipeline and may also perform research and development on other potential products as opportunities arise.

We currently purchase and/or lease, on an as-needed basis, the equipment necessary for performing research and development activities related to our products.

We plan to hire new personnel, primarily in the area of research and development, on an as-needed basis as we enter into partnership agreements and increase our research and development activities.

Key Developments

We achieved a number of milestones in our strategic development, growth and future income potential throughout the first six months of 2011, most notably:

Financing:

On June 22, 2011, we announced the closing of two concurrent private placement offerings in the USA and Canada. We issued approximately 4.8 million shares of common stock at a per share purchase price of US$0.67, and three-year warrants to purchase up to approximately 2.4 million shares of common stock at an exercise price of US$0.74 per share, for aggregate gross proceeds of approximately US$3.2 million. We intend to use the net proceeds to support our strategic development projects and for working capital.

CPI-300 Antidepressant Tablet:

Background:

CPI-300 is a higher strength of the antidepressant bupropion HCl, the active ingredient in Wellbutrin XL®.

April 2009: submitted a New Drug Application (“NDA”) to the FDA.

August 2009: sued by Biovail Laboratories SLR (“Biovail”) for patent infringement under the Hatch-Waxman Act.

January 2010: announced manufacturing site change for the manufacture of CPI-300 to Pillar5 Pharma.

March 2010: U.S. PTO issued patent number US 7,674,479 protecting CPI-300 against generic copies.

February 2010: Complete Response Letter (“CRL”) received from FDA.

June 2010: met with FDA to clarify steps necessary to obtain regulatory approval.

Progress in 2011:

On January 4, 2011, we announced that the United States District Court of Delaware has ruled in our favor regarding claim construction for the two patent terms at issue in the patent infringement action brought forward by Biovail. The ruling arises from a special proceeding required under U.S. patent law called a "Markman Hearing" where both sides present to the court their arguments on how they believe the patent terms at issue should be interpreted.

On February 3, 2011, we announced that the United States District Court of Delaware had dismissed the lawsuit against us. Biovail agreed to dismissal of the action following the ruling on the Markman Hearing.

On May 16, 2011, we announced that we had submitted our reply to the CRL issued in February 2010 by the FDA.

On June 14, 2011, we announced that the FDA has accepted the resubmission of our NDA 505(b)(2) in response to the February 2010 CRL as a complete, Class 2 response. In addition, the FDA has established November 13, 2011 as its target action date under the Prescription Drug User Fee Act ("PDUFA").

Anti-Psychotic Film:

On February 7, 2011, we announced the completion of a pilot study that indicates that we have successfully developed a novel oral film, INT0022, which is likely to be bioequivalent to a leading anti-psychotic in a pivotal bioequivalency study. INT0022 has been developed using our proprietary immediate release "VersaFilm" drug delivery technology. This was a randomized, two-period, two-way crossover study in healthy male subjects. The study was designed to determine whether INT0022 will be bioequivalent to a leading anti-psychotic product in a pivotal bioequivalency study as measured by industry standard pharmacokinetic measures, peak plasma concentration (Cmax) and area under the curve (AUC). The study results indicate that INT0022 will likely be bioequivalent with the brand product and allow us to advance the product to the pivotal stage.

On June 14, 2011, we announced the execution of a binding term-sheet with RedHill Biopharma Ltd. ("RedHill"), an Israeli corporation, to co-develop and license our anti-psychotic oral thin film. The term-sheet sets forth the main criteria to be incorporated into a definitive development and license agreement under which RedHill would obtain exclusive worldwide rights to market and sell our rapidly dissolving anti-psychotic oral film product. In exchange, we would receive upfront, milestone, and external development fees totaling up to US$2.3 million from RedHill and, upon commercialization of the product, we would receive up to 50% of all proceeds including, but not limited to, all sales milestones and income from the product world-wide.

Insomnia Film:

On April 6, 2011 we announced the completion of a pilot biostudy indicating that we have developed a novel oral film, INT0020, that suggests bioequivalency to a leading branded product for the treatment of insomnia. INT0020 has been developed using our proprietary immediate release "VersaFilm" drug delivery technology.

This was a randomized, two-period, two-way crossover study in healthy male subjects. The study was designed to determine whether INT0020 is bioequivalent to a leading insomnia product as measured by industry standard pharmacokinetic measures, peak plasma concentration (Cmax) and area under the curve (AUC). The study results indicate that INT0020 should meet acceptance criteria for bioequivalency for both Cmax and AUC once we decide to advance the product to the larger pivotal bioequivalency study.

Currency rate fluctuations

Our operating currency is Canadian dollars, while our reporting currency is U.S. dollars. Accordingly, our results of operations and balance sheet position have been affected by currency rate fluctuations. The following management discussion and analysis takes this into consideration whenever material.

Results of Operations for the six month period ended June 30, 2011 compared to the six month period ended June 30, 2010.

In U.S.$ thousands	2011	2010	Increase/ (Decrease)	Percentage Change
Revenue	$ 144	$ 308	$ (164)	53%
Research and Development Expenses	634	579	55	9%
Research and Development Tax Credit	(83)	(48)	35	73%
Management Salaries	268	316	(48)	15%
General and Administrative Expenses	163	105	58	55%
Professional Fees	274	1,050	(776)	74%
Net Loss	(1,180)	(1,715)	(535)	31%

Revenue

Total revenue and other income decreased from $308 thousand in the first six months of 2010 to $144 thousand in the first six months of 2011.

Royalty revenues earned from commercialization of the first product fully-developed by us, a prenatal multivitamin supplement marketed as Gesticare® in the USA, decreased to approximately $52 thousand in the first six months of 2011 from $154 thousand in the same period of the previous year. The deterioration results from increased competition in the nutritional supplement market.

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Revenue earned from our pharmaceutical partners for development milestones achieved decreased from $143 thousand in the first six months of 2010 to $89 thousand in the first six months of 2011. The decrease reflects the changing status of research and development projects as they progress and development milestones are realized, new development projects are undertaken, or projects are completed.

Research and Development ("R&D") Expenses

R&D expenses totaled $634 thousand in the first six months of 2011, compared with $579 thousand in the first six months of 2010.

Included within R&D expenses for 2011 are R&D Salaries of $318 thousand, of which approximately $7 thousand represents non-cash compensation. This compares to R&D Salaries of $242 thousand in 2010, of which approximately $2 thousand represented non-cash compensation. Approximately $21 thousand of the increase in R&D Salaries is related to the foreign exchange impact arising from the translation of our operating currency into our reporting currency, and approximately $55 thousand of the increase is attributable to the addition of a scientist in May 2010, the return of a scientist from maternity leave, and R&D staff salary increases.

In the first six months of 2011 we recorded estimated Research and Development Tax Credits and refunds of $83 thousand, compared with $48 thousand that was recorded in the first six months of the previous year.

Management Salaries and General and Administrative Expenses

Management salaries decreased from $316 thousand in the first six months of 2010 to $268 thousand in the first six months of 2011. The decrease relates to the termination of a consultancy agreement for business development activities in the fourth quarter of 2010, which was partially compensated by the additional costs of temporary assistance for business development through the first quarter of 2011, plus approximately $18 thousand related to the foreign exchange impact arising from the translation of our operating currency into our reporting currency.

Included in management salaries are approximately $5 thousand (2010: $14 thousand) in non-cash compensation resulting from options granted to management employees in 2008 and 2009, and $5 thousand (2010: $21 thousand) in non-cash compensation from options granted to non-employee directors in 2010.

General and administrative expenses increased from $105 thousand in the first six months of 2010 to $163 thousand in the first six months of 2011. The increase relates to the write-off of a receivable in the amount of approximately $52 thousand, which is no longer collectible, plus approximately $11 thousand related to the foreign exchange impact

arising from the translation of our operating currency into our reporting currency

Professional Fees

Professional fees for the first six months of 2011 decreased by $776 thousand, or 74%, to $274 thousand from $1,050 thousand in the first six months of 2010.

The decrease in professional fees is primarily attributable to the dismissal in February 2011 of the patent infringement lawsuit that was initiated by Biovail against us in August 2009. The dismissal of the litigation followed our previous announcement on January 4th, 2011 that the court had ruled in favor of IntelGenx regarding claim construction for the two patent terms at issue in the patent infringement action brought forward by Biovail under the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). The ruling arose from a special proceeding required under U.S. patent law called a "Markman Hearing" where both sides presented to the court their arguments on how they believed the patent terms at issue should be interpreted. Subsequent to the ruling on the Markman Hearing, Biovail agreed to dismissal of the action.

In the first six months of 2010 we incurred legal expenses in respect of the Biovail litigation of approximately $705 thousand, compared with $20 thousand in the first six months of 2011.

Included within professional fees in the first six months of 2011 is a non-cash expense of approximately $7 thousand (2010: $7 thousand) for options granted to investor relation firms for investor relation services.

Share-Based Compensation Expense, Warrants and Stock Based Payments

Share-based compensation expense, warrants and share-based payments totaled $24 thousand in the first six months of 2011, compared with $44 thousand in the first six months of 2010.

We expensed approximately $12 thousand in the first six months of 2011 for options granted to our employees in 2009, 2010 and 2011 under the 2006 Stock Option Plan and approximately $5 thousand for options granted to non-employee directors in 2010, compared with $16 thousand and $21 thousand, respectively, which was expensed in the first six months of the previous year.

We also expensed $7 thousand in the first six months of 2011 for options granted to investor relation firms for investor relation services, compared to $7 thousand that was expensed in the first six months of 2010.

There remains approximately $45 thousand in stock-based compensation to be expensed in fiscal 2011, 2012 and 2013 of which approximately $39 thousand relates to the issuance of options to our employees and directors during 2009 and 2010, and approximately $6 thousand relates to options granted to investor relations firms. We anticipate the issuance of additional options and warrants in the future, which will continue to result in stock-based compensation expense.

Net Loss

The net loss for the first six months of 2011 declined by $535 thousand, or 31%, versus the net loss of $1,715 thousand in the same period of the previous year. Included within the net loss for the first six months of 2011 is a loss of approximately $80 thousand related to a foreign exchange impact arising from the translation of our operating currency into our reporting currency, which is the effect of the strengthening of the Canadian dollar versus the U.S. dollar. The decrease in net loss primarily relates to the decrease in legal fees of $685 thousand related to the dismissal of the Biovail litigation, partly offset by a decrease in revenue and other income of $164 thousand, the write-off of an accounts receivable in the amount of $52 thousand deemed to be no longer collectible

Key items from the Balance Sheet as at June 30, 2011 compared to December 31, 2010

In U.S.$ thousands

	2011	2010	Increase/ (Decrease)	Percentage Change
Current Assets	$ 3,629	$ 1,666	$ 1,963	118%
Property and Equipment	150	159	(9)	6%
Current Liabilities	382	349	33	9%
Additional Paid-in Capital	14,090	11,087	3,003	27%

Current Assets

Current assets totaled $3,629 thousand at June 30, 2011 compared with $1,666 thousand at December 31, 2010. The increase of $1,963 thousand is primarily attributable to an increase in cash and cash equivalents of approximately $2,057 thousand arising from the private placement offerings completed on June 21, 2011 and an increase in investment tax credits receivable of approximately $89 thousand, partially off-set by a decrease in accounts receivable of approximately $202 thousand.

Prepaid Expenses

As of June 30, 2011 prepaid expenses totaled $66 thousand, compared to $47 thousand at December 31, 2010. The increase relates primarily to a deposit paid in respect of planned attendance at an exhibition in the fourth quarter of 2011.

Liquidity and Capital Resources

On June 21, 2011, as part of two concurrent private placement offerings, we issued approximately 4.8 million shares of common stock, and three-year warrants to purchase up to approximately 2.4 million shares of common stock, for aggregate gross proceeds of approximately US$3.2 million. Each warrant entitles the holder to purchase one half of one common share at an exercise price of $0.74 per common share and expires 36 months after the date of issuance.

The private placements consisted of a definitive securities purchase agreement with certain accredited and institutional investors for the issuance and sale in a private placement transaction (the "US Private Offering") of 2,582,536 shares and warrants to purchase up to 1,291,268 shares of common stock, for aggregate gross proceeds of approximately $1.7 million, and a definitive subscription agreement solely with Canadian investors for the issuance and sale in a concurrent non-brokered private placement transaction (the "Canadian Private Offering") of 2,238,806 shares and warrants to purchase up to 1,119,403 shares of common stock, for aggregate gross proceeds of approximately $1.5 million.

We paid an agent cash commissions in the amount of approximately $121 thousand, representing 7% of the aggregate gross proceeds received by us in the US Private Offering, plus expenses in the amount of approximately $28 thousand, and issued warrants to the agent to purchase 180,778 shares of common stock, representing 7% of the amount of shares sold in the US Private Offering. We also paid cash finder's fees in the amount of approximately $105 thousand, representing 7% of the aggregate gross proceeds received by us in the Canadian Private Offering; and issued warrants to purchase 156,716 shares of common stock, representing 7% of the amount of shares sold in the Canadian Private Offering. Each warrant entitles the holder to

purchase one half of one common share at an exercise price of $0.74 per common share and expires 36 months after the date of issuance. In addition, we paid approximately $114 thousand in cash consideration for other transaction costs, which have been reflected as a reduction of the common shares and the warrants based on their relative fair values.

Cash and cash equivalents totaled $3,201 thousand as at June 30, 2011, representing an increase of $2,057 thousand, compared to $1,144 thousand as at December 31, 2010.

On March 4, 2011, $108 thousand agents' warrants were exercised for 227,625 common shares having a par value of $0 thousand for cash consideration of $108 thousand, resulting in an increase in additional paid-in capital of $108 thousand.

On June 29, 2011, $9 thousand agents' warrants were exercised for 18,531 common shares having a par value of $0 thousand for cash consideration of $9 thousand, resulting in an increase in additional paid-in capital of $9 thousand.

As at June 30, 2011, we had accumulated a deficit of $10,941 thousand compared with an accumulated deficit of $9,761 thousand as at December 31, 2010. Total assets amounted to $3,779 thousand and shareholders' equity totaled $3,397 thousand as at June 30, 2011, compared with total assets and shareholders' equity of $1,825 thousand and $1,476 thousand, respectively, as at December 31, 2010.

Accounts receivable totaled $76 thousand as at June 30, 2011 compared with $278 thousand as at December 31, 2010. The decrease relates primarily to a sales tax refund in the amount of approximately $135 thousand that we received in the second quarter of 2011, and the write-off of a receivable in the first quarter of 2011 in the amount of approximately $52 thousand that was no longer deemed to be collectible.

In addition, we had R&D investment tax credits receivable of approximately $286 thousand as at June 30, 2011 as compared to $197 thousand as at December 31, 2010. We expect to receive a refund of approximately $200 thousand of the R&D investment tax credits during the second half of 2011.

Accounts payable and accrued liabilities as at June 30, 2011 amounted to $382 thousand (December 31, 2010 - $349 thousand), of which approximately $30 thousand relates to research and development activities, approximately $219 thousand relates to professional fees, and approximately $123 thousand relates to accrued payroll liabilities.

Property and Equipment

As at June 30, 2011, the net book value of property and equipment amounted to $150 thousand, compared to $159 thousand at December 31, 2010. In the six months ended June 30, 2011 additions to assets totaled $3 thousand, total depreciation amounted to $17 thousand and a foreign exchange gain of $5 thousand was recorded.

Capital Stock

As at June 30, 2011, capital stock amounted to $449 compared to $396 at December 31, 2010. The increase reflects the following issuances of shares at par value of $0.00001:

- 227,625 shares issued related to the exercise of agents' warrants on March 4, 2011
- 75,428 shares issued related to the cashless exercise of warrants on May 18, 2011
- 4,821,342 shares issued related to the US and Canadian private placements on June 21, 2011
- 221,710 shares issued related to the cashless exercise of warrants on June 23, 2011
- 18,531 shares issued related to the exercise of agents' warrants on June 29, 2011

Capital stock is disclosed at its par value with the excess of proceeds shown in Additional Paid-in-Capital.

