

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: September 30, 2015

**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: **000-50571**

RESPONSE BIOMEDICAL CORP.

(Exact name of registrant as
specified in its charter)

Vancouver, British Columbia, Canada

98 -1042523

(State or other jurisdiction of incorporation or
organization)

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

1781 - 75th Avenue W.
Vancouver, British Columbia, Canada, V6P 6P2
(Address of principal executive offices)

(604) 456-6010
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) 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 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 No

Indicate by check mark whether 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

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company as defined in Rule 12b-2 of the Exchange Act:

Yes No

As of November 1, 2015, the registrant had 9,925,256 shares of common stock outstanding.

RESPONSE BIOMEDICAL CORP.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "hope", "expects", "plans", "intends", "anticipates", "believes", "estimates", "projects", "predicts", "potential" and similar expressions intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements relating to future events, future results, and future economic conditions in general and statements about:

- Our future strategy, structure, and business prospects and our ability to retain distributors and increase product sales in existing and new markets;
- The development of new products, regulatory approvals of new and existing products and the expansion of the market for our current products;
- Implementing aspects of our business plan and strategies, including our strategy to increase our sales and distribution in China;
- Our ability to attain and maintain profitability;
- Our financing goals and plans;
- Our ability to conserve cash and reduce costs;
- Whether and how long our existing working capital and cash flows will be sufficient to fund our operations;
- Our ability to meet the milestones required by our collaboration agreement with Joinstar;
- Our ability to meet the covenants required by our debt obligations; and
- Our raising of additional capital through future equity and debt financings.

These statements involve known and unknown risks, uncertainties and other factors, including the risks described in Part II of this Quarterly Report on Form 10-Q, which may cause our actual results, performance or achievements to be materially different from any future results, performances, time frames or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Information regarding market and industry statistics contained in this Quarterly Report on Form 10-Q is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources and cannot assure you of the accuracy of the market and industry data we have included.

Unless the context indicates or requires otherwise, in this Quarterly Report on Form 10-Q, references to the "Company" or "Response Biomedical" shall mean Response Biomedical Corp. References to "\$" or "dollars" shall mean Canadian dollars and in thousands where indicated.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

RESPONSE BIOMEDICAL CORP.

CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

(EXPRESSED IN THOUSANDS OF CANADIAN DOLLARS, EXCEPT SHARE DATA)

AS OF SEPTEMBER 30, 2015 AND DECEMBER 31, 2014 AND FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2015 AND 2014.

RESPONSE BIOMEDICAL CORP
CONSOLIDATED BALANCE SHEETS
[SEE NOTE 2 - BASIS OF PRESENTATION AND GOING CONCERN UNCERTAINTY]
(UNAUDITED)
(IN THOUSANDS OF CANADIAN DOLLARS)

	Sept 30, 2015	December 31, 2014
	\$	\$
ASSETS		
Current		
Cash and cash equivalents	2,878	3,221
Trade receivables, net	445	702
Other receivables	112	89
Inventories <i>[note 5]</i>	2,102	2,056
Prepaid expenses and other	145	183
Deferred debt financing costs - current portion	57	88
Total current assets	5,739	6,339
Deferred debt financing costs	9	45
Long-term prepaid expenses	93	93
Restricted deposits <i>[note 8]</i>	901	901
Property, plant and equipment	5,907	6,250
Total assets	12,649	13,628
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current		
Accounts payable and accrued liabilities <i>[note 6]</i>	3,669	3,867
Term loan - current portion <i>[note 7]</i>	808	494
Lease inducements - current portion <i>[note 8]</i>	169	169
Repayable leasehold improvement allowance - current portion <i>[note 8]</i>	500	461
Deferred revenue	1,588	873
Warrant liability <i>[notes 4 and 9]</i>	454	1,249
Total current liabilities	7,188	7,113
Term loan <i>[note 7]</i>	555	1,004
Lease inducements <i>[note 8]</i>	1,070	1,197
Repayable leasehold improvement allowance <i>[note 8]</i>	4,828	5,208
	13,641	14,522
Commitments <i>[note 11]</i>		
Shareholders' deficit		
Common shares <i>[note 9]</i>	104,314	104,124
Additional paid-in capital <i>[note 9]</i>	15,326	15,241
Deficit	(120,632)	(120,259)
Total shareholders' deficit	(992)	(894)
Total liabilities and shareholders' deficit	12,649	13,628

See accompanying notes

RESPONSE BIOMEDICAL CORP.
CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)
(IN THOUSANDS OF CANADIAN DOLLARS)

	Three Months Ended September 30,		Nine Months Ended September 30	
	2015	2014	2015	2014
	\$	\$	\$	\$
REVENUE				
Product sales <i>[note 12]</i>	2,425	2,199	9,259	7,835
Collaborative revenue <i>[note 10]</i>	1,103	-	2,075	-
Total revenue	3,528	2,199	11,334	7,835
Cost of sales <i>[notes 5, 9, and 11]</i>	1,423	1,494	5,719	4,639
Gross profit	2,105	705	5,615	3,196
EXPENSES <i>[notes 9 and 11]</i>				
Research and development	786	881	2,220	2,505
General and administrative	596	1,294	1,952	2,691
Sales and marketing	493	819	1,626	1,948
Total operating expenses	1,875	2,994	5,798	7,144
OTHER EXPENSES (INCOME)				
Interest expense and amortization of deferred financing costs and debt discount <i>[note 7]</i>	215	226	675	649
Interest income	(2)	(3)	(7)	(12)
Other expense	12	18	17	50
Foreign exchange loss	166	60	300	68
Unrealized gain on revaluation of warrant liability <i>[note 4]</i>	(890)	(1,472)	(795)	(2,350)
Total other expenses (income)	(499)	(1,171)	190	(1,595)
Net income (loss) and comprehensive income (loss) for the period	729	(1,118)	(373)	(2,353)
Income (loss) per common share - basic <i>[note 9]</i>	0.07	(0.14)	(0.04)	(0.30)
Income (loss) per common share - diluted <i>[note 9]</i>	0.07	(0.14)	(0.04)	(0.30)
Weighted average number of common shares outstanding - basic <i>[note 9]</i>	9,925,256	7,947,737	9,863,609	7,924,440

See accompanying notes

RESPONSE BIOMEDICAL CORP.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
(UNAUDITED)
(IN THOUSANDS OF CANADIAN DOLLARS, EXCEPT SHARE DATA)

	Common Stock Issued and Outstanding # of shares	\$	Additional paid in capital \$	Deficit \$	Total Shareholders' Equity/(Deficit) \$
Balance at December 31, 2013	7,870,925	101,945	14,742	(118,169)	(1,482)
Net loss	-	-	-	(2,090)	(2,090)
Private placement, net of issue costs	1,800,000	2,024	-	-	2,024
Net shares issued upon conversion of restricted share units	88,635	155	(155)	-	-
Net warrants issued per terms of loan	-	-	113	-	113
Stock-based compensation expense	-	-	381	-	381
Restricted share units	-	-	160	-	160
Balance at December 31, 2014	9,759,560	104,124	15,241	(120,259)	(894)
Net loss	-	-	-	(373)	(373)
Net shares issued upon conversion of restricted share units	165,696	190	(190)	-	-
Stock-based compensation expense	-	-	160	-	160
Restricted share units	-	-	115	-	115
Balance at September 30, 2015	9,925,256	104,314	15,326	(120,632)	(992)

See accompanying notes

RESPONSE BIOMEDICAL CORP
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(IN THOUSANDS OF CANADIAN DOLLARS)

Nine Months Ended September 30, OPERATING ACTIVITIES	2015 \$	2014 \$
Net loss for the period	(373)	(2,353)
Add (deduct) items not involving cash:		
Depreciation of property, plant and equipment	753	743
Amortization of deferred lease inducements	(127)	(128)
Amortization of deferred financing costs	71	72
Amortization of discount on debt	42	23
Stock-based compensation	160	327
Unrealized loss (gain) on revaluation of warrant liability	(795)	(2,350)
Other non-cash items	221	20
Changes in non-cash working capital:		
Trade receivables	257	552
Other receivables	(23)	85
Inventories	(46)	(331)
Prepaid expenses and other	38	(93)
Accounts payable and accrued liabilities	(72)	1,139
Deferred revenue	715	18
Cash provided by (used in) operating activities	821	(2,276)
INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(425)	(179)
Cash used in investing activities	(425)	(179)
FINANCING ACTIVITIES		
Repayment of repayable leasehold improvement allowance	(341)	(306)
Repayment of term loan	(398)	-
Proceeds from term loan	-	1,661
Debt financing cost	-	(148)
Cash provided by (used in) financing activities	(739)	1,207
Decrease in cash during the period	(343)	(1,248)
Cash and cash equivalents, beginning of period	3,221	2,958
Cash and cash equivalents, end of period	2,878	1,710

See accompanying notes

RESPONSE BIOMEDICAL CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. DESCRIPTION OF BUSINESS

Response Biomedical Corp. (“Response” or the “Company”) was incorporated on August 20, 1980 under the predecessor to the Business Corporations Act (British Columbia). The Company’s wholly owned US subsidiary, Response Point of Care Inc., was incorporated on November 9, 2012 in the State of Delaware. The Company is engaged in the research, development, commercialization and distribution of diagnostic technologies for the medical point of care (POC), laboratory and on-site environmental testing markets. POC and on-site diagnostic tests (or assays) are simple, non-laboratory based tests performed using portable hand-held devices, compact desktop analyzers, single-use test cartridges and/or dipsticks. Since 1996, the Company has developed and commercialized a proprietary diagnostic system called RAMP®.

The RAMP® System is a portable fluorescence immunoassay-based diagnostic technology that combines the performance of a clinical lab with the convenience of a dipstick test, establishing a new paradigm in diagnostic testing. Immunoassays are extremely sensitive and specific tests used to identify and measure small quantities of materials, such as proteins. A large variety of biological molecules and inorganic materials can be targeted. Accordingly, the RAMP® technology is applicable to multiple distinct market segments and many products within those segments. RAMP® tests are now commercially available for use in the early detection of heart attack, congestive heart failure, influenza A+B, the respiratory syncytial virus, environmental detection of West Nile Virus and Dengue Fever antigen, and biodefense applications including the rapid on-site detection of anthrax, smallpox, ricin and botulinum toxin.

2. BASIS OF PRESENTATION AND GOING CONCERN UNCERTAINTY

These unaudited interim consolidated financial statements have been prepared by management in Canadian dollars in accordance with United States generally accepted accounting principles (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited consolidated financial statements reflect, in the opinion of management, all adjustments (which include reclassifications and normal recurring adjustments) necessary for a fair presentation of the results for the interim periods presented. The accompanying consolidated balance sheet at December 31, 2014 has been derived from the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year then ended. The consolidated financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2014 and filed with the United States Securities and Exchange Commission (“SEC”) on March 19, 2015.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business.

During the nine month period ended September 30, 2015, the Company incurred a net loss of \$373,000 and had negative cash flows of \$343,000. As of September 30, 2015, the Company had a cash balance of \$2.9 million, an accumulated deficit of \$120.6 million, a shareholders’ deficit of \$992,000, and a negative working capital balance of \$1.4 million. In addition, the Company has various operating leases and purchase commitments for inventory (refer to note 11). Included in current liabilities is a warrant liability in the amount of \$454,000 that is required to be measured at fair value. The potential settlement of these warrants would not have a cash impact as they may only be exercised on a net cashless basis. Without taking into account the warrant liability mentioned above, current liabilities exceed current assets by \$995,000.

Sales to the Company’s national distributor in China represented 64% of product sales in the first nine months of 2015. While this distributor met its contractual minimums for purchases of products from the Company in the first six months of the year, it advised the Company that it has built up inventory at a higher rate than its current sales to end-users. Consequently, this distributor made lower purchases from the Company during the third quarter of 2015 compared to the first two quarters of 2015. No returns of the products purchased by the national distributor are either expected or permitted under the terms of its distribution agreement.

As a result, to address the recent expected near term reductions in product sales, the Company implemented several cash conservation and cost reduction initiatives to extend its available cash resources. In addition, the Company is also seeking additional financing alternatives. While the Company is pursuing these various initiatives, there is no assurance that these efforts will be sufficient to fund the Company’s operations or that quarter-over-quarter product sales will increase.

The ability of the Company to continue as a going concern is uncertain and dependent on the Company's ability to obtain additional financing and/or achieve cash flow positive operations. Management has, thus far, financed the operations through a series of equity financings, debt financing, and collaborative arrangements. The Company has received milestones totaling US\$2.3 million to date from the Joinstar Agreements described in Note 10 and is eligible to receive a further US\$1.5 million in development milestones over the remaining planned six month project period. In addition, under the terms of the Supply Agreement with Joinstar, Response is eligible to receive a guaranteed US\$1.8 million in revenue-based payments over the first five years of commercialization of the co-developed assays.

In addition to the Joinstar agreements, the Company has a term loan from Silicon Valley Bank ("SVB") with an outstanding principal balance of approximately US\$1.0 million as of September 30, 2015. Refer to note 7 for the significant terms of the loan.

Management believes that, with a combination of some or all of the various cost reduction, cash conservation, sales and marketing, and, if necessary, financing initiatives, and with the targeted execution under the Joinstar Agreements and strengthening of our China sales and distribution, based on the current level of operations and excluding out of the ordinary cash management measures, the Company's cash and cash equivalent balances, including cash generated from operations, will be sufficient to meet the anticipated cash requirements through the next twelve months. However, due to the Company's history of losses, there is substantial doubt over the Company's ability to continue as a going concern as it is dependent on meeting the development milestones required to earn the additional US\$1.5 million in development fees under the Collaboration Agreement with Joinstar, achieving profitable operations, or obtaining additional financing, the outcomes of which cannot be predicted at this time. The consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should the Company be unable to continue as a going concern. Such adjustments could be material.

3. RECENT ACCOUNTING PRONOUNCEMENTS

Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued Accounting Standard Update ("ASU") 2014-09, "Revenue from Contracts with Customers", which will supersede most of the existing revenue recognition guidance under U.S. GAAP. This ASU requires an entity to recognize revenue when it transfers 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. This pronouncement is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is not permitted. The ASU allows for either full retrospective or modified retrospective adoption. The Company is currently evaluating the potential effect of this ASU on its financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 2015-40) ("ASU 2014-15"). ASU 2014-15 provides guidance to U.S. GAAP about management's responsibility to evaluate whether there is a substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. This new rule requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles currently in the U.S. auditing standards. Specifically, ASU 2014-15 (1) defines the term substantial doubt, (2) requires an evaluation of every reporting period including interim periods, (3) provides principles for considering the mitigating effect of management's plans, (4) requires an express statement and other disclosures when substantial doubt is not alleviated, and (5) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This guidance is effective for annual periods ending after December 15, 2016. The Company is currently evaluating the potential effect of this ASU on its financial statements and related disclosures.

In April 2015, the FASB issued ASU 2015-03, Interest-Imputation of Interest (Subtopic 835-30) ("ASU 2015-03"). ASU 2015-03 was issued to simplify the presentation of debt issuance costs. The guidance requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by these amendments. This guidance should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The guidance will be effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The adoption of this newly issued guidance would result in the reclassification of the Deferred Debt Financing Costs (both current and long term), which are included under the assets section of the consolidated balance sheet, as a deduction of the Term loan (both current and long term) on the consolidated balance sheet.

4. FAIR VALUE MEASUREMENTS

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability ("exit price") in an orderly transaction between market participants at the measurement date. Fair value measurements of financial instruments are determined by using a fair value hierarchy that prioritizes the inputs to valuation techniques into three levels according to the relative reliability of the inputs used to estimate the fair values.

The three levels of inputs used to measure fair value are as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical financial instruments;
- Level 2 – Inputs other than quoted prices that are observable for the financial instrument either directly or indirectly; and
- Level 3 – Inputs that are not based on observable market data.

In determining fair value measurements, the Company uses the most observable inputs when available.

For certain of the Company's financial instruments, including cash and cash equivalents, trade receivables, other receivables, and accounts payable and accrued liabilities the carrying amounts approximate fair values due to their short-term nature. The carrying value of the restricted deposits approximates its fair value due to the nature of the cash deposit. The fair value of the term loan approximates its carrying value as the term loan with SVB was secured during the first quarter of 2014 and renegotiated in the fourth quarter of 2014 and therefore approximates the current market rate for the term loan. The fair value of the repayable leasehold improvement allowance approximates its carrying value as the fixed interest rate of 11% is considered to approximate the current market rate.

The fair value hierarchy level at which a financial instrument is categorized is determined on the basis of the lowest level input that is significant to the fair value measurement (in thousands):

Financial Instruments carried at fair value as of September 30, 2015

Liabilities	Level 1	Level 2	Level 3	Total
	\$	\$	\$	\$
Warrant Liability	-	-	454	454

As of September 30, 2015, the warrant liability is recorded at its fair value of \$454,000. The Company reassesses the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, contractual term of the warrant, and risk-free interest rate (refer to note 9[g]). The computation of expected volatility was based on the historical volatility of the Company's stock. A small change in the estimates used in the Black-Scholes pricing model may have a relatively large change in the estimated valuation of the common stock warrants.

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the nine month period ended September 30, 2015 (in thousands):

	Balance at December 31, 2014	Unrealized gain	Exercise of Warrants	Balance at September 30, 2015
Warrant Liability	1,249	(795)		454

Quantitative information about unobservable inputs used in Level 3 fair value measurements is presented below:

	Valuation Technique	Unobservable Input	As at September 30, 2015	As at December 31, 2014
Warrant Liability	Option Model	Stock Price Volatility	121%	106%

A 5% increase or decrease in stock price volatility would cause an approximate corresponding \$40,000 increase or decrease to the Warrant Liability (\$82,000 – December 31, 2014).

5. INVENTORIES

Inventories are comprised of the following (in thousands):

	September 30, 2015	December 31, 2014
	\$	\$
Raw materials	1,168	1,212
Work in progress	379	309
Finished goods	555	535
	2,102	2,056

The carrying value of inventory as of September 30, 2015 includes a write-down and a provision for expired, obsolete, and damaged inventory in the amount of \$57,000 [December 31, 2014 - \$135,000]. For the three and nine month period ended September 30, 2015, inventory write-downs and obsolescence charges were \$68,000 and \$196,000 [2014 - \$76,000 and \$198,000].

6. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities comprise (in thousands):

	September 30, 2015	December 31, 2014
	\$	\$
Trade accounts payable	1,441	1,624
Employee related accounts payable and accrued liabilities	1,203	1,307
Royalties	219	287
Other accrued liabilities	806	649
	3,669	3,867

7. TERM LOAN

On February 11, 2014, the Company entered into a loan and security agreement with SVB providing for up to a US\$2.5 million term loan. The loan is secured by substantially all of the assets of the Company. The loan included financial covenants that were later removed in an amendment (refer to discussion below). The loan also includes certain non-financial covenants as well as a subjective acceleration clause. Under the terms of the original loan agreement, the loan bears an interest rate of Wall Street Journal Prime Rate plus 2.5% annually. Interest only payments were made until October 1, 2014 at which time, 32 equal monthly installments of principal plus accrued interest started to be made. On December 15, 2014, the Company entered into an amendment to the original loan agreement with SVB. Under the amendment, SVB agreed to continue to advance the remaining outstanding principal of US\$1.4 million for the same term and interest rate under the original agreement. In addition, SVB waived its rights in respect of certain breaches and removed any future financial covenants. Interest only payments were made until April 1, 2015, at which time, 26 equal monthly installments of principal plus accrued interest are being made through to maturity on May 1, 2017. In addition, the Company will pay an additional final payment of up to 4% of the outstanding principal advanced upon repayment. The loan contains a voluntary prepayment option whereby the principal amount can be prepaid in whole, or in part, for a fixed fee if a prepayment is made on or before December 15, 2016.

In connection with the original loan and amendment discussed above, 107,701 warrants with exercise prices ranging from \$1.00 to \$1.831 per warrant and a term of 10 years were granted to SVB. These warrants were measured at their fair market value using the Black-Scholes model on the date of their grants and had a combined estimated fair market value of \$113,000, which was recorded as a debt discount that is being amortized into income over the term of the loan using the effective interest method. In addition, there were \$233,000 of fees related to the term loan that are also being amortized over the term of the loan using the effective interest method.

Amortization of the deferred financing costs for the three and nine month periods ended September 30, 2015 were \$21,000 and \$71,000 (2014 – \$29,000 and \$72,000) and amortization of the debt discount for the three and nine month periods ended September 30, 2015 was \$12,000 and \$42,000 (2014 – \$9,000 and \$23,000). Both of these amounts are included in interest expense and amortization of deferred financing costs and debt discount on the consolidated statements of income (loss) and comprehensive income (loss).

The term loan is comprised of the following amounts (in thousands):

	September 30, 2015	December 31, 2014
	\$	\$
Current portion of term loan	840	546
Current portion of unamortized debt discount	(32)	(52)
Current portion of long-term debt, net debt discount	808	494
Long-term portion of term loan	560	1,031
Long-term portion of unamortized debt discount	(5)	(27)
Long-term of long-term debt, net debt discount	555	1,004
Total	1,363	1,498

Future principal payments for the term loan as of September 30, 2015, are as follows (in thousands):

September 30,	\$
2016	840
2017	560
Total	1,400

8. LEASE INDUCEMENTS

Lease agreements entered into by the Company for its offices provides for lease inducements to be provided by the landlord to the Company, which are summarized as follows (in thousands):

	September 30, 2015	December 31, 2014
	\$	\$
Current Portion		
Rent-free inducement [i]	54	54
Non-repayable leasehold improvement allowance [ii]	115	115
	169	169
Repayable leasehold improvement allowance [iii]	500	461
Total Current Portion	669	630
Long-Term Portion		
Rent-free inducement [i]	344	385
Non-repayable leasehold improvement allowance [ii]	726	812
	1,070	1,197
Repayable leasehold improvement allowance [iii]	4,828	5,208
Total Long-Term Portion	5,898	6,405
Total	6,567	7,035

The lease inducements disclosed on the consolidated balance sheets as a result of these benefits is comprised of the following:

[i] In 2007, the Company entered into a long-term facility lease agreement that included an eight and one half month rent-free period from May 17, 2007 to February 1, 2008. The lease inducement benefit arising from the rent-free period is being amortized on a straight-line basis over the term of the operating lease as a reduction to rental expense. Amortization expense for the three and nine month periods ended September 30, 2015 amounted to \$14,000 and \$41,000 [2014 - \$14,000 and \$41,000].

[ii] The Company received a non-repayable allowance for an amount of \$1.7 million for expenditures related to general upgrades to the facility. The lease inducement benefit arising from the non-repayable leasehold improvement allowance is being amortized on a straight-line basis over the balance of the term of the lease beginning April 1, 2008 as a reduction to rental expense. Amortization expense for the three and nine month periods ended September 30, 2015 amounted to \$29,000 and \$86,000 [2014 - \$29,000 and \$86,000].

[iii] The Company received a repayable leasehold improvement for an amount of \$7.8 million used for additional improvements to the facility. This lease inducement is being repaid over the term of the operating lease commencing February 1, 2008 at approximately \$89,000 per month including interest calculated at an interest rate negotiated between the Company and the landlord. Principal repayments for the three and nine month periods ended September 30, 2015 amounted to \$117,000 and \$341,000 [2014 - \$105,000 and \$306,000]. Interest payments for the three and nine month periods ended September 30, 2015 amounted to \$149,000 and \$455,000 [2014 - \$161,000 and \$491,000].

To secure the lease, the Company is maintaining a security deposit with the landlord in the form of an irrevocable letter of credit in the amount of \$871,000 collateralized by a term deposit with a market value of \$871,000 that is presented as part of restricted deposits in the long-term asset section of the balance sheets. Of this amount, \$581,000 will be released to the Company if the Company achieves an operating profit in a calendar year.

9. SHARE CAPITAL AND ADDITIONAL PAID-IN CAPITAL

[a] Authorized - Unlimited common shares without par value.

[b] Issued

2014 Private Placement

On December 12, 2014, the Company closed a private placement with Joinstar related entities consisting of 1,800,000 common shares at a price of \$1.21 per share for total gross proceeds of \$2,178,000. The net proceeds were \$2,024,000 after deduction of \$154,000 of financing costs.

[c] Stock option plan

At the Annual General Meeting held September 3, 2008, the Company's shareholders approved a stock option plan ("2008 Plan"). Under the plan, the Company may grant options to purchase common shares in the Company to employees, directors, officers and consultants of the Company. The exercise price of the options is determined by the Board to be equal to the fair market value of the common shares on the grant date. The Company estimates the fair value of options on the date of the grant. The options vest over the requisite service period in accordance with terms as determined by the Board, typically over four years. Stock options expire no later than ten years from the date of grant.

At the Annual General and Special Meeting held on September 18, 2013, the Company's shareholders' approved a change to the Company's 2008 stock option plan permitting the maximum shares authorized to be issued under the plan to be up to 20% of the issued and outstanding common shares outstanding at any point in time.

Of the 1,985,051 stock options authorized for grant under the 2008 Plan as at September 30, 2015, options for 1,287,631 shares were outstanding and 697,420 stock options were available for future grant.

The following assumptions were used to estimate the fair value of options granted during the nine month period ended September 30, 2015 and 2014 using a Black-Scholes option-pricing model:

Nine months ended September 30,	2015	2014
Risk-free interest rates	1.31%	2.04%
Expected dividend yield	0%	0%
Expected life (in years)	5.78	5.88
Expected volatility	121%	126%
Fair value per stock option	\$ 0.67	\$ 1.33

The expected volatility reflects the assumption that the historical volatility of common stock of the Company over a period similar to the expected life of the options is indicative of future trends. The Company estimates the risk-free interest rate using the Bank of Canada bond yield with a remaining term equal to the expected life of the option. The Company uses the simplified method for estimating the stock option term for stock option grants during the nine month period ended September 30, 2015 as the Company has determined that the stock options are "plain vanilla" and historical share option exercises do not apply as the vesting term and contractual lives have significantly changed from those stock options exercised previously.

At September 30, 2015, the following stock options were outstanding:

Range of exercise price \$	Number of shares under option #	Weighted average remaining contractual life (years)	Weighted average exercise price \$	Number of options currently exercisable #	Weighted average exercise price \$
0.72 - 0.92	492,898	9.53	0.79	-	-
1.02 - 1.80	243,470	7.74	1.48	172,864	1.46
2.20 - 2.20	384,014	6.53	2.20	368,460	2.20
3.00 - 3.10	165,425	7.47	3.10	155,979	3.10
6.80 - 8.20	1,824	0.37	7.70	1,824	7.70
0.72 - 8.20	1,287,631	8.02	1.65	699,127	2.23

The options expire at various dates from December 1, 2015 to May 20, 2025.

Stock option transactions and the number of stock options outstanding are summarized below:

	Number of optioned common shares #	Weighted average exercise price \$
Balance, December 31, 2014	1,007,629	1.99
Options granted	449,743	0.78
Options forfeited	(169,741)	1.40
Balance, September 30, 2015	1,287,631	1.65

[d] Restricted share unit plan

At the Annual General and Special Meeting held on September 18, 2013, the Company's shareholders approved a new restricted share unit plan (the "RSU Plan"). Under the RSU Plan, the Company may grant Restricted Share Units ("RSUs") to employees, directors, and eligible consultants which entitle each participant to either one common share of the Company on a time vested basis or a cash payout equal to the number of vested RSUs multiplied by the then current market value of the RSUs. The fair market value of the RSUs is determined based upon the number of RSUs granted and the quoted closing price of the Company's stock on the trading day immediately preceding the date of determination. The duration of the vesting period and other vesting terms applicable to the grant of the RSUs shall be determined by the Board.

	Number of RSUs #	Weighted average exercise price \$
Balance, December 31, 2014	136,348	1.39
RSUs granted	141,837	0.81
RSUs converted to common shares	(165,696)	(1.15)
Balance, September 30, 2015	112,489	1.02

The restricted share units that were granted during the nine month period ended September 30, 2015 were to settle a director compensation liability that was recorded in accounts payable and accrued liabilities. The \$115,000 liability has been excluded from the change in accounts payable and accrued liabilities on the consolidated statement of cash flows.

Of the 248,131 RSUs authorized for grant under the RSU Plan as at September 30, 2015, 135,642 RSUs are available for grant.

[e] Deferred share unit plan

At the Annual General and Special Meeting held on September 18, 2013, the Company's shareholders approved a new non-employee director deferred share unit plan (the "DSU Plan"). A Deferred Share Unit ("DSU") is a right granted to non-employee directors which entitle each participant to either one common share of the Company on a time vested basis or a cash payout equal to the number of DSUs multiplied by the then current market value of the DSUs. The fair market value of the DSU's is determined based upon the number of DSUs granted and the quoted price of the Company's stock on the trading day immediately preceding the determination date. The duration of the vesting period and other vesting terms applicable to the grant of the DSU's shall be determined by the Board.

Of the 248,131 DSUs authorized for grant under the DSU Plan as at September 30, 2015, all are available for grant.

[f] Stock-based compensation

The following table shows stock-based compensation allocated by type of cost (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015 \$	2014 \$	2015 \$	2014 \$
Cost of sales	6	9	23	27
Research and development	10	11	32	34
General and administrative	32	68	82	236
Sales and marketing	7	7	23	30
	55	95	160	327

As of September 30, 2015, the total unrecognized compensation related to stock options granted amounts to \$436,000, which is expected to be recognized over a weighted average service period of 2.14 years.

[g] Common share purchase warrants

At September 30, 2015, there were 86,865,691 warrants outstanding to purchase shares of common stock, with expiry dates ranging from November 7, 2015 to December 15, 2024. Of the total 86,865,691 warrants outstanding, 86,103,744 warrants (the warrants related to the 2011 financing) entitle the holder thereof to purchase 1/20th of a common share of the Company at a price of \$1.461 per whole common share; 636,557 warrants (the private placement warrants) entitle the holder thereof to purchase one common share of the Company at a price of \$3.58 per common share; 17,689 warrants (the agent warrants) entitle the holder thereof to purchase one common share of the Company at a price of \$2.45 per common share; 52,796 warrants entitle the holder thereof to purchase one common share of the Company at a price of \$1.831 per common share; and 54,905 warrants entitle the holder thereof to purchase one common share of the Company at a price of \$1.00 per common share. The 86,103,744 warrants associated with the 2011 financing expire on December 30, 2016.

There have been no common share purchase warrant transactions during the nine months ended September 30, 2015.

The estimated fair value of the warrants related to the 2011 financing is reassessed at each balance sheet date using the Black-Scholes option pricing model. The following assumptions were used to value the warrants on the following balance sheet dates:

As at September 30,	2015	2014
Risk-free interest rates	0.52%	1.12%
Expected dividend yield	0%	0%
Expected life (in years)	1.25	2.25
Expected volatility	121%	106%
Fair value of warrant	\$ 0.0053	\$ 0.0337

[h] Earnings per common share

The following is a reconciliation of the weighted average number of common shares outstanding used in calculating basic and diluted earnings (loss) per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	\$	\$	\$	\$
Numerator:				
Net income (loss) available to common shareholders	\$ 729	\$ (1,118)	\$ (373)	\$ (2,353)
Denominator:				
Weighted average number of common shares outstanding - basic	9,925,256	7,947,737	9,863,609	7,924,440
Weighted average effect of dilutive securities:				
RSUs	112,489	-	-	-
Weighted average number of common shares outstanding - diluted	10,037,745	7,947,737	9,863,609	7,924,440

Basic net income per share is computed by dividing the net income attributable to common shareholders by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income attributable to common shareholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding using the treasury stock method. Dilutive potential common shares outstanding include outstanding warrants, stock options, and restricted share units.

86,865,691 warrants and 1,287,631 stock options have been excluded from the computation of diluted earnings per share for the three month period ended September 30, 2015 as their inclusion would be anti-dilutive to the earnings per share. 86,865,691 warrants, 1,287,631 stock options, and 112,489 RSUs have been excluded from the computation of diluted earnings per share for the nine month period ended September 30, 2015 as the Company has incurred a net loss during the period and their inclusion would be anti-dilutive to the loss per share (2014 – 86,810,786 warrants, 1,177,843 stock options, and 92,282 RSUs were excluded for the three and nine month periods ended September 30, 2015).

10. RELATED PARTY TRANSACTIONS

On October 15, 2014, the Company entered into a funded Technology Development Agreement and on February 16, 2015, a Collaboration Agreement with Hangzhou Joinstar Biomedical Technology Co. Ltd. (“Joinstar”) to support the co-development by Response and Joinstar of components and multiple assays that will run on a high throughput rapid immunoassay analyzer developed by Joinstar. Under the terms of the agreements, Response has received milestones totaling US\$2.3 million to date and is eligible to receive a further US\$1.5 million in development milestones over the remaining planned six month project period. In conjunction with the signing of the Collaborative Agreement, Response and Joinstar entered into a definitive Supply Agreement whereby Response will provide certain materials required for Joinstar to manufacture and sell the developed assays specifically to run on their analyzer. Under the terms of the Supply Agreement, Response is eligible to receive a guaranteed US\$1.8 million in revenue-based payments over the first five years of commercialization of the co-developed assays. In addition, Joinstar related entities purchased 1,800,000 of our common shares of at a price of \$1.21 per share for net proceeds of \$2.0 million on December 12, 2014.

The Company received US\$1.3 million from Joinstar upon signing of the Technology Development Agreement and Collaboration Agreement. These upfront payments are being recognized into income over the expected development period and for the three and nine month periods ended September 30, 2015, \$246,000 and \$761,000 was recognized (2014 – nil). These development fees are included under collaborative revenue in the consolidated statements of income (loss) and comprehensive income (loss). The unrecognized portion of the development fees are included under deferred revenue on the consolidated balance sheet.

In addition, the Company received US \$648,000 upon achieving the fourth milestone under the Collaboration Agreement with Joinstar during the three month period ended September 30, 2015. For the three and nine month periods ended September 30, 2015, \$857,000 and \$1.3 million (2014 – nil) was included under collaborative revenue in the consolidated statements of income (loss) and comprehensive income (loss).

11. COMMITMENTS

[a] License agreements

The Company entered into a non-exclusive license agreement, effective July 2005, as amended June 2008, to use and sublicense certain technology (the “Technology”) for one of the Company’s cardiac tests. In consideration for these rights, the Company paid a non-refundable license issuance fee of \$2.0 million in the first two years after execution of the agreement and is required to pay quarterly royalties on the sale of products that incorporate the Technology. For the three and nine month periods ended September 30, 2015, the Company incurred an expense of \$158,000 and \$623,000 [2014 - \$119,000 and \$393,000] for royalties. Royalty and license fees incurred are included in cost of sales.

[b] Supply agreement

The Company entered into a supply agreement, effective September 2003 for certain reagents for the Company’s RAMP[®] West Nile Virus Test. In addition to paying for the reagent purchased, the Company is required to pay the supplier semi-annual royalties equal to 10% of net revenue generated from the sale of the Company’s RAMP[®] West Nile Virus Test. The initial term of the agreement was three years from the effective date and is automatically renewed for successive periods of one year until either party terminates the agreement. For the three and nine month periods ended September 30, 2015, the Company incurred an expense of \$21,000 and \$56,000 [2014 – \$12,000 and \$47,000] for royalties to the supplier. These royalties are included in cost of sales.

[c] Lease agreements

[i] The Company entered into a long-term agreement to lease a single tenant 46,000 square foot facility to house all of the Company’s operations. Rent is payable from February 1, 2008 to January 31, 2023. The Company is required to pay the landlord total gross monthly payments of approximately \$173,000, which is comprised of base rent, administrative and management fees, estimated property taxes and repayments of the repayable leasehold improvement allowance [note 8[iii]].

[ii] The Company entered into a lease agreement for office space for our Shanghai representative office that expires on December 9, 2015. The Company is required to make monthly payments of approximately \$8,000 for base rent and management fees under the lease agreement.

[iii] The Company has entered into operating leases for administrative equipment.

For the three and nine month periods ended September 30, 2015, \$211,000 and \$617,000 [2014 - \$199,000 and \$587,000] was incurred for expenses related to base rent, administrative and management fees and estimated property taxes offset by amortization of both the rent-free inducement [note 8[i]] and non-repayable leasehold improvement allowance [note 8[ii]]. These expenses are allocated to cost of sales, research and development, general and administrative, and sales and marketing expenses.

[d] Purchase Commitments

As at September 30, 2015, the Company has outstanding purchase commitments of \$2.5 million to purchase inventory and capital equipment over the next five years of which \$1.1 million will be completed during the next twelve months.

[e] Indemnification of directors and officers

Under the Articles of the Company, applicable law and agreements with its directors and officers, the Company, in circumstances where the individual has acted legally, honestly and in good faith, may, or is required to indemnify its directors and officers against certain losses. The Company's liability in respect of the indemnities is not limited. The maximum potential of the future payments is unlimited. However, the Company maintains appropriate liability insurance that limits the exposure and enables the Company to recover any future amounts paid, less any deductible amounts pursuant to the terms of the respective policies, the amounts of which are not considered material.

[f] Indemnification of third parties

The Company has entered into license and research agreements with third parties that include indemnification provisions that are customary in the industry. These indemnifications generally require the Company to compensate the other party for certain damages and costs incurred as a result of third party claims for damages arising from these transactions. The nature of the indemnification obligations prevents the Company from making a reasonable estimate of the maximum potential amount that it could be required to pay. To date, the Company has not made any indemnification payments under such agreements and no amount has been accrued in these consolidated financial statements with respect to these indemnification obligations.

12. SEGMENTED INFORMATION

The Company operates primarily in one business segment, the research, development, commercialization and distribution of diagnostic technologies, with primarily all of its assets and operations located in Canada. The Company's revenues are generated from product sales primarily in Asia, the United States, and Europe. Expenses are primarily incurred from purchases made from suppliers in Canada and the United States.

Customers that represent a concentration risk are those whose outstanding receivable is 10% or greater than the total balance or those customers who represent 10% or greater of our total revenue. For the three month period ended September 30, 2015, \$1.1 million (46%) in product sales was generated from one customer [2014 - \$1.4 million (61%) from two customers of which one customer represented 31% and the other 30%]. For the nine month period ended September 30, 2015, \$6.0 million (64%) in product sales was generated from one customer [2014 - \$5.0 million (64%) from three customers of which one customer represented 29%, one customer represented 24%, and the other customer represented 10%].

Product sales by customer location were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30	
	2015	2014	2015	2014
	\$	\$	\$	\$
China	1,120	1,366	6,043	4,772
United States	409	232	1,095	964
Asia (excluding China)	264	24	543	306
Europe	259	265	663	977
Canada	5	57	29	67
Other	368	255	886	749
Total	2,425	2,199	9,259	7,835

Product sales by type of product were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30	
	2015	2014	2015	2014
	\$	\$	\$	\$
Cardiovascular	2,105	2,017	8,337	7,064
Infectious Diseases	22	4	72	83
Biodefense products	53	57	252	227
West Nile Virus (Environmental)	245	121	598	461
Total	2,425	2,199	9,259	7,835

13. COMPARATIVE FIGURES

Certain comparative figures have been reclassified from the amounts previously reported to confirm to the presentation adopted in the current year. For the three and nine month periods ended September 30, 2014, \$18,000 and \$49,000 of taxes paid in China for the representative office previously presented as income taxes have been retroactively reclassified as other expenses.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes. Unless otherwise specified, all dollar amounts are in Canadian dollars.

OVERVIEW

Response Biomedical develops manufactures and sells diagnostic tests for use with its proprietary RAMP® System, a portable fluorescence immunoassay-based diagnostic testing platform. Our RAMP® technology utilizes a unique method to account for sources of error inherent in conventional lateral flow immunoassay technologies, thereby providing the ability to quickly and accurately detect and quantify an analyte present in a liquid sample. Consequently, an end-user in a medical facility's central-lab or in a point-of-care diagnostic testing setting can rapidly obtain important diagnostic information. We currently have fourteen tests available for clinical and environmental testing applications, and we have plans to commercialize additional tests.

We generally operate with a limited order backlog because our products are typically shipped shortly after orders are received. Product sales in any quarter are generally dependent on orders booked and shipped in that quarter. Our sales for any future periods are not predictable with a significant degree of certainty, and may depend on a number of factors outside of our control, including but not limited to the performance of our distributors including their inventory or timing considerations, their changing local competitive and/or reimbursement environments, and/or their ability or failure to meet minimum purchase commitments. As a result, any revenue shortfall would negatively affect our operating results and financial condition. In addition, our sales may be adversely impacted by pricing pressure and new product offerings from competitors. Our ability to be consistently profitable will depend, in part, on our ability to increase the sales volumes of our products, improve our gross margins, control our expenses and to successfully compete with other competitors. In addition, individual shipments to our largest distributors are sometimes very large—up to 70% of a quarter's revenue may be in a single shipment. Timing of these large shipments can have a large impact on individual quarter revenues. Our financial performance from quarter to quarter may vary substantially based on timing of one or two large shipments. As a result of the foregoing, we believe that period to period comparisons of our quarterly results of operations are not necessarily meaningful indicators of future results.

Sales to the Company's national distributor in China represented 64% of product sales in the first nine months of 2015. While this distributor met its contractual minimums for purchases of products from the Company in the first six months of the year, it advised the Company that it has built up inventory at a higher rate than its current sales to end-users. Consequently, this distributor made lower purchases from the Company during the third quarter of 2015 compared to the first two quarters of 2015. This national distributor is still in the process of expanding into additional territories within China and determining end-user buying patterns. No returns of the products purchased by the national distributor are either expected or permitted under the terms of its distribution agreement.

To address the recent expected near term reductions in our shipments to this China distributor, we implemented several cash conservation and cost reduction initiatives to extend our available cash resources during the third quarter. These actions included selected staff layoffs and work-sharing programs, reductions in discretionary spending, and additional efforts to sell inventory accumulated late in the second quarter. In parallel, our new China General Manager is now actively engaged in expanding our sales and marketing activities in China working with our distributor. As a further step to strengthen our financial position, the Company is also seeking additional financing alternatives. While the Company is pursuing these various initiatives, there is no assurance that these efforts will be sufficient to fund the Company's operations or that quarter-over-quarter product sales will increase.

We have thus far financed our operations through a series of equity financings, debt financing, and collaborative arrangements. On October 15, 2014, we entered into a funded Technology Development Agreement and on February 16, 2015, a Collaboration Agreement with Hangzhou Joinstar Biomedical Technology Co. Ltd. ("Joinstar") to support the co-development by Response and Joinstar of components and multiple assays that will run on a high throughput rapid immunoassay analyzer developed by Joinstar. Under the terms of the agreements, we have received milestones totaling US\$2.3 million to date and are eligible to receive a further US\$1.5 million in development milestones over the remaining planned six month project period. In conjunction with the signing of the Collaborative Agreement, we entered into a definitive Supply Agreement with Joinstar whereby we will provide certain materials required for Joinstar to manufacture and sell the developed assays specifically to run on their analyzer. Under the terms of the Supply Agreement, we are eligible to receive a guaranteed US\$1.8 million in revenue-based payments over the first five years of commercialization of the co-developed assays. To date, commercialization of the co-developed assays has not commenced.

In addition to the Joinstar agreements, the Company has a term loan from Silicon Valley Bank ("SVB") with an outstanding principal balance of approximately US\$1.0 million as of September 30, 2015, which is being repaid monthly over the next twenty months. We believe that with a combination of some or all of the various cost reduction, cash conservation, sales and marketing, and, if necessary, financing initiatives and with the targeted execution under the Joinstar Agreements and strengthening of our China sales/distribution, based on the projected level of operations, our cash and cash equivalent balances, including cash generated from operations, will be sufficient to meet our anticipated cash requirements through the next twelve months. However, due to our history of losses, the challenges of our sales activities in our China market and uncertain success of our various cost, cash, and financing efforts, there is substantial doubt over our ability to continue as a going concern as we are dependent on meeting the development milestones required to earn the additional US\$1.5 million in development fees under the Collaboration Agreement with Joinstar, achieving profitable operations, and/or additional financings, the outcomes of which cannot be predicted at this time. In the event that we are unable to generate adequate revenues, cash flow or earnings, to support our operations, or we are unable to raise sufficient capital to do so, we may be forced to cease operations and either sell our business or liquidate our assets.

RECENT DEVELOPMENTS

- On August 6, 2015, following a successful search process, we hired Julius Wu as our new General Manager for China. We believe Mr. Wu has the background and experience to expand our sales in China, which is the key market today for Response, representing 65% of the 2015 year to date product sales and 64% of 2014 calendar year revenues, respectively.
- On September 9, 2015, we received the fourth milestone of US\$648,000 in the funded Technology Development Agreement with Joinstar. The milestone was earned upon the delivery of certain components for the high throughput rapid immunoassay analyzer developed by Joinstar.

RESULTS OF OPERATIONS

For the three month periods ended September 30, 2015 and 2014:

REVENUES, COST OF GOODS SOLD AND GROSS MARGIN (IN THOUSANDS)

	<u>Three Months Ended September 30,</u>		<u>Change 2014 to 2015</u>	
	<u>2015</u>	<u>2014</u>	<u>Increase / (Decrease)</u>	<u>Percent Change</u>
Product Sales	2,425	2,199	226	10%
Collaborative revenue	1,103	-	1,103	100%
Total revenue	3,528	2,199	1,329	60%
Cost of sales	1,423	1,494	(71)	(5%)
Gross profit	\$ 2,105	\$ 705	\$ 1,400	199%
Gross margin on product sales	41.3%	32.1%		

Product Sales

Product sales increased 10%, or \$0.2 million, during the three month period ended September 30, 2015 as compared to September 30, 2014. The change is due to an increase in sales outside of China including cardiovascular sales increasing by \$0.3 million primarily due to increased sales in Asia Pacific and Latin America and non-cardiac sales increased by \$0.1 million as timing of shipments fluctuate upon demand. These increases offset the \$0.2 million decrease in cardiovascular sales in China due to our national distributor decreasing its purchases from us in the third quarter as they draw down their previously built up inventory.

Collaborative Revenue

Collaborative revenue was \$1.1 million during the three month period ended September 30, 2015. This revenue represents the recognition of a portion of the initial payments received from Joinstar in the fourth quarter of 2014 and first quarter of 2015 and the recognition of the fourth milestone under the Collaboration agreement with Joinstar that was achieved during the quarter. There was no such revenue during the three month period ended September 30, 2014.

Gross Profit

Gross profit increased 199% during the three month period ended September 30, 2015 in comparison to the same period in 2014. Excluding the collaborative revenue, gross profit increased 25%, or \$297,000. Gross margin on product sales increased by 9.2 percentage points due to the following factors:

- Increased sales outside of China which are sold at relatively higher margins than China sales;
- A decrease in manufacturing overhead costs in comparison to the same period in 2014 due to improved efficiencies; and
- Inflation and foreign exchange fluctuations from an appreciated US dollar relative to the Canadian dollar during the quarter, which is significant because a substantial portion of our sales to overseas markets are priced in US dollars.

OPERATING EXPENSES (IN THOUSANDS)

	<i>Three Months Ended September 30,</i>		<i>Change 2014 to 2015</i>	
	<i>2015</i>	<i>2014</i>	<i>Increase / (Decrease)</i>	<i>Percent Change</i>
Research and development	786	881	(95)	(11%)
General and administrative	596	1,294	(698)	(54%)
Sales and marketing	493	819	(326)	(40%)
Total Operating Expenses	\$ 1,875	\$ 2,994	\$ (1,119)	(37%)

Research and Development Expenses

Research and development expenses decreased by 11%, or \$95,000, during the three month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. This was the result of lower legal and professional fees due to the timing of the collaboration negotiation with Joinstar in the prior year and lower salaries due to higher government funding which offsets some of our development salaries. These decreases were partially offset by higher development costs incurred during the quarter related to the Joinstar collaboration.

General and Administrative Expenses

General and administrative expenses decreased by 54%, or \$698,000, during the three month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. The decrease is primarily due to lower personnel costs as severance was accrued in the prior year upon the departure of our former chief executive officer. In addition, we incurred lower legal costs in the current year in comparison to 2014.

Sales and Marketing Expenses

Sales and marketing expenses decreased by 40%, or \$326,000, during the three month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. The decrease is primarily due to decreased personnel costs as severance was accrued in 2014 upon the departure of our former senior vice president of worldwide sales.

OTHER INCOME, NET (IN THOUSANDS)

	<i>Three Months Ended September 30,</i>		<i>Change 2014 to 2015</i>	
	<i>2015</i>	<i>2014</i>	<i>Increase / (Decrease)</i>	<i>Percent Change</i>
Interest expense and amortization of deferred financing costs and debt discount	215	226	(11)	(5%)
Interest income	(2)	(3)	1	(33%)
Other expense	12	18	(6)	100%
Foreign exchange loss	166	60	106	177%
Unrealized gain on revaluation of warrant liability	(890)	(1,472)	582	(40%)
Total Other Income	\$ (499)	\$ (1,171)	\$ 672	(57%)

Interest Expense and Amortization of Deferred Financing Costs and Debt Discount

Interest expenses and amortization of deferred financing costs and debt discount remained relatively unchanged during the three month period ended September 30, 2015 compared to the same period ended September 30, 2014 as the decrease in principal was offset by an appreciated US dollar resulting in only a slightly lower interest expense.

Foreign Exchange Loss

Foreign exchange loss increased by \$106,000 during the three month period ended September 30, 2015 compared to the same period ended September 30, 2014. Foreign exchange gains and losses are largely due to U.S. dollar balances of cash and cash equivalents, accounts receivable, accounts payable and SVB debt affected by the fluctuations in the value of the U.S. dollar as compared to the Canadian dollar. The increase in the loss is due to the appreciation of the U.S. dollar in 2015 versus 2014 on our net US dollar liabilities.

Unrealized Gain on Revaluation of Warrant Liability

The unrealized gain on revaluation of the warrant liability is solely due to the mark-to-market revaluation each reporting period of the outstanding warrants, issued during our 2011 rights offering. The fair market value decreased from June 30, 2015 resulting in an unrealized gain of \$890,000. The fair market value is calculated using a Black-Scholes model with inputs for volatility, risk free interest rate, and expected life of the warrants. The primary reason for the decrease in the value of the liability is the decrease in the share price of our stock during the period from \$0.92 to \$0.46. A small change in the estimates used in the Black-Scholes pricing model may have a relatively large change in the estimated valuation of the common stock warrants.

For the nine month periods ended September 30, 2015 and 2014:

REVENUES, COST OF GOODS SOLD AND GROSS MARGIN (IN THOUSANDS)

	<i>Nine Months Ended September 30,</i>		<i>Change 2014 to 2015</i>	
	<i>2015</i>	<i>2014</i>	<i>Increase / (Decrease)</i>	<i>Percent Change</i>
Product Sales	9,259	7,835	1,424	18%
Collaborative revenue	2,075	-	2,075	100%
Total revenue	11,334	7,835	3,499	45%
Cost of sales	5,719	4,639	1,080	23%
Gross profit	\$ 5,615	\$ 3,196	\$ 2,419	76%
Gross margin on product sales	38.2%	40.8%		

Product Sales

Product sales increased 18%, or \$1.4 million, during the nine month period ended September 30, 2015 as compared to September 30, 2014. The change is due to an increase of 18%, or \$1.3 million, in instrument and cardiovascular test sales —particularly in China in the first half of 2015. As mentioned above, our national distributor in China met its contractual minimums in each of the first two quarters of 2015 representing approximately 72% of sales in the first half of 2015. However, as a new national distributor still in the process of expanding into additional territories within China and determining end-user buying patterns, the national distributor built up inventory at a higher rate than its current sales to end-users. Consequently, the distributor made fewer purchases from us during the third quarter of 2015.

Collaborative Revenue

Collaborative revenue was \$2.1 million during the nine month period ended September 30, 2015. This revenue represents the recognition of a portion of the initial payments received from Joinstar in the fourth quarter of 2014 and first quarter of 2015 and the recognition of the third and fourth milestones under the Collaboration agreement with Joinstar that were achieved during the period. There was no such revenue during the nine month period ended September 30, 2014.

Gross Profit

Gross profit increased 76% during the nine month period ended September 30, 2015 in comparison to the same period in 2014. Excluding the collaborative revenue, gross profit increased 11%, or \$344,000. Gross margin on product sales decreased by 2.6 percentage points due to the following factors:

- A significant increase in promotional reader placement programs intended to increase our customer base and stimulate future test sales growth;
- An increase in our estimated product warranties;
- An increase in the estimated volume rebate earned by our largest distributor; and
- Inflation and foreign exchange fluctuations from an appreciated US dollar relative to the Canadian dollar during the period which partially offset the above;

OPERATING EXPENSES (IN THOUSANDS)

	<i>Nine Months Ended September 30,</i>		<i>Change 2014 to 2015</i>	
	<i>2015</i>	<i>2014</i>	<i>Increase / (Decrease)</i>	<i>Percent Change</i>
Research and development	2,220	2,505	(285)	(11%)
General and administrative	1,952	2,691	(739)	(27%)
Sales and marketing	1,626	1,948	(322)	(17%)
Total Operating Expenses	\$ 5,798	\$ 7,144	\$ (1,346)	(19%)

Research and Development Expenses

Research and development expenses decreased by 11%, or \$285,000, during the nine month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. This was the result of lower professional costs associated with the timing of clinical and regulatory work being done in 2015, which were partially offset by higher development costs related to the Joinstar collaboration.

General and Administrative Expenses

General and administrative expenses decreased by 27%, or \$739,000, during the nine month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. The decrease is primarily due to decreased stock based compensation and salaries and wages as a result of the resignation of our former CEO in the third quarter of 2014 and an associated severance accrual in the 2014 quarter.

Sales and Marketing Expenses

Sales and marketing expenses decreased by 17%, or \$322,000, during the nine month period ended September 30, 2015 in comparison to the same period ended September 30, 2014. This was primarily the result of lower salaries and wages due to a smaller staff and severance accrued for the resignation of our senior vice president of sales in 2014.

OTHER EXPENSES (INCOME), NET (IN THOUSANDS)

	<u>Nine Months Ended September 30,</u>		<u>Change 2014 to 2015</u>	
	<u>2015</u>	<u>2014</u>	<u>Increase / (Decrease)</u>	<u>Percent Change</u>
Interest expense and amortization of deferred financing costs and debt discount	675	649	26	4%
Interest income	(7)	(12)	5	(42%)
Other expense	17	50	(33)	(66%)
Foreign exchange loss	300	68	232	341%
Unrealized gain on revaluation of warrant liability	(795)	(2,350)	1,555	(66%)
Total Other Expenses (Income)	<u>\$ 190</u>	<u>\$ (1,595)</u>	<u>\$ 1,785</u>	<u>(112%)</u>

Interest Expense and Amortization of Deferred Financing Costs and Debt Discount

Interest expenses and amortization of deferred financing costs and debt discount increased by 4%, or \$26,000, during the nine month period ended September 30, 2015 compared to the same period ended September 30, 2014. The increase is primarily due to the interest and amortization costs related to the SVB debt, offset by a decrease in interest paid on the repayable leasehold improvement allowance as a result of a decrease in principal in 2015 versus 2014.

Foreign Exchange Loss

Foreign exchange loss increased by \$232,000 during the nine month period ended September 30, 2015 compared to the same period ended September 30, 2014. Foreign exchange gains and losses are largely due to U.S. dollar balances of cash and cash equivalents, accounts receivable, accounts payable and SVB debt affected by the fluctuations in the value of the U.S. dollar as compared to the Canadian dollar. The increase in the loss is due to the appreciation of the U.S. dollar in 2015 versus 2014 on our net US dollar liabilities.

Unrealized Gain on Revaluation of Warrant Liability

The unrealized gain on revaluation of the warrant liability is solely due to the mark-to-market revaluation each reporting period of the outstanding warrants, issued during our 2011 rights offering. The fair market value decreased from December 31, 2014 resulting in an unrealized gain of \$795,000. The fair market value is calculated using a Black-Scholes model with inputs for volatility, risk free interest rate, and expected life of the warrants. The primary reason for the decrease in the value of the liability is the decrease in the share price in comparison to December 31, 2014. A small change in the estimates used in the Black-Scholes pricing model may have a relatively large change in the estimated valuation of the common stock warrants.

LIQUIDITY AND CAPITAL RESOURCES

Total cash and cash equivalents and working capital at September 30, 2015, and December 31, 2014 were as follows (in thousands):

As at,	September 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 2,878	\$ 3,221
Percentage of total assets	23%	24%
Working capital	\$ (1,449)	\$ (774)
Warrant liability	\$ 454	\$ 1,249
Working capital, excluding Warrant liability	\$ (995)	\$ 475

As at September 30, 2015, the Company had a negative working capital balance. Included in current liabilities is a warrant liability that is required to be measured at fair value and is presented as a current liability in accordance with ASC 815. Each warrant may only be exercised on a net cashless exercise basis and no warrant may be exercised at a time when the exercise price equals or exceeds the current market price. As a result, the potential settlement of any warrant does not require any cash disbursement. Without taking into account the warrant liability mentioned above, the Company's working capital as at September 30, 2015 is negative \$995,000 (December 31, 2014 – positive \$475,000). The decrease of \$1.5 million during the nine months ended September 30, 2015 is primarily due to the cash used in investing and financing activities and the change in non-cash working capital.

FINANCIAL CONDITION

We have financed our operations primarily through equity and debt financings. As of September 30, 2015, the Company has raised approximately \$107.8 million from the sale and issuance of equity securities and debt, net of issue costs. On October 15, 2014, we entered into a funded Technology Development Agreement and on February 16, 2015, a Collaboration Agreement with Joinstar to support the co-development by Response and Joinstar of components and multiple assays that will run on a high throughput rapid immunoassay analyzer developed by Joinstar. Under the terms of the agreements, we have received milestones totaling US\$2.3 million to date and are eligible to receive a further US\$1.5 million in development milestones over the remaining planned six month project period. We expect these funds, in part, to be used to reduce any working capital deficiency at the time they are received. In conjunction with the signing of the Collaborative Agreement, we entered into a definitive Supply Agreement with Joinstar whereby we will provide certain materials required for Joinstar to manufacture and sell the developed assays specifically to run on their analyzer. Under the terms of the Supply Agreement, we are eligible to receive a guaranteed US\$1.8 million in revenue-based payments over the first five years of commercialization of the co-developed assays.

In addition to the Joinstar agreements, the Company has a term loan from SVB with an outstanding principal balance of approximately US\$1.0 million as of September 30, 2015. Sales to the Company's national distributor in China represented 64% of product sales in the first nine months of 2015. While this distributor met its contractual minimums for purchases of products from the Company in the first six months of the year, it advised the Company that it has built up inventory at a higher rate than its current sales to end-users. Consequently, this distributor made lower purchases from the Company during the third quarter of 2015 compared to the first two quarters of 2015. This new national distributor is still in the process of expanding into additional territories within China and determining end-user buying patterns. No returns of the products purchased by the national distributor are either expected or permitted under the terms of its distribution agreement.

In order to address the past quarter and expected temporary decline in our shipments to this China distributor, we implemented several cash conservation and cost reduction initiatives to extend our available cash resources. These actions included selected staff layoffs and work-sharing programs, reductions in discretionary spending, and additional efforts to sell inventory accumulated late in the second quarter in anticipation of Q3 sales in China. In parallel, our new China General Manager is now actively engaged in expanding our sales and marketing activities in China working with our distributor. As a further step to strengthen our financial position, the Company is also seeking additional financing alternatives. While the Company is pursuing these various cost, sales, and financing initiatives, there is no assurance that these efforts will be sufficient to fund the Company's operations.

Cash flows from operations are generally impacted by our level of quarterly sales and our ability to manage operating expenses. However, increased quarter over quarter growth also requires additional working capital in the form of higher accounts receivable and greater inventory balances to meet the increased demand. We expect that we will have net negative cash flow over the next several quarters, excluding development milestones from Joinstar, until our growth initiatives provide sufficient cash flow to cover internal operating expenses and provide the additional working capital required to support the growth. In addition, we continue to require cash for our contractual debt and other obligations outlined below.

We believe that with a combination of some or all of the various cost reduction, cash conservation, sales and marketing, and, if necessary, financing initiatives and with the targeted execution under the Joinstar Agreements and strengthening of our China sales/distribution, based on the projected level of operations, our cash and cash equivalent balances, including cash generated from operations, will be sufficient to meet our anticipated cash requirements through the next twelve months. However, due to our history of losses, the challenges of our sales activities in our China market and uncertain success of our various cost, cash, and financing efforts, there is substantial doubt over our ability to continue as a going concern as we are dependent on meeting the development milestones required to earn the additional US\$1.5 million in development fees under the Collaboration Agreement with Joinstar, achieving profitable operations, and/or additional financings, the outcomes of which cannot be predicted at this time.

ONGOING SOURCES AND USES OF CASH

CHANGES IN CASH FLOWS

Changes in cash flows were as follows (in thousands):

<i>For the Nine Months Ended September 30,</i>	<i>2015</i>	<i>2014</i>
Cash provided by (used in) operating activities	821	(2,276)
Cash used in investing activities	(425)	(179)
Cash provided by (used in) financing activities	(739)	1,207
Decrease in cash during the period	<u>\$ (343)</u>	<u>\$ (1,248)</u>

As at September 30, 2015, our cash and cash equivalents balance was \$2.9 million. The decrease in our cash and cash equivalents during the nine months ended September 30, 2015 was the result of \$425,000 of cash used in investing activities and \$739,000 of cash used in financing activities. These were offset by \$821,000 of cash provided by operating activities. These are described in more detail below

Cash Provided By (Used In) Operating Activities

Cash provided by operating activities during the nine month period ended September 30, 2015 was \$821,000 versus the \$2.3 million of cash used in the prior year. The net cash provided by operating activities in 2015 was primarily the result of \$869,000 of a net change in non-cash working capital (as described below) offsetting \$48,000 of cash used in operations because our cash expenses exceeded our gross profit earned on our revenue. The significant changes in non-cash working capital are as follows (in thousands):

<i>For the Nine Months Ended September 30,</i>	<i>2015</i>	<i>2014</i>
Trade receivables	257	552
Other receivables	(23)	85
Inventories	(46)	(331)
Prepaid expenses and other	38	(93)
Accounts payable and accrued liabilities	(72)	1,139
Deferred revenue	715	18
Total change in non-cash working capital	<u>\$ 869</u>	<u>\$ 1,370</u>

Explanations of the more significant net changes in working capital during the three month period ended March 31, 2015 are as follows:

- Trade receivable balances decreased from \$702,000 to \$445,000 as a result of more product sales that were prepaid during the third quarter;
- Inventory balances stayed the same at \$2.1 million as we started to deplete the inventory that was built up at the end of the second quarter in anticipation of higher sales in China,
- Accounts payable and accrued liabilities decreased from \$3.9 million to \$3.7 million due to the timing of vendor payments; and
- Deferred revenue increased from \$873,000 to \$1.6 million as a result of the increase in prepaid orders and volume rebates accrued for future sales.

Cash Used in Investing Activities

Net cash used in investing activities for the nine month period ended September 30, 2015 and 2014 was \$425,000 and \$179,000 respectively which represents cash that was used primarily for the purchase of manufacturing equipment to further automate our manufacturing process which we expect will reduce unit manufacturing costs.

Cash Provided by (Used in) Financing Activities

Net cash used in financing activities in the nine month period ended September 30, 2015 is related to principal payments of our leasehold improvement allowance and the repayment of our term loan. The cash provided by financing activities in 2014 was the result of \$1.7 million of debt proceeds received from SVB offset by \$148,000 of deferred financing costs related to this debt and \$306,000 of principal payments for the repayable leasehold improvement allowance.

OFF-BALANCE-SHEET ARRANGEMENTS

The Company does not have any off-balance sheet financing arrangements at September 30, 2015.

TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

There have been no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within "Management's Discussion and Analysis of Financial Condition and Results of Operations", as contained in our Annual Report on Form 10K filed by the Company with the SEC on March 19, 2015.

RELATED PARTY TRANSACTIONS

In December, 2014, Joinstar, and an affiliate, purchased a total of 1,800,000 common shares, which represents approximately 18% of our issued and outstanding common shares. In addition to the equity investment, we received US\$1.3 million from Joinstar upon signing of the Technology Development Agreement and Collaboration Agreement. These upfront payments are being recognized into income over the expected development period and for the three and nine month periods ended September 30, 2015, \$246,000 and \$857,000 was recognized. These development fees are included under collaborative revenue in the consolidated statements of income (loss) and comprehensive income (loss). The unrecognized portion of the development fees are included under deferred revenue on the consolidated balance sheet.

In addition, we received US \$648,000 upon achieving the fourth milestone under the Collaboration Agreement with Joinstar during the three month period ended September 30, 2015. For the three and nine month periods ended September 30, 2015, \$857,000 and \$1.3 million (2014 – nil) was included under collaborative revenue in the consolidated statements of income (loss) and comprehensive income (loss).

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A summary of the significant accounting policies is as follows:

USE OF ESTIMATES

Our consolidated financial statements are prepared in accordance with U.S. GAAP. In the application of U.S. GAAP, we are required to make estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities in our consolidated financial statements. Changes in the accounting estimates from period to period are reasonably likely to occur. Accordingly, actual results could differ significantly from the estimates made by management. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation of our financial condition or results of operations may be affected.

On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, valuation of stock based compensation, valuation of long-lived assets, tax related contingencies, recoverability of receivables, valuation of inventories, and warranty accruals. We base our estimates on historical experience and on various other assumptions, including expected trends that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

In addition to making critical accounting estimates, we must ensure that our financial statements are properly stated in accordance with U.S. GAAP. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP and does not require a high degree of management judgment in its application, while in other cases, management's judgment is required in selecting among available alternative accounting standards that allow different accounting treatment for similar transactions.

Our significant accounting policies are discussed in Note 3, "Significant Accounting Policies," to the consolidated financial statements included in Item 8 of our Annual Report on Form 10-K that we filed with the SEC on March 19, 2015. We believe that the following are our most critical accounting policies and estimates, each of which is critical to the portrayal of our financial condition and results of operations and requires our most difficult, subjective and complex judgments. Our management has reviewed our critical accounting policies and the related disclosures with the Audit Committee of our Board of Directors.

INVENTORIES

Raw material, finished goods, and work in progress inventories are carried at the lower of actual cost, determined on a first-in first-out basis, and market value. Cost of finished goods and work in progress inventories includes direct materials, direct labor and applicable overhead. We write down our inventory balances for estimates of excess and obsolete amounts. These write-downs are recorded as a component of cost of sales. At the point of the write-down, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

LONG LIVED ASSET IMPAIRMENT

Long-lived assets to be held and used are periodically reviewed to determine whether any events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. For long-lived assets to be held and used, we base our evaluation on such impairment indicators such as the nature of the assets, the future economic benefit of the assets, any historical or future profitability measurements, as well as other external market conditions or factors that may be present. In the event that facts and circumstances indicate that the carrying amount of an asset may not be recoverable and an estimate of future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss will be recognized for the difference between the carrying value and the fair value.

REVENUE RECOGNITION

Product sales are recognized when legal title passes to distributors or customers, the sales price is fixed and determinable, collection of the resulting receivables is reasonably assured and no uncertainties with regard to customer acceptance exist. Sales are recorded net of discounts and sales returns.

When arrangements include multiple elements, we use objective evidence of fair value to allocate revenue to the elements, and recognize revenue when the criteria for revenue recognition have been met for each element, in accordance with authoritative guidance on multiple-element arrangements.

Upfront fees from collaborative research arrangements that are non-refundable, require our ongoing involvement and are not directly linked to specific milestones are deferred and amortized into income on a straight-line basis over the term of ongoing development. Upfront fees from collaborative research arrangements that are non-refundable, require our ongoing involvement and are directly linked to specific milestones are deferred and amortized into income as services are rendered. Upfront fees from collaborative research arrangements that are refundable are deferred and recognized once the refundable period has lapsed.

WARRANT LIABILITY

We account for warrants, issued in the 2011 rights offering, pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock. We have classified the warrants on the consolidated balance sheet as a liability that is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model, and calculating the fair value of warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of shares of our common stock for a period that coincides with the expected life of the warrants. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the warrants.

STOCK-BASED COMPENSATION

The Company uses the fair value method of accounting for all stock-based awards for non-employees and for all stock-based awards to employees that were granted, modified or settled since January 1, 2003. The fair value of stock options is determined using the Black-Scholes option-pricing model, which requires certain assumptions, including future stock price volatility, estimated forfeiture rates and expected time to exercise. Stock-based compensation expense is recorded net of estimated forfeitures such that expense is recorded only for those stock-based awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. Changes to any of these assumptions could produce different fair values for stock-based compensation. The expense is amortized on a straight-line basis over the graded vesting period.

See note 3, "Recent Accounting Pronouncements," of the consolidated financial statements in Item 1 for information related to upcoming new accounting standards introduced by the FASB. We are evaluating the impact of these upcoming standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under the rules and regulations of the United States Securities and Exchange Commission, (the “SEC”) and Canadian regulatory authorities, as a smaller reporting company, we are not required to provide information required under this item.

ITEM 4. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed or submitted under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures are also designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including its principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure.

During the quarter ended September 30, 2015, we carried out an evaluation, under the supervision and with the participation of our management, including the principal executive officer and the 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) under the Exchange Act. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this report.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

We have not made any changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not aware of any material litigation involving us that is outstanding, threatened or pending.

ITEM 1A. RISK FACTORS

Our future performance is subject to a number of risks. If any of the following risks actually occur, our business could be harmed and the trading price of our common stock could decline. In evaluating our business, you should carefully consider the following risks in addition to the other information in this Annual Report on Form 10-K. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors and, therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

RISKS RELATED TO OUR COMPANY

We may need to raise additional capital to fund operations. If we are unsuccessful in attracting capital to our Company, we will not be able to continue operations or will be forced to sell assets to do so. Alternatively, capital may not be available to our Company on favorable terms, or at all. If available, financing terms may lead to significant dilution to the shareholders' equity in our Company.

We are not profitable and have had negative cash flow from operations. Additionally, we were informed in the second quarter that our national distribution partner in China, who represented approximately 70% of our product sales in the first half of the year, would make less purchases from us during the third quarter of 2015. We believe that with a combination of some or all of the various cost reduction, cash conservation, sales and marketing, and financing initiatives, and with the targeted execution under the Joinstar Agreements, based on the projected level of operations, our cash and cash equivalent balances, including cash generated from operations, will be sufficient to meet our anticipated cash requirements through the next twelve months. If additional financing is not obtained or we are unable to achieve cash flow positive operations, we will be required to reduce or restructure operations or we may be required to cease operations. We have relied primarily on debt and equity financings to fund our operations and commercialize our products. Additional capital may not be available, at such times or in amounts as needed by us. Even if capital is available, it might be on adverse terms. Any additional equity financing will be dilutive to our shareholders. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development, manufacturing improvement, or sales generation programs, attempt to obtain funds through collaborative partners or others that may require us to relinquish rights to certain technologies or product candidates, or we may be required to significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

In February 2014, we secured a US\$2.5 million term loan from SVB of which an initial US\$1.5 million was drawn. This term loan contains covenants that may limit our flexibility in planning for or reacting to changes in our business and our industry, including limitations on incurring additional indebtedness, making investments, granting liens and merging or consolidating with other companies. Complying with these covenants may impair our ability to finance our future operations or capital needs or to engage in other favorable business activities.

If a future event of default under the term loan were to occur and it is not cured, waived, or forfeited, SVB could cause all amounts outstanding with respect to the term loan to be due and payable immediately. We cannot assure that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments, either upon maturity or if accelerated upon the event of default, or that we would be able to refinance or restructure the payments on those debt instruments.

Our inability to generate sufficient cash flows may result in our Company not being able to continue as a going concern.

We have incurred significant losses to date and we expect these losses to continue for the near future. As of September 30, 2015, we had an accumulated deficit of \$120.6 million and until the last two fiscal quarters, have only generated positive cash flow from operations in one other period, the first quarter of 2013. Our existing cash resources, along with the additional cash milestones anticipated from the funded development from our collaboration agreement, may not be sufficient to fund operations for at least the next twelve months. In addition, we may not be able to successfully earn the development milestones in our collaboration agreement with Joinstar on a timely basis or at all. Accordingly, there is substantial doubt about our ability to continue as a going concern. We may need to seek additional financing to support our continued operations and there are no assurances that any such financing can be obtained on favorable terms, if at all. In view of these conditions, our ability to continue as a going concern is dependent upon our ability to obtain such financing and, ultimately, on achieving profitable operations. The outcome of these matters cannot be predicted at this time. The consolidated financial statements for the nine months ended September 30, 2015 do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue in business. Such adjustments could be material. If we are unable to generate sufficient revenue, positive cash flow or earnings, or raise sufficient capital to maintain operations, we may not be able to continue operating our business and be forced to sell our Company or liquidate our assets.

We have evolved from a pure development company to a commercial enterprise but to date have realized minimal operating revenues from product sales. For the nine months ended September 30, 2015 and 2014, we have a net loss of \$0.4 million and \$2.4 million respectively; however, excluding the non-cash unrealized loss or gain on revaluation of our warrant liability we have incurred adjusted losses of \$1.2 million and \$4.7 million respectively. We currently are not profitable from operations and expect that operating losses could continue in the near future. Generating revenues and profits will depend significantly on our ability to obtain sufficient financing and to successfully develop, commercialize, manufacture and market our products. The time necessary to achieve market success for any individual product is uncertain. No assurance can be given that product development efforts will be successful, that required regulatory approvals can be obtained on a timely basis, if at all, or that approved products can be successfully manufactured or marketed. Consequently, we cannot assure that we will ever generate significant revenue or achieve or sustain profitability. As well, there can be no assurance that the costs and time required to complete commercialization will not exceed current estimates. We may also encounter difficulties or problems relating to research, development, manufacturing, distribution and marketing of our products. In the event that we are unable to generate adequate revenues, cash flow or earnings, to support our operations, or we are unable to raise sufficient capital to do so, we may be forced to cease operations and either sell our business or liquidate our assets.

We must increase sales of our products and/or decrease our expenses, or we may not be able to become profitable.

Our ability to achieve and maintain profitability will depend, in part, on our ability to increase our sales volumes, including through increased purchases from our national distribution partner in China. Increasing the sales volume of our products will depend upon, among other things, our ability to:

- continue to improve our existing products and develop new and innovative products;
- increase our sales and marketing activities;
- effectively manage our manufacturing activities; and
- effectively compete against current and future competitors.

We cannot provide assurance that we will be able to successfully increase our sales volumes of our products and/or decrease our expenses to become profitable or sustain profitability.

Current and future conditions in the global economy and in key country markets we serve may have a material adverse effect on our business prospects, financial condition and results of operations.

Economic performance in markets we serve has been mixed, with some countries experiencing slow growth or recessions. In addition, country specific crises such as the impact of low oil prices on certain oil producing countries and economic sanctions on countries, such as Russia, may impact our sales in those specific countries. Though we cannot predict the extent, timing, or ramifications of future financial crisis, world political events, and the economic outlook in different economies, we believe that a downturn in the world's major economies and the related constraints in the credit markets will heighten a number of material risks to our business, results of operations, cash flows and financial condition, as well as our future prospects, including the following:

- Credit availability and access to equity markets — Issues involving liquidity and capital adequacy affecting lenders could affect our ability to fully obtain credit facilities or additional debt and could affect the ability of any lenders to meet their funding requirements when we need to borrow. Further, the high level of volatility in the equity markets and the decline in our stock price may make it difficult for us to access the equity markets for additional capital at attractive prices, if at all. If we are unable to obtain credit, or access the capital markets, where required, our business could be negatively impacted.
- Credit availability to our customers — We believe that many of our customers are reliant on liquidity from global credit markets and, in some cases, require external financing to fund their operations. As a consequence, if our customers lack liquidity, it would likely negatively impact their ability to pay amounts due to us.
- Currency and import controls — Our customers may be impacted by various governmental controls on currency and restrictions on imports. These controls may impact our customers' ability to order and pay for our product.
- Commitments from our customers — There is a greater risk that customers may be slower to make purchase commitments during times of economic uncertainty or significant currency fluctuations, which may negatively impact the sales of our new and existing products.
- Supplier difficulties — If one or more of our suppliers experiences difficulties that result in a reduction or interruption in supplies or services to us, or they fail to meet any of our manufacturing requirements, our business could be adversely impacted until we are able to secure alternative sources, if any.

Many of these and other factors affecting the diagnostic technology industry are inherently unpredictable and beyond our control.

We rely significantly on third party distributors and alliance partners to market and sell our products. If we are unable to successfully negotiate or maintain acceptable agreements with potential distributors, our ability to access various markets with our products may be significantly restricted. Further, we may not be able to negotiate agreements that would permit us to sell our products at a profit.

Our marketing strategy in both the environmental and the medical diagnostics markets depends significantly on our ability to establish and maintain arrangements with third party distributors for marketing and distribution. We have recently added new distributors in a number of markets, including China, and we plan to add additional new distributors in existing and new markets. There can be no assurance that we will be able to negotiate or maintain acceptable arrangements with new and/or existing distributors enabling us to sell our products in new and existing markets or be able to sell our products at acceptable prices or volumes. Consequently, we may not be able to generate sufficient revenue or gross margins to achieve and maintain profitability.

We rely on a limited number of third party distributors to market and sell our products in China.

In the first quarter of 2015, we granted Shanghai Elite exclusive distribution rights to all of China excluding Taiwan, Hong Kong and Macao Special Administration Region effective April 23, 2015. We cannot predict whether our new national distributor will fully replace the sales previously provided by our former distributors or that our new national distributor will be able to accurately determine end-user buying patterns, which would have an adverse impact on our business performance in future years, as was the case in the second and third quarters of 2013 and the first quarter of 2014. Additionally, our national distributor in China made fewer purchases from us during the third quarter of 2015 as they are still trying to determine end-user buying patterns.

A substantial portion of our business is in China where we have limited direct presence to closely monitor and understand the rapidly expanding market.

Approximately 64% of our product revenue during the nine months ended September 30, 2015 came from sales of our products through our distribution channel partners in China. China is a dynamic and rapidly evolving market for medical technology including the POC diagnostic testing market in which we compete. While we have established a direct presence in China via a Representative Office to allow us to better monitor and understand this market, there is no assurance that these activities will be effective and will enable us to anticipate changes in this market or may impact the relationships that we have with existing Chinese distributors which could materially and adversely impact our product sales in China. In addition, as mentioned above, we have granted exclusive national rights to China to Shanghai Elite.

As we generate a large part of our revenues from international product sales and services for international customers, we are subject to risks inherent in international business, including currency exchange risk, difficulty in collecting accounts receivable, and possible marketing restrictions. Consequently, we may be restricted from selling our products in certain jurisdictions or our products may not be able to be sold at a profit.

There are various operational and financial risks associated with international activity. We may face difficulties and risks in our international business, including changing economic or political conditions, export restrictions, currency risks, export controls relating to technology, compliance with existing and changing regulatory requirements, tariffs and other trade barriers, longer payment cycles, problems in collecting accounts receivable, reimbursement levels, government mandated price reductions, reduced protection for intellectual property, potentially adverse tax consequences, limits on repatriation of earnings, the burdens of complying with a wide variety of foreign laws, nationalization, war, insurrection, terrorism and other political risks and factors beyond our control. As a consequence, these potential international risks may prevent us from selling our products in certain jurisdictions, lead to competitive products similar to ours developed and sold without properly licensing our IP, may make it very difficult or even impossible to collect on accounts receivable or may impose a variety of additional expenses on our business such that we cannot sell our products at a profit. For international sales, we price and invoice our products primarily in U.S. dollars and consequently incur a U.S./Canadian foreign exchange risk. Similarly, our customers in countries that do not have the U.S. dollar as their home currency, such as China and Russia, may face additional pricing pressure if the U.S. dollar moves unfavorably against their home currency. We also expect that there may be a greater requirement in the future for sales to European customers to be priced and invoiced in Euros. Any significant adverse change in currency exchange rates may negatively impact our profit margins such that we may not be able to generate positive cash flow or earnings from our operations. To date, we have not made any provision for a currency-hedging program. We periodically evaluate options to mitigate our exposure to currency fluctuations, but there can be no assurance that we will be able to do so.

We are not able to predict sales in future quarters and a number of factors affect our periodic results, which makes our quarterly operating results less predictable.

We are not able to accurately predict our sales in future quarters. A significant portion of our product sales is made through distributors, both domestically and internationally. Many of our distributors or sales agencies in our biggest markets are new. We do not have adequate experience working with them to accurately predict their future performance. As a result, our financial results, quarterly product sales, trends and comparisons are affected by as-yet-untried new distributors, seasonal factors and fluctuations in the buying patterns of end-user customers, our distributors, and by the changes in inventory levels of our products held by these distributors. For example, higher utilization rates of our NT-proBNP test may be due to a higher number of emergency department visits by patients exhibiting shortness of breath, a symptom of both heart failure and of influenza. However, higher utilization may also result from greater awareness, education and acceptance of the uses of our tests, as well as from additional users within the hospitals. Accordingly, our sales in any one quarter or period are not indicative of our sales in any future period.

We generally operate with a limited order backlog, because we ship our products shortly after we receive the orders from our customers. As a result, our product sales in any quarter are generally dependent on orders that we receive and ship in that quarter. As a result, any such revenue shortfall would immediately materially and adversely impact our operating results and financial condition. The sales cycle for our products can fluctuate, which may cause revenue and operating results to vary significantly from period to period. We believe this fluctuation is primarily due to (i) seasonal patterns in the decision-making processes by our independent distributors and direct customers, (ii) inventory or timing considerations by our distributors (iii) the purchasing requirements by various international governments to acquire our products and (iv) the ordering frequency of our distributors and direct customers. In addition, distributors may fail to make their contractually required minimum purchases, may change their own business priorities and interests without notifying us in advance, may otherwise violate distribution agreements or may not renew upon the expiration of current distribution agreements.

Accordingly, we believe that period to period comparisons of our results of operations are not necessarily meaningful. In the future, our periodic operating results may vary significantly depending on, but not limited to, a number of factors, including:

- new product announcements made by us or our competitors;
- changes in our pricing structures or the pricing structures of our competitors;
- our ability to develop, introduce and market new products on a timely basis, or at all;
- the timing and size of orders from our distributors;
- country specific issues or restrictions affecting the ability of our distributors to purchase our products;
- the seasonality of sales of our Influenza A+B products and the impact on demand based on the severity of the Influenza season;
- our ability to maintain existing distributors and grow our Cardiovascular and Influenza A+B and RSV testing revenues;
- our manufacturing capacities and our ability to increase the scale of these capacities;
- the mix of product sales between our instruments and our consumable products;
- our ability to take advantage of supply constraