

IntelGenx Technologies Corp.  
Form 10-Q  
August 08, 2013

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended **June 30, 2013** 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 000-31187**

**INTELGENX TECHNOLOGIES CORP.**

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

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**87-0638336**

(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 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  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, 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

Smaller reporting company

company)

**APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDS DURING THE PRECEDING FIVE YEARS**

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes  No

**APPLICABLE TO CORPORATE ISSUERS:**

52,710,421 shares of the issuer's common stock, par value \$.00001 per share, were issued and outstanding as of August 6, 2013.

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IntelGenx Technologies Corp.  
Form 10-Q

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**IntelGenx Technologies Corp.**

**Consolidated Interim Financial Statements**

**June 30, 2013**

**(Expressed in U.S. Funds)**

**(Unaudited)**

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## IntelGenx Technologies Corp.

## Consolidated Balance Sheet

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

	June 30, 2013	December 31, 2012
<b>Assets</b>		
<b>Current</b>		
Cash and cash equivalents	\$ 2,284	\$ 2,059
Accounts receivable	360	1,282
Prepaid expenses	94	102
Investment tax credits receivable	268	213
<b>Total Current Assets</b>	<b>3,006</b>	<b>3,656</b>
<b>Leasehold Improvements and Equipment, net</b>	<b>507</b>	<b>387</b>
<b>Intangible Assets (note 4)</b>	<b>97</b>	<b>116</b>
<b>Total Assets</b>	<b>\$ 3,610</b>	<b>\$ 4,159</b>
<b>Liabilities</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	336	1,058
Deferred license revenue (note 5)	308	308
<b>Total Current Liabilities</b>	<b>644</b>	<b>1,366</b>
<b>Deferred License Revenue, non-current portion (note 5)</b>	<b>461</b>	<b>615</b>
<b>Total Liabilities</b>	<b>1,105</b>	<b>1,981</b>
<b>Shareholders' Equity</b>		
<b>Capital Stock (note 6)</b>	<b>1</b>	<b>0</b>
<b>Additional Paid-in-Capital</b>	<b>17,171</b>	<b>16,342</b>
<b>Accumulated Deficit</b>	<b>(14,859)</b>	<b>(14,463)</b>
<b>Accumulated Other Comprehensive Income</b>	<b>192</b>	<b>299</b>
	<b>2,505</b>	<b>2,178</b>
	<b>\$ 3,610</b>	<b>\$ 4,159</b>

See accompanying notes

## Approved on Behalf of the Board:

/s/ J. Bernard Boudreau Director

/s/ Horst G. Zerbe Director

**IntelGenx Technologies Corp.****Consolidated Statement of Shareholders' Equity****For the Period Ended June 30, 2013****(Expressed in Thousands of U.S. Dollars (\$000 s) Except Share and Per Share Data)****(Unaudited)**

	<u>Capital Stock</u>		Additional	Accumulated	Accumulated	Other	<b>Total</b>
	Number	Amount	Paid-In	Deficit	Comprehensive	Income	<b>Shareholders'</b>
			Capital		Income		<b>Equity</b>
<b>Balance - December 31, 2012</b>	49,890,421	\$ 0	\$ 16,342	\$ (14,463)	\$ 299		<b>\$ 2,178</b>
Foreign currency translation adjustment	-	-	-	-	(107)		<b>(107)</b>
Warrants exercised (note 7)	1,584,000	1	750	-	-		<b>751</b>
Options exercised (note 7)	75,000	-	31	-	-		<b>31</b>
Stock-based compensation (note 7)	-	-	48	-	-		<b>48</b>
Net loss for the period	-	-	-	(396)	-		<b>(396)</b>
<b>Balance June 30, 2013</b>	<b>51,549,421</b>	<b>\$ 1</b>	<b>\$ 17,171</b>	<b>\$ (14,859)</b>	<b>\$ 192</b>		<b>\$ 2,505</b>

