IntelGenx Technologies Corp. Form 10-Q August 07, 2014

# 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, 2014

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 <u>000-31187</u>

# **INTELGENX TECHNOLOGIES CORP.**

(Exact name of small business issuer as specified in its charter)

#### **Delaware**

#### <u>87-0638336</u>

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

#### 6425 Abrams, Ville Saint Laurent, Quebec H4S 1X9, Canada

(Address of principal executive offices)

#### (514) 331-7440

(Issuer's telephone number)

(Former Name former Address if shaped since lest report)

(Former Name, former Address, if changed since last report)

Indicate by checkmark 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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, a accelerated filer, non-accelerated filer

and smaller reporting company in Rule 12b-2 of the Exchange Act.	
Large accelerated filer [ ]	Accelerated filer [
Non-accelerated filer [ ] (Do not check if a smaller reporting company)  APPLICABLE ONLY TO ISSUERS INVOLVED IN  PROCEEDS DURING THE PRECEDING FIV	
Indicate by check mark whether the registrant has filed all documents and rep 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribut by a court.	
	Yes [ ] No [ ]
APPLICABLE TO CORPORATE ISSUE	ERS:

63,465,256 shares of the issuer s common stock, par value \$.00001 per share, were issued and outstanding as of August 7, 2014.

# IntelGenx Technologies Corp. Form 10-Q

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Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

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# Consolidated Balance Sheet (Expressed in Thousands of U.S. Dollars (\$000~s) Except Share and Per Share Data) (Unaudited)

	June 30, 2014	Dec	cember 31, 2013
Assets			
Current	- 1-0		
Cash and cash equivalents	\$ 5,178	\$	5,005
Accounts receivable	53		144
Prepaid expenses	93		133
Investment tax credits receivable	217		268
Total Current Assets	5,541		5,550
Leasehold Improvements and Equipment, net	744		588
Intangible Assets (note 4)	59		79
Total Assets	\$ 6,344	\$	6,217
	 -,	•	-,
Liabilities			
Current			
Accounts payable and accrued liabilities	266		593
Deferred license revenue (note 5)	358		308
Total Current Liabilities	624		901
<b>Deferred License Revenue, non-current portion</b> (note 5)	154		308
Total Liabilities	778		1,209
Shareholders' Equity			
Capital Stock (note 6)	1		1
Additional Paid-in-Capital	22,618		20,934
-	·		·
Accumulated Deficit	(17,158)		(16,102)
Accumulated Other Comprehensive Income	105		175
Total Shareholders Equity	5,566		5,008

\$ 6,344 \$ 6,217

See accompanying notes

Approved on Behalf of the Board:

/s/ J. Bernard Boudreau Director

/s/ Horst G. Zerbe Director

Consolidated Statement of Shareholders' Equity
For the Period Ended June 30, 2014
(Expressed in Thousands of U.S. Dollars (\$000 s) Except Share and Per Share Data)
(Unaudited)

	Capital Number	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
Balance - December 31, 2013	60,984,267	\$ 1	\$ 20,934	\$ (16,102)	\$ 175	\$ 5,008
Foreign currency translation adjustment	-	-	-	-	(70)	(70)
Warrants exercised (note 7)	2,480,988	-	1,619	-	-	1,619
Stock-based compensation (note 7)	-	-	65	-	-	65
Net loss for the period	-	-	-	(1,056)	-	(1,056)
Balance June 30, 2014 See accompanying in	63,465,255	\$ 1	, , , , ,	\$ (17,158)	\$ 105	\$ 5,566
			3			

Consolidated Statement of Comprehensive Income (Loss) (Expressed in Thousands of U.S. Dollars (\$000 s) Except Share and Per Share Data) (Unaudited)

	For the Three-Month Period Ended June 30,					For the Six-Month Period Ended June 30,		
		2014		2013		2014	2013	
Revenues								
Royalties	\$	84	\$	14	\$	181	\$ 91	
License and other revenue		76		533		201	613	
Total Revenues		160		547		382	704	
Expenses								
		225		40		412	215	
Research and development expense Selling, general and administrative expense		225 543		48 394		413 1,003	215 850	
Depreciation of tangible assets		7		7		1,003	17	
Amortization of intangible assets		11		9		20	19	
<b>Total Costs and Expenses</b>		786		458		1,450	1,101	
Profit (Loss) from Operations		(626)		89		(1,068)	(397)	
Other Income								
Interest and other income		12		1		12	1	
<b>Total Other Income</b>		12		1		12	1	
Net Profit (Loss)		(614)		90		(1,056)	(396)	
Other Comprehensive Income (Loss)								
Foreign currency translation adjustment		161		(71)		(70)	(107)	
Comprehensive Profit (Loss)	\$	(453)	\$	19	\$	(1,126)	\$ (503)	
Basic and Diluted Weighted Average Number of Shares Outstanding		63,187,029		51,166,323		62,628,686	51,133,173	
Basic and Diluted Profit (Loss) Per Common Share (note 9)	\$	(0.01)	\$	0.00	\$	(0.02)	\$ (0.01)	
(note 9) See accompanying notes	\$	(0.01)	\$	0.00	<b>\$</b>	(0.02)	\$ (0.01)	