Additional Paid-in-Capital

Additional paid-in capital totaled $14,090 thousand at June 30, 2011 compared with $11,087 thousand at December 31, 2010. The change is made up of increases of $2,414 thousand, $817 thousand, and $153 thousand for the private placements completed on June 21, 2011 in relation to common stock issued, warrants, and agent's compensation respectively as well as a decrease of $522 thousand for transaction costs. Additional paid in capital also increased by $117 thousand related to the exercise of agents' warrants and $24 thousand for stock-based compensation, of which approximately $7 thousand is attributable to the amortization of stock options granted to our investor relations consultants and approximately $17 thousand is attributable to the amortization of stock options granted to employees and directors.

Key items from the Statement of Cash Flows for the six month period ended June 30, 2011 compared to the six month period ended June 30, 2010

In U.S.$ thousands	2011	2010	Increase/ (Decrease)	Percent Chang
Operating Activities	$ (1,013)	$ (1,157)	$ (144)	1
Financing Activities	2,978	-	2,978	1
Investing Activities	(3)	(5)	(2)	4
Cash and cash equivalents - end of period	3,201	375	2,826	75

Statement of cash flows

Net cash used by operating activities was $1,013 thousand in the six months ended June 30, 2011 compared to $1,157 thousand for the same period in 2010. In the first six months of 2011, net cash used by operating activities consisted of an operating loss of $1,180 thousand and an increase in non-cash operating elements of working capital of $74 thousand.

Operating activities will continue to consume our available funds until we are able to generate increased revenues.

The net cash provided by financing activities was $2,978 thousand in the first six months of 2011, compared to $Nil in the same period of the previous year. The net cash provided in 2011 resulted primarily from the US and Canadian private placements completed on June 21, 2011 for gross proceeds of approximately $3.2 million, less related transaction costs of $369 thousand, plus the exercise of agents warrants for 246,156 common shares having a par value of $0 thousand for cash consideration of $117 thousand, resulting in an increase in additional paid-in capital of $117 thousand.

Net cash used in investing activities amounted to $3 thousand in the six months ended June 30, 2011 compared to $5 thousand in the first six months of 2010.

The balance of cash and cash equivalents as at June 30, 2011 amounted to $3,201 thousand, compared to $375 thousand at June 30, 2010.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Forward-Looking and Cautionary Statements

This report contains certain forward-looking statements that involve risks and uncertainties relating to, among other things, our future financial performance or future events. Forward-looking statements give management s current expectations, plans, objectives, assumptions or forecasts of future events. All statements other than statements of current or historical fact contained in this Form 10Q, including

statements regarding our future financial position, business strategy, budgets, projected costs and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipate, estimate, plans, potential, projects, ongoing, exp management believes, we believe, "we intend," and similar expressions. These statements involve known and unknown risks, estimates, assumptions and uncertainties that could cause actual results to differ materially from the results set forth in this Annual Report. You should not place undue reliance on these forward-looking statements. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors such as: continued development of our technology; lack of product revenues successful completion of clinical trials and obtaining regulatory approval to market ability to protect our intellectual property dependence on collaborative partners ability to generate positive cash flow ability to raise additional capital if and when necessary dependence on key personnel; competitive factors; the operation of our business; and general economic conditions.

These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward looking statements. These forward-looking statements speak only as of the date on which they are made, and except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Item 3. Controls and Procedures.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of management, including our chief executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934. Based upon that evaluation, our chief executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to cause the material information required to be disclosed by us in the reports that we file or submit under the Exchange Act to be recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. There have been no significant changes in our internal controls or in other factors which could significantly affect internal controls subsequent to the date we carried out our evaluation.

PART II

Item 1. Legal Proceedings

This Item is not applicable

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

This Item is not applicable.

Item 3. Defaults Upon Senior Securities

This Item is not applicable.

Item 4. (Reserved)

Item 5. Other Information

This Item is not applicable.

Item 6. Exhibits

Exhibit 31.1	Certification of C.E.O. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 31.2	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.1	Certification of C.E.O. pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.2	Certification of Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTELGENX TECHNOLOGIES CORPORATION

Date: August 8, 2011 By: /S/ *Horst Zerbe*
Horst G. Zerbe
President, C.E.O. and Director

Date: August 8, 2011 By: /S/ *Paul Simmons*
Paul A. Simmons
Principal Accounting Officer