See accompanying notes

**IntelGenx Technologies Corp.****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 Pe riod Ended June 30,	
	2013	2012	2013	2012
<b>Revenues</b>				
Royalties	\$ 14	\$ -	\$ 91	\$ -
License and other revenue	533	20	613	20
<b>Total Revenues</b>	<b>547</b>	<b>20</b>	<b>704</b>	<b>20</b>
<b>Expenses</b>				
Research and development expense	48	310	215	310
Selling, general and administrative expense	394	332	850	332
Amortization of tangible assets	7	9	17	9
Amortization of intangible assets	9	-	19	-
<b>Total Costs and Expenses</b>	<b>458</b>	<b>651</b>	<b>1,101</b>	<b>651</b>
<b>Profit (Loss) from Operations</b>	<b>89</b>	<b>(631)</b>	<b>(397)</b>	<b>(631)</b>
<b>Other Income</b>				
Interest and other income	1	1	1	1
<b>Total Other Income</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Net Profit (Loss)</b>	<b>90</b>	<b>(630)</b>	<b>(396)</b>	<b>(630)</b>
<b>Other Comprehensive Income (Loss)</b>				
Foreign currency translation adjustment	(71)	(73)	(107)	(73)
<b>Comprehensive Profit (Loss)</b>	<b>\$ 19</b>	<b>\$ (703)</b>	<b>\$ (503)</b>	<b>\$ (703)</b>
<b>Basic and Diluted Weighted Average Number of Shares Outstanding</b>	<b>51,166,323</b>	<b>49,622,028</b>	<b>51,133,173</b>	<b>49,473,000</b>
Basic and Diluted Profit (Loss) Per Common Share (note 9)	\$ 0.00	\$ (0.01)	\$ (0.01)	\$ (0.01)
			\$	\$

See accompanying notes

**IntelGenx Technologies Corp.****Consolidated Statement of Cash Flows****(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,	
	2013	2012	2013	2012
<b>Funds Provided (Used) -</b>				
<b>Operating Activities</b>				
Net profit (loss)	\$ 90	\$ (630)	\$ (396)	\$ (1,214)
Amortization	16	9	36	17
Stock-based compensation	30	14	48	29
	<b>136</b>	<b>(607)</b>	<b>(312)</b>	<b>(1,168)</b>
Changes in assets and liabilities				
Accounts receivable	(190)	(145)	922	(127)
Prepaid and other assets	(5)	-	8	(15)
Other receivables	(25)	(20)	(55)	229
Accounts payable and other accrued liabilities	(163)	(115)	(724)	(383)
Deferred revenue	(76)	-	(153)	1,000
<b>Net change in assets and liabilities</b>	<b>(459)</b>	<b>(280)</b>	<b>(2)</b>	<b>704</b>
<b>Net cash provided (used) by operating activities</b>	<b>(323)</b>	<b>(887)</b>	<b>(314)</b>	<b>(464)</b>
<b>Financing Activities</b>				
Proceeds from exercise of warrants and stock options	587	1	782	234
<b>Net cash provided by financing activities</b>	<b>587</b>	<b>1</b>	<b>782</b>	<b>234</b>
<b>Investing Activities</b>				
Additions to property and equipment	(92)	(53)	(161)	(242)
<b>Net cash used in investing activities</b>	<b>(92)</b>	<b>(53)</b>	<b>(161)</b>	<b>(242)</b>
<b>Increase (Decrease) in Cash and Cash Equivalents</b>	<b>172</b>	<b>(939)</b>	<b>307</b>	<b>(472)</b>
<b>Effect of Foreign Exchange on Cash and Cash</b>				

<b>Equivalents</b>	<b>(56)</b>		<b>(65)</b>		<b>(82)</b>		<b>22</b>
<b>Cash and Cash Equivalents</b>							
<b>Beginning of Period</b>	<b>2,168</b>		4,059		<b>2,059</b>		3,505
<b>End of Period</b>	\$ <b>2,284</b>	\$	3,055	\$	<b>2,284</b>	\$	3,055
See accompanying notes							

**IntelGenx Technologies Corp.**

**Notes to Consolidated Interim Financial Statements**

**June 30, 2013**

**(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, 2012. Operating results for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. 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**

In December 2011, the FASB issued Update No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities . The objective of this Update is to provide enhanced disclosures that will enable users of financial statements to evaluate the effect or potential effect of netting arrangements on an entity's financial position. This includes the effect or potential effect of rights of setoff associated with an entity's recognized assets and recognized liabilities within the scope of this Update. The amendments require enhanced disclosures by requiring improved information about derivatives, repurchase agreements and reverse purchase agreements, and securities borrowing and securities lending transactions that are either offset in accordance with specific criteria or subject to a master netting arrangement or similar agreement. In January 2013, the FASB also issued Update No. 2013-01, which clarifies that ordinary trade receivables and receivables are not in the scope of ASU 2011-11. ASU 2011-11 and ASU 2013-01 are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. Retrospective disclosure is required for all comparative periods presented. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Interim Financial Statements**

**June 30, 2013**

**(Expressed in U.S. Funds)**

**(Unaudited)**

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

In February 2013, the FASB has issued Update No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income . This Update has been issued to improve the transparency of reporting these reclassifications. The amendments in this Update supersede and replace the presentation requirements for reclassifications out of accumulated other comprehensive income in ASUs 2011-05 and 2011-12 for all public and private organizations. The amendments would require an entity to provide additional information about reclassifications out of accumulated other comprehensive income. Public companies are required to comply with these amendments for all reporting periods (interim and annual), effective for reporting periods beginning after December 15, 2012. 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**

In December 2011, the FASB issued Update No. 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 . The amendments in this Update supersede changes to those paragraphs in Update 2011-05 that pertain to how, when, and where reclassification adjustments are presented. The adoption of this amendment is not expected to have a material effect on the Company's financial position or results of operations, but may affect the presentation of Other Comprehensive Income in the Company's financial statements.

In February 2013, 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 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments shall be applied retrospectively to all prior periods presented for those obligations that exist at the beginning of the fiscal year of adoption. Early adoption is permitted. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Interim Financial Statements**

**June 30, 2013**

**(Expressed in U.S. Funds)**

**(Unaudited)**

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

In March 2013, 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 are effective prospectively for fiscal years, and interim reporting periods within those years, beginning after December 15, 2013. Early adoption is permitted. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

In April 2013, 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 are effective for entities that determine liquidation is imminent during annual reporting periods beginning after December 15, 2013, and interim reporting periods therein. Entities should apply the requirements prospectively from the day that liquidation becomes imminent. Early adoption is permitted. The adoption of this amendment is not expected to have a material effect on the Company's financial position or results of operations.

**4. Intangible Assets**

As of June 30, 2013 NDA acquisition costs of \$97 thousand (December 31, 2012 - \$116 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 will be amortized over its estimated useful life of 39 months. The Company commenced amortization upon commercial launch of the product in October 2012.

**IntelGenx Technologies Corp.****Notes to Consolidated Interim Financial Statements****June 30, 2013****(Expressed in U.S. Funds)****(Unaudited)****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 will be amortized in income over a period of 39 months, which is the minimum period where sales of Forfivo XL are expected to be exclusive. As a result of this policy, the Company has a deferred revenue balance of \$769 thousand at June 30, 2013 that has not been recognized as revenue.

**6. Capital Stock**

	<b>June 30, 2013</b>	<b>December 31, 2012</b>
Authorized -		
100,000,000 common shares of \$0.00001 par value		
20,000,000 preferred shares of \$0.00001 par value		
Issued -		
51,549,421 (December 31, 2012 - 49,890,421) common shares	<b>\$ 515</b>	<b>\$ 499</b>

**7. Additional Paid-In Capital****Stock options**

On April 24, 2013 the Company granted 480,000 stock options to an officer to purchase common shares. The stock options are exercisable at \$0.65 per share and vest on December 31, 2015. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$157 thousand, using the following assumptions:

Expected volatility	78%
Expected life	3.83 years
Risk-free interest rate	0.34%
Dividend yield	Nil

**IntelGenx Technologies Corp.****Notes to Consolidated Interim Financial Statements****June 30, 2013****(Expressed in U.S. Funds)****(Unaudited)****7. Additional Paid-In Capital (Cont d)**

On April 24, 2013 the Company granted 200,000 stock options to an officer to purchase common shares. The stock options are exercisable at \$0.65 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$59 thousand, using the following assumptions:

Expected volatility	77%
Expected life	3.13 years
Risk-free interest rate	0.34%
Dividend yield	Nil

During the six month period ended June 30, 2013 a total of 75,000 (2012 - Nil) stock options were exercised for 75,000 (2012 - Nil) common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$31 thousand (2012 - \$Nil), resulting in an increase in additional paid-in capital of \$31 thousand (2012 - \$Nil).

Compensation expenses for stock-based compensation of \$48 thousand and \$29 thousand were recorded during the six month period ended June 30, 2013 and 2012 respectively. Of the amount expensed in 2013, \$37 thousand (2012 - \$28 thousand) relates to stock options granted to employees and directors, and \$11 thousand (2012 - \$Nil) relates to options granted to independent third party consultants. In addition, \$1 thousand was expensed in 2012 related to stock options granted to investor relations firms as compensation for investor relation services. As at June 30, 2013, the Company has \$229 thousand (2012 - \$65 thousand) of unrecognized stock-based compensation.

**Warrants**

During the six month period ended June 30, 2013 a total of 1,584,000 (2012 - 1,207,818) warrants were exercised for 1,584,000 (2012 - 728,230) common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$751 thousand (2012 - \$234 thousand), resulting in an increase in additional paid-in capital of \$750 thousand (2012 - \$234 thousand).

**IntelGenx Technologies Corp.**

**Notes to Consolidated Interim Financial Statements**

**June 30, 2013**

**(Expressed in U.S. Funds)**

**(Unaudited)**

**8. Related Party Transactions**

Included in management salaries for the six months ended June 30, 2013 are \$5 thousand (2012 - \$3 thousand) for options granted to the Chief Executive Officer, \$10 thousand (2012 - \$Nil) for options granted to the Chief Operating Officer and \$9 thousand (2012 - \$3 thousand) for options granted to the Chief Financial Officer under the 2006 Stock Option Plan and \$6 thousand (2012 - \$13 thousand) for options granted to non-employee directors.

Also included in management salaries are director fees of \$44 thousand (2012 - \$55 thousand) for attendance to board meetings and audit committee meetings and \$66 thousand (2012 - \$Nil) for fees paid to a director under a management consultancy agreement.

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, share-based compensation and convertible notes have been excluded from the calculation of diluted loss per share since they are anti-dilutive.

**10. Subsequent Events**

Subsequent to the end of the quarter, 1,161,000 warrants were exercised for 1,161,000 common shares having a par value of \$0 thousand for cash consideration of approximately \$550 thousand, resulting in an increase in additional paid-in capital of approximately \$550 thousand.

**11. Comparative Figures**

Certain reclassifications of June 30, 2012 amounts have been made to facilitate comparison with the current period.

## 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 IntelGenx 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

### *ANDA for Buprenorphine/Naloxone Sublingual Film Product for the Treatment of Opiate Addiction:*

Subsequent to the end of the quarter, on July 22, 2013 we announced that an Abbreviated New Drug Application ( ANDA ) has been submitted to the U.S. Food and Drug Administration ( FDA ) for approval of a generic formulation of buprenorphine and naloxone Sublingual Film, indicated for maintenance treatment of opioid dependence. The ANDA was filed by our U.S. based co-development and commercialization partner for this product. The reference listed drug is Suboxone® (buprenorphine and naloxone) Sublingual Film.

According to IMS Health, U.S. retail sales of Suboxone® Sublingual Film were approximately \$1.5 billion in 2012.

In accordance with confidentiality clauses contained in the co-development and commercialization agreement, the specifics of the product description and financial terms remain confidential. We will receive a share of the profits of commercialization, in addition to upfront and milestone payments.

The FDA approved Suboxone® in October of 2002 for use in the treatment of opioid addiction. Suboxone® is a registered trademark of Reckitt Benckiser Pharmaceuticals. Suboxone® contains the two active ingredients: buprenorphine and naloxone.

Naloxone is used to block the effect of opioids. Buprenorphine is a partial opioid agonist that stimulates opioid receptors but does not produce the same effects as an opioid. In other words it does not produce a euphoric "high" effect. The combination of these two actives has been shown to be efficacious in managing the treatment of opioid addiction. Suboxone® is most often taken sublingually (dissolved under the tongue). Taken properly, it can reduce opioid use, help patients to be successfully managed in an addiction r