# Consolidated Statement of Cash Flows (Expressed in thousands of U.S. Dollars (\$000~s) Except Share and Per Share Data) (Unaudited)

	Fo	r the Three Ended.		30,	Ended J	Month Period June 30,
		2014		2013	2014	2013
Funds Provided (Used) -						
Operating Activities						
Net profit (loss)	\$	(614)	\$	90	\$ (1,056)	\$ (396)
Amortization and depreciation		18		16	34	36
Stock-based compensation		33		30	65	48
·		(563)		136	(957)	(312)
Changes in assets and liabilities:						
Accounts receivable		(27)		(190)	91	922
Prepaid expenses		1		(5)	40	8
Investment tax credits receivable		68		(25)	51	(55)
Accounts payable and accrued liabilities		<b>(17)</b>		(163)	(327)	(724)
Deferred revenue		(77)		(76)	(104)	(153)
Net change in assets and liabilities		(52)		(459)	(249)	(2)
Net cash used by operating activities		(615)		(323)	(1,206)	(314)
Financing Activities						
Proceeds from exercise of warrants and stock						
options		555		587	1,619	782
Net cash provided by financing activities		555		587	1,619	782
Investing Activities						
Additions to property and equipment		(63)		(92)	(168)	(161)
Net cash used in investing activities		(63)		(92)	(168)	(161)
		(100)		170	245	207
Increase (Decrease) in Cash and Cash Equivalents		(123)		172	245	307
Effect of Foreign Exchange on Cash and Cash		105		(5.6)	(50)	(02)
Equivalents		135		(56)	(72)	(82)
Cash and Cash Equivalents		<b>5</b> 166		2.160	5.005	2.050
Beginning of Period	φ	5,166	ф	2,168	5,005	2,059
End of Period	\$	5,178	\$	2,284	\$ 5,178	\$ 2,284
See accompanying notes						
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Notes to Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

#### 1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete consolidated financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation have been included. All such adjustments are of a normal and recurring nature.

These financial statements should be read in conjunction with the audited consolidated financial statements at December 31, 2013. Operating results for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. The Company prepares its financial statements in accordance with accounting principles generally accepted in the United States (U.S. GAAP). This basis of accounting involves the application of accrual accounting and consequently, revenues and gains are recognized when earned, and expenses and losses are recognized when incurred.

The consolidated financial statements include the accounts of the Company and its subsidiary companies. On consolidation, all inter-entity transactions and balances have been eliminated.

The financial statements are expressed in U.S. funds.

Management has performed an evaluation of the Company s activities through the date and time these financial statements were issued and concluded that there are no additional significant events requiring recognition or disclosure.

#### 2. Adoption of New Accounting Standards

#### **Revenue Recognition and Disclosures**

The FASB issued Update No. 2013-04, Liabilities (Topic 405) Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date . The amendments in this Update provide guidance for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation within the scope of this Update is fixed at the reporting date, except for obligations addressed within existing guidance in U.S. GAAP. The guidance requires an entity to measure those obligations as the sum of the amount the reporting entity agreed to pay on the basis of its arrangement among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The guidance in this Update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. For public entities, the amendments in this ASU were applicable for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this Statement did not have a material effect on the Company s financial position or results of operations.

Notes to Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

#### 2. Adoption of New Accounting Standards (Cont d)

The FASB issued Update No. 2013-05, Foreign Currency Matters (Topic 830) Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity. The amendments in this Update resolve the diversity in practice about whether Subtopic 810-10, Consolidation Overall, or Subtopic 830-30, Foreign Currency Matters Translation of Financial Statements, applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. In addition, the amendments in this Update resolve the diversity in practice for the treatment of business combinations achieved in stages (sometimes also referred to as step acquisitions) involving a foreign entity. For public entities, the amendments in this ASU were effective prospectively for fiscal years, and interim reporting periods within those years, beginning after December 15, 2013. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued Update No. 2013-07, Presentation of Financial Statements Liquidation Basis of Accounting. The objective of this Update is to clarify when an entity should apply the liquidation basis of accounting and to provide principles for the measurement of assets and liabilities under the liquidation basis of accounting, as well as any required disclosures. These amendments were effective for entities that determine liquidation is imminent during annual reporting periods beginning after December 15, 2013, and interim reporting periods therein. Entitles should apply the requirements prospectively from the day that liquidation becomes imminent. The adoption of this Statement did not have a material effect on the Company s financial position or results of operations.

The FASB issued Update No. 2013-11, Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. The amendments in this ASU provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss, or tax credit carryforward exists. The amendments were effective for fiscal years, and interim periods within those years, beginning after December 15, 2013 and should be applied prospectively to all unrecognized tax benefits that exist at the effective date. The adoption of this Statement did not have a material effect on the Company s financial position or results of operations.

#### 3. Significant Accounting Policies

#### **Recently Issued Accounting Pronouncements**

ASU 2014-12, Compensation Stock Compensation (Topic 718): Accounting for shared-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period.

The FASB has issued ASU No. 2014-12 which requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718, *Compensation Stock Compensation*, as it relates to awards with performance conditions that affect vesting to account for such awards. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of ASU-2014-12 is not expected to have material effect on the Company s financial position or results of operations.

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Notes to Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

#### 3. Significant Accounting Policies (Cont d)

ASU No. 2014-09, Revenues from Contracts with Customers (Topic 606)

The FASB and IASB (the Boards) have issued converged standards on revenue recognition. ASU No. 2014-09 affects any entity using U.S. GAAP that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. This ASU will supersede the revenue recognition requirements in Topic 605, *Revenue Recognition* and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

For a public entity, the amendments in this ASU are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. This ASU is to be applied retrospectively, with certain practical expedients allowed. Early application is not permitted. The Company is currently evaluating the impact of this statement on its consolidated financial statements.

ASU No. 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity

The FASB has issued ASU No. 2014-08 which enhance convergence between U.S. GAAP and International Financial Reporting Standards (IFRS). The amendments in the ASU change the criteria for reporting discontinued operations while enhancing disclosures in this area. It also addresses sources of confusion and inconsistent application related to financial reporting of discontinued operations guidance in U.S. GAAP. Under the new guidance, only disposals representing a strategic shift in operations should be presented as discontinued operations. Those strategic shifts should have a major effect on the organization—s operations and financial results. Examples include a disposal of a major geographic area, a major line of business, or a major equity method investment. In addition, the new guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The amendments in the ASU are effective in the first quarter of 2015 for public organizations with calendar year ends. Early adoption is permitted. The adoption of ASU-2014-08 is not expected to have material effect on the Company—s financial position or results of operations.

Notes to Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

#### 4. Intangible Assets

As of June 30, 2014 NDA acquisition costs of \$59 thousand (December 31, 2013 - \$79 thousand) were recorded as intangible assets on the Company s balance sheet and represent the net book value of the final progress payment related to the acquisition of 100% ownership of Forfivo XL®. The asset is being amortized over its estimated useful life of 39 months. The Company commenced amortization upon commercial launch of the product in October 2012.

#### 5. Deferred License Revenue

Deferred license revenue represents upfront payments received for the granting of licenses to the Company s patents, intellectual property, and proprietary technology, for commercialization. Deferred license revenue is recognized in income over the period where sales of the licensed products will occur.

Upon entering into the licensing agreement with Edgemont Pharmaceuticals the Company received an upfront fee of \$1 million, which the Company recognized as deferred license revenue. The deferred license revenue is being amortized in income over a period of 39 months, which is the minimum period where sales of Forfivo XL® are expected to be exclusive.

In January, 2014 IntelGenx entered into a development and commercialization agreement with Par Pharmaceutical, Inc. for two products. The Company received \$100 thousand upon execution of the agreement, of which \$50 thousand has been recognized as deferred revenue until certain development milestones have been achieved.

As a result of this policy, the Company has a deferred revenue balance of \$512 thousand at June 30, 2014 (December 31, 2013 - \$616 thousand) that has not been recognized as revenue.

#### 6. Capital Stock

	June 30, 2014	December 31, 2013	
Authorized - 100,000,000 common shares of \$0.00001 par value 20,000,000 preferred shares of \$0.00001 par value			
Issued -			
63,465,255 (December 31, 2013 - 60,984,267) common shares	\$ 635	\$ 610	

Notes to Consolidated Interim Financial Statements June 30, 2014 (Expressed in U.S. Funds) (Unaudited)

#### 7. Additional Paid-In Capital

#### **Stock options**

No stock options were exercised during the six month period ended June 30, 2014. During the six month period ended June 31, 2013 a total of 75,000 stock options were exercised for 75,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$31 thousand, resulting in an increase in additional paid-in capital of \$31 thousand.

Compensation expenses for stock-based compensation of \$65 thousand and \$48 thousand were recorded during the six month periods ended June 30, 2014 and 2013 respectively. The entire amount expensed in 2014 relates to stock options granted to employees and directors. Of the amount expensed in 2013, \$37 thousand relates to stock options granted to employees and directors and \$11 thousand relates to options granted to independent third party consultants. As at June 30, 2014 the Company has \$161 thousand (2013 - \$229 thousand) of unrecognized stock-based compensation.

#### Warrants

During the six month period ended June 30, 2014 a total of 2,480,988 (2013 - 1,584,000) warrants were exercised for 2,480,988 (2013 - 1,584,000) common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$1,619 thousand (2013 - \$751 thousand), resulting in an increase in additional paid-in capital of \$1,619 thousand (2013 - \$750 thousand).

#### 8. Related Party Transactions

Included in management salaries are \$29 thousand (2013 - \$5 thousand) for options granted to the Chief Executive Officer, \$Nil (2013 - \$10 thousand) for options granted to the Chief Operating Officer and \$22 thousand (2013 - \$9 thousand) for options granted to the Chief Financial Officer under the 2006 Stock Option Plan and \$8 thousand (2013 - \$6 thousand) for options granted to non-employee directors.

Also included in management salaries are director fees of \$88 thousand (2013 - \$44 thousand) for attendance to board meetings and audit committee meetings.

In addition, during the first six months of 2013 the Company paid \$66 thousand in fees to a director under a management consultancy agreement. No such fees were paid during the first six months of 2014.

The above related party transactions have been measured at the exchange amount which is the amount of the consideration established and agreed to by the related parties.

#### 9. Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share is calculated based on the weighted average number of shares outstanding during the period. The warrants and stock options have been excluded from the calculation of diluted loss per share since they are anti-dilutive.

# Item 2: MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Introduction to management s discussion and analysis

The purpose of this section, Management s Discussion and Analysis of Financial Condition and Results of Operations, is to provide a narrative explanation of the financial statements that enables investors to better understand the business of the Company, to enhance the Company s overall financial disclosures, to provide the context within which the Company s financial information may be analyzed, and to provide information about the quality of, and potential variability of, the Company s financial condition, results of operations and cash flows. Unless otherwise indicated, all financial and statistical information included herein relates to continuing operations of the Company. Unless otherwise indicated or the context otherwise requires, the words, IntelGenx, Company, we, us, and our refer to Intel-Technologies Corp. and its subsidiaries, including IntelGenx Corp. This information should be read in conjunction with the accompanying unaudited Consolidated Financial Statements and Notes thereto.

#### 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 areas of research and development, manufacturing, and administration on an as-needed basis as we enter into partnership agreements, establish our pilot plant VersaFilm manufacturing capability, and increase our research and development activities.

#### **Key developments**

#### Anti-migraine VersaFilm product

On February 4, 2014, together with our co-development partner RedHill Biopharma Ltd. ("RedHill"), we announced receipt of a Complete Response Letter ("CRL") from the FDA regarding the New Drug Application ("NDA") for our VersaFilm product for the treatment of acute migraines. The anti-migraine VersaFilm product is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT1 receptor agonist and the active drug in Merck & Co.'s Maxalt®.

A CRL is issued by the FDA's Center for Drug Evaluation and Research to inform companies that certain questions and deficiencies remain that preclude the approval of the application in its present form. The questions raised by the FDA in the CRL regarding the NDA for the anti-migraine VersaFilm product primarily relate to Chemistry, Manufacturing and Controls ("CMC") and to the packaging and labeling of the product. No questions or deficiencies were raised relating to the product's safety and the FDA's CRL does not require additional clinical studies.

On March 3, 2014 IntelGenx and RedHill (the Companies) announced the submission of a response to the FDA s CRL and on April 24, 2014 the Companies reported that the FDA had acknowledged receipt of our response and has requested additional CMC data, which the Companies believe they can supply based on available information.

The Companies further reported that a supplier of raw material for the anti-migraine VersaFilm product is currently holding compliance discussions with the FDA, which are independent of RedHill and IntelGenx and are not specific to our anti-migraine VersaFilm product. The Companies are diligently working on a variety of options to ensure continued supply of the raw material regardless of the result of these compliance discussions and have already identified and audited an alternative active pharmaceutical ingredient (API) supplier and are preparing to manufacture the batches required for the CRL response and to conduct the stability studies that are required to support the switch to the new API.

On April 28, 2014 the Companies announced the commencement of a comparative bioavailability clinical study comparing the anti-migraine VersaFilm product to the European reference drug. The study is intended to support the planned submission of a European Marketing Authorization Application ("MAA") and follows a positive scientific advice meeting with the German Federal Institute for Drugs and Medical Devices ("BfArM") announced by RedHill in November 2013. This single-dose, crossover, comparative bioavailability study includes 26 healthy volunteers and is intended to evaluate and compare the relative bioavailability and to assess the bioequivalence of the anti-migraine VersaFilm product and the reference drug, Maxalt® lingua, marketed in Germany by MSD SHARP & DOHME GMBH.

On May 21, 2014 the Companies announced positive results from the comparative bioavailability study. The results are subject to final quality assurance and an independent study report by the Canadian clinical research organization ("CRO") that conducted the study. The final independent report from the CRO is expected in the coming weeks.

In light of the positive results from the bioavailability study and data from prior clinical studies conducted with the anti-migraine VersaFilm product, and subject to various regulatory requirements, the Companies plan to submit a European MAA during the third quarter of 2014.

#### Par Pharmaceutical, Inc.

On January 13, 2014 we announced the execution of a second development and commercialization agreement with Par Pharmaceutical, Inc. ("Par") for two new products utilizing our proprietary oral drug delivery platforms.

Under the terms of the agreement, Par has obtained certain exclusive rights to market and sell our products in the USA. In exchange we will receive upfront and milestone payments, together with a share of the profits upon commercialization. In accordance with confidentiality clauses contained in the agreement, the specifics of the products and financial terms remain confidential.

#### Erectile Dysfunction VersaFilm product

On February 24, 2014 we announced the completion of a pilot biostudy with our proprietary VersaFilm tadalafil product for erectile dysfunction that indicated bioequivalence with the leading brand reference listed drug ( RLD ) tadalafil product.

This was a randomized, two-period, two-way crossover study in healthy male subjects. The study was designed to determine whether VersaFilm tadalafil was bioequivalent as measured by industry standard pharmacokinetic measures of peak plasma concentration (Cmax) and area under the curve (AUC). The study results demonstrated that VersaFilm tadalafil was within an acceptable range of bioequivalency with the RLD on both of these measures.

#### Government Funding for CNS VersaFilm product

On April 30, 2014 we announced financial support from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP). In addition to advisory services and technological expertise, the funding provided by NRC-IRAP will support further development of a product for the treatment of central nervous system (CNS) diseases and disorders. The product will be based upon our proprietary, oral thin film, VersaFilm, technology.

In order to maintain our competitive advantage, no specific details related to this project are being disclosed at this time.

#### U.S. patent allowances

On February 26, 2014 we announced receipt of a Notice of Allowance ("NOA") from the United States Patent and Trademark Office ("USPTO") for U.S. Patent Application Serial No. 11/647,033 entitled "Multilayer tablet" which covers the technology used in our hypertension product currently under development. A second NOA has been received for U.S. Patent Application Serial No. 11/782,838 entitled "Controlled-release pharmaceutical tablets" which is related to the drug delivery technology used in Forfivo XL®, our first FDA-approved product currently commercialized in the U.S. These two NOA's conclude the examination of each U.S. patent application and will result in the issuance of two U.S. patents after administrative processes are completed.

On April 16, 2014 we announced receipt of a further NOA from the USPTO for U.S. Patent Application Serial No. 12/836,810 entitled "Oral mucoadhesive dosage form" which covers IntelGenx' proprietary AdVersa mucoadhesive drug delivery technology. This NOA concludes the examination of the U.S. patent application and will result in the issuance of a U.S. patent after the administrative process is completed.

#### Equity Analyst Coverage by H.C. Wainwright

Subsequent to the end of the quarter, on July 1, 2014 we announced that H.C. Wainwright initiated equity analyst coverage of IntelGenx with a "buy" rating and price target of \$2. The stock closed at US\$0.70 on the OTCQX and at CAD\$0.74 on the TSX-V on Friday, June 27, 2014.

A copy of the initiation report can be accessed by clicking: <a href="https://hcwco.bluematrix.com/docs/pdf/ff51024b-71e2-47c5-ab58-7d05118ab4aa.pdf">https://hcwco.bluematrix.com/docs/pdf/ff51024b-71e2-47c5-ab58-7d05118ab4aa.pdf</a>.

All reports on us prepared by analysts represent the views of such analysts and are not necessarily those of IntelGenx. We are not responsible for the content, accuracy or timelines provided by analysts.

#### **Management Changes**

Subsequent to the end of the quarter, on July 15, 2014 we announced that the board of directors (the "Board") of IntelGenx had accepted, with immediate effect, the resignation of Dr. Rajiv Khosla as President and Chief Executive Officer ("CEO") of IntelGenx and as a member of the Board. The Board immediately appointed Dr. Horst G. Zerbe to serve as our interim President and CEO until a successor is found, and a Search Committee has been formed by the Board to begin the search, selection and appointment of a new President and CEO.

#### Management Call

Subsequent to the end of the quarter, on July 18, 2014 we announced that our interim CEO, Dr. Horst G. Zerbe, would host a conference call on July 23, 2014 at 10:00 AM Eastern Time. During the conference call, Dr. Zerbe provided a business update, discussed recent management changes, and answered questions.

A replay of the call is available via the homepage of our website, www.intelgenx.com, and will remain available until at least September, 2014.

#### **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, 2014 compared with the six month period ended June 30, 2013.

In U.S.\$ thousands		2014	2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Revenue	\$	382	\$ 704	\$ (322)	(46%)
Research and Development Expenses		413	215	198	92%
Selling, General and Administrative Exper	ises	1,003	850	153	18%
Depreciation of tangible assets		14	17	(3)	(18%)
Amortization of intangible assets		20	19	1	5%
Net Loss		( <b>1,056</b> ) 14	(396)	660	167%

#### Revenue

Total revenue decreased from \$704 thousand in the first six months of 2013 to \$382 thousand in the first six months of 2014.

Of the total revenue recorded during the first six months of 2014, \$332 thousand (2013: \$247 thousand) relates to Forfivo XL®, our first FDA approved product, which was launched in October 2012 under a licensing partnership with Edgemont Pharmaceuticals LLP ("Edgemont"). Upon entering into the licensing agreement, Edgemont paid us an upfront fee of \$1 million, which we recognized as deferred license revenue. The deferred license revenue is being amortized in income over the period where sales of Forfivo XL® are expected to be exclusive. As a result of this policy, we recognized \$153 thousand in income during the first six months of 2014 (2013: \$156 thousand). In addition, we recognized approximately \$179 thousand (2013: \$91 thousand) of royalty income in the first six months of 2014 that was earned from commercial sales of Forfivo XL®. Pursuant to the contractual terms, royalty income relates to sales of Forfivo XL® recorded by Edgemont during the quarter preceding receipt of the royalty income by us. Forfivo XL® is indicated for the treatment of Major Depressive Disorder ("MDD") and is the only extended-release bupropion HCl product to provide a once-daily, 450mg dose in a single tablet.

Sales of Forfivo XL® continue to be below expectations and Management continues to explore options to accelerate sales growth of Forfivo XL®.

Revenue for the six months ended June 30, 2014 also includes a \$50 thousand milestone payment in respect of one of the two new projects being developed in accordance with our new development and commercialization agreement with Par, utilizing our proprietary oral drug delivery platforms. As previously stated, in accordance with confidentiality clauses contained in the agreement, the specifics of the product and financial terms remain confidential.

Revenue for the 6 months ended June 30, 2013 includes \$256 thousand related to a development milestone for our VersaFilm<sup>TM</sup> buprenorphine/naloxone product for the treatment of opiate addiction. The milestone became due following the successful completion of the pivotal bioequivalence study.

Also included in revenue for the first six months of 2013 is \$201 thousand related to a development milestone for our anti-migraine VersaFilm<sup>TM</sup> oral film product. The milestone became due following confirmation that our NDA submission to the FDA was sufficiently complete to permit a substantive review in accordance with the FDA's "standard" classification process.

#### Research and development ("R&D") expenses

R&D expenses, net of R&D investment tax credits, totaled \$413 thousand in the six months ended June 30, 2014, representing an increase of \$198 thousand to the amount of \$215 thousand expensed in the same period of 2013.

The increase in R&D expenses relates primarily to the costs of a pilot clinical study for our VersaFilm<sup>TM</sup> product for erectile dysfunction that was completed in Q1, 2014 and indicated bioequivalence with the leading brand reference listed drug tadalafil product. R&D expenses also increased as a result of costs incurred in the development of our second Par project, which is progressing according to plan.

Included within R&D expenses for the first six months of 2014 are R&D Salaries of \$240 thousand, of which approximately \$4 thousand represents non-cash compensation. This compares to R&D salaries of \$284 thousand in the first six months of 2013, of which approximately \$5 thousand represented non-cash compensation. The reduction in R&D salaries is primarily attributable to the retirement, effective December 31, 2013, of Dr. Horst Zerbe, our founder, and former President and CEO. 50% of Dr. Zerbe's expenses were previously apportioned to the R&D department. Dr. Zerbe remained available to us to consult on R&D activities until, following the resignation of Dr.

Rajiv Khosla, the Board appointed Dr. Zerbe Interim President and Interim CEO with effect from July 14, 2014.

In the six months ended June 30, 2014 we recorded estimated research and development tax credits and refunds of \$36 thousand, compared with \$69 thousand that was recorded in the same period of the previous year. The amounts of research and development tax credits and refunds recorded by us may fluctuate from reporting period to reporting period depending upon the level of activity surrounding projects that we are currently progressing, together with whether or not we are able to fulfill Canadian eligibility criteria for obtaining such tax credits and refunds.

#### Selling, general and administrative ("SG&A") expenses

SG&A expenses totaled \$1,003 thousand in the first 6 months of 2014, representing an increase of \$153 thousand compared with \$850 thousand in the first six months of 2013.

The increase in SG&A expenses relates primarily to an increase in legal expenses of approximately \$82 thousand related to our Paragraph IV litigation with Wockhardt Bio AG ("Wockhardt"). In August 2013 we received a Paragraph IV Certification Letter from Wockhardt, advising of the submission of an Abbreviated New Drug Application ("ANDA") to the FDA requesting authorization to manufacture and market generic versions of Forfivo XL® ("Forfivo") 450 mg capsules in the United States. We continue to enforce our intellectual property rights for Forfivo XL®, which is currently protected by an issued patent listed in the FDA's Approved Drug Products List (Orange Book).

SG&A expenses also increased by approximately \$47 thousand due to an increase in the remuneration of our Board of Directors that was effective from April 1, 2014.

Included in SG&A expenses are approximately \$53 thousand (2013: \$26 thousand) in non-cash compensation from options granted to management employees in 2012 and 2013, \$8 thousand (2013: \$6 thousand) in non-cash compensation from options granted to non-employee directors in 2013, and \$Nil (2013: \$11 thousand) in non-cash compensation from options granted to consultants in 2012.

#### **Depreciation of tangible assets**

In the six months ended June 30, 2014 we recorded an expense of \$14 thousand for the depreciation of tangible assets, compared with an expense of \$17 thousand for the same period of the previous year. As at June 30, 2014 we are carrying approximately \$608 thousand of assets, primarily VersaFilm<sup>TM</sup> manufacturing equipment, that are not being depreciated as they are not currently in service.

#### **Amortization of intangible assets**

The amortization of intangible assets expensed for the first six months of 2014 totaled \$20 thousand, compared with \$19 thousand in the same period of last year. The expense relates to the amortization of NDA acquisition costs in respect of the final progress payment to acquire 100% ownership of Forfivo XL®. Commercialization of Forfivo XL® in October 2012 triggered amortization of the asset over its estimated useful life of 39 months.

#### Share-based compensation expense, warrants and stock based payments

Share-based compensation expense, warrants and share-based payments totaled \$65 thousand for the six months ended June 30, 2014, compared with \$48 thousand for the six months ended June 30, 2013.

We expensed approximately \$57 thousand in the first six months of 2014 for options granted to our employees in 2011 and 2012 under the 2006 Stock Option Plan, and approximately \$8 thousand for options granted to non-employee directors in 2013, compared with \$31 thousand and \$6 respectively that was expensed in the same period of the previous year.

We also expensed \$11 thousand in the first six months of 2013 for options granted to consultants.

There remains approximately \$161 thousand in stock based compensation to be expensed in fiscal 2014 and 2015, all of which relates to the issuance of options to our employees and directors during 2012 and 2013. We anticipate the issuance of additional options and warrants in the future, which will continue to result in stock-based compensation expense.

#### Key items from the balance sheet.

In U.S.\$ thousands	June 30, 2014	December 31, 2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current Assets \$	5,541	\$ 5,550	\$ (9)	(0%)
Leasehold improvements and Equipment	744	588	156	27%
Intangible Assets	59	79	(20)	(25%)
Current Liabilities	624	901	(277)	(31%)
Deferred License Revenue	154	308	(154)	(50%)
Capital Stock	1	1	0	0%
Additional Paid-in-Capital	22,618	20,934	1,684	8%

#### **Current assets**

Current assets totaled \$5,541 thousand at June 30, 2014 compared with \$5,550 thousand at December 31, 2013. The decrease of \$9 thousand is attributable to a decrease in accounts receivable of approximately \$91 thousand, a decrease in prepaid expenses of approximately \$40 thousand, and a decrease in investment tax credits receivable of approximately \$51 thousand, partly offset by an increase in cash and cash equivalents of approximately \$173 thousand

#### Cash and cash equivalents

Cash and cash equivalents totaled \$5,178 thousand as at June 30, 2014 representing an increase of \$173 thousand compared with the balance of \$5,005 thousand as at December 31, 2013. The increase in cash on hand relates to net cash provided by financing activities of \$1,619 thousand, partly offset with net cash used by operating activities of \$1,206 thousand, net cash used in investing activities of \$168 thousand and an unrealized foreign exchange loss of \$72 thousand.

The cash provided by financing activities derives from the exercise of 2,480,988 warrants that were exercised for 2,480,988 common shares for cash consideration of \$1,619 thousand.

#### **Accounts receivable**

Accounts receivable totaled \$53 thousand as at June 30, 2014 representing a decrease of \$91 thousand compared with the balance of \$144 thousand as at December 31, 2013. The decreased balance relates to the payment of invoices in Q1, 2014 that were issued and outstanding at December 31, 2013.

#### **Prepaid expenses**

As of June 30, 2014 prepaid expenses totaled \$93 thousand compared with \$133 thousand as of December 31, 2013. The decrease in prepaid expenses relates to a deposit paid in December 2013 for a biostudy undertaken in the first quarter of 2014, and a deposit paid in 2013 for R&D machinery to be supplied and installed in 2014.

#### Investment tax credits receivable

R&D investment tax credits receivable totaled approximately \$217 thousand as at June 30, 2014 compared with \$268 thousand as at December 31, 2013. The decrease relates to the receipt in Q2, 2014 of the balance of the fiscal 2012 investment tax credit receivable in the amount of \$106 thousand, partly offset by the accrual recorded for the first six months of 2014.

#### Leasehold improvements and equipment

As at June 30, 2014, the net book value of leasehold improvements and equipment amounted to \$744 thousand, compared to \$588 thousand at December 31, 2013. In the six months ended June 30, 2014 additions to assets totaled \$168 thousand and comprised \$36 thousand for pilot plant manufacturing equipment for our VersaFilm<sup>TM</sup> products, \$107 thousand for R&D equipment, \$16 thousand for leasehold improvements and \$9 thousand for computer equipment. In the six months ended June 30, 2014 we recorded depreciation on leasehold improvements and equipment of \$14 thousand and incurred an unrealized foreign exchange gain of \$2 thousand.

#### **Intangible assets**

As at June 30, 2014 NDA acquisition costs of \$59 thousand (December 31, 2013 - \$79 thousand) were recorded as intangible assets on our balance sheet and are related to the acquisition of 100% ownership of Forfivo XL®. The asset is being amortized over its expected useful life of 39 months and amortization commenced upon commercial launch of Forfivo XL® in the fourth quarter of 2012.

#### **Current liabilities**

Current liabilities totaled \$624 thousand as at June 30, 2014 (December 31, 2013 - \$901 thousand) and consisted of accounts payable and accrued liabilities of \$266 thousand (December 31, 2013 - \$593 thousand) and the current portion of deferred license revenue of \$358 thousand (December 31, 2013 - \$308 thousand).

Included in the accounts payable and accrued liabilities balance of \$266 thousand as at June 30, 2014 is approximately \$41 thousand relating to research and development activities, approximately \$34 thousand relating to professional fees, and approximately \$146 thousand relates to accrued payroll liabilities. This compares with approximately \$100 thousand relating to research and development activities, approximately \$180 thousand relating to professional fees, of which approximately \$87 thousand relates to the public offering completed in December, 2013, and approximately \$301 thousand relates to accrued payroll liabilities, that was included in the accounts payable and accrued liabilities balance as at December 31, 2013.

#### Deferred license revenue

Pursuant to the execution of a licensing agreement for Forfivo XL®, we received an upfront fee from Edgemont Pharmaceuticals in the first quarter of 2012, which we recognized as deferred license revenue. The deferred license revenue is being amortized in income over the period where sales of Forfivo XL®<sup>TM</sup> are expected to be exclusive. As a result of this policy, we have a deferred revenue balance related to this upfront fee of \$462 thousand at June 30, 2014 (December 31, 2013: \$616 thousand) that has not been recognized as revenue, of which \$154 thousand is recognized as the non-current portion and \$308 thousand is recognized in current assets as the current portion. This compares

with \$308 thousand and \$308 thousand respectively as at December 31, 2013.

In January, 2014 IntelGenx entered into a development and commercialization agreement with Par Pharmaceutical, Inc. for two products. The Company received \$100 thousand upon execution of the agreement, of which \$50 thousand has been recognized in current liabilities as deferred revenue until certain development milestones that are expected to be achieved in 2014 have been realised.

#### Shareholders equity

As at June 30, 2014 we had accumulated a deficit of \$17,158 thousand compared with an accumulated deficit of \$16,102 thousand as at December 31, 2013. Total assets amounted to \$6,344 thousand and shareholders equity totaled \$5,566 thousand as at June 30, 2014, compared with total assets and shareholders equity of \$6,217 thousand and \$5,008 thousand respectively, as at December 31, 2013.

#### Capital stock

As at June 30, 2014 capital stock amounted to \$635 compared to \$610 at December 31, 2013. The increase reflects the issuance of 2,480,988 shares related to the exercise of warrants, with all shares issued at par value of \$0.00001. 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 \$22,618 thousand at June 30, 2014, compared with \$20,934 thousand at December 31, 2013. Additional paid-in capital increased by \$1,619 thousand for warrants exercised during the first quarter, and by \$65 thousand for stock based compensation attributable to the amortization of stock options granted to employees and directors.

#### **Taxation**

As at December 31, 2013, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately \$8,874 thousand (2012: \$8,390 thousand) and \$9,040 thousand (2012: \$8,566 thousand) respectively, which may be applied against earnings of future years. Utilization of the net operating losses is subject to significant limitations imposed by the change in control provisions. Canadian and provincial losses will be expiring between 2027 and 2033. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2013, we had non-refundable tax credits of \$1,098 thousand (2012 - \$914 thousand) of which \$22 thousand is expiring in 2017, \$212 thousand is expiring in 2018, \$186 thousand is expiring in 2019, \$158 thousand is expiring in 2020, \$169 thousand is expiring in 2021, \$232 thousand is expiring in 2022 and \$119 thousand is expiring in 2023. We also had undeducted research and development expenses of \$4,354 thousand (2012: \$4,464 thousand) with no expiration date.

The deferred tax benefit of these items was not recognized in the accounts as it has been fully provided for.

#### Key items from the statement of cash flows

In U.S.\$ thousands	June 30, 2014	June 30, 2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	\$ (1,206) \$	(314)	\$ 892	284%
Financing Activities	1,619 \$	782	\$ 837	107%
Investing Activities	(168)	(161)	7	4%
Cash and cash equivalents - end of period <b>Statement of cash flows</b>	5,178	2,284	2,894	127%

Net cash used by operating activities was \$1,206 thousand in the six months ended June 30, 2014, compared with \$314 thousand for the six months ended June 30, 2013. In the first six months of 2014, net cash used by operating activities consisted of an operating loss of \$957 thousand (2013: \$312 thousand) net of non-cash related expenses of approximately \$99 thousand (2013: \$84 thousand), and a decrease in non-cash operating elements of working capital of \$249 thousand, compared with a decrease of \$2 thousand in the same period of the previous year.

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 \$1,619 thousand in the first six months of 2014, compared with \$782 thousand provided in the same period of the previous year. The net cash provided in the first six months of 2014 resulted from the exercise of 2,480,988 warrants, whereas the cash provided in the first six months of 2013 resulted from the exercise of 1,584,000 warrants and 75,000 stock options.

Net cash used in investing activities amounted to \$168 thousand in the six months ended June 30, 2014 compared with \$161 thousand in the six months ended June 30, 2013. Included within the use of funds in the first six months of 2014 is an investment of approximately \$36 thousand (2013: \$160 thousand) for pilot plant manufacturing equipment for our VersaFilm products, \$107 thousand (2013: \$Nil) for R&D equipment, \$16 thousand (2013: \$Nil) for leasehold improvements and \$9 thousand (2013: \$1 thousand) for computer equipment.

The balance of cash and cash equivalents as at June 30, 2014 amounted to \$5,178 thousand, compared with \$2,284 thousand at June 30, 2013.

#### **Off-balance sheet arrangements**

We have no off-balance sheet arrangements.

#### 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.
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#### **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 7, 2014 By: /s/ Horst G. Zerbe

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Horst G. Zerbe

Interim President, Interim Chief Executive Officer

and Director

Date: August 7, 2014 By: /s/ Paul A. Simmons

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Paul A. Simmons Chief Financial Officer

(Principal Accounting Officer)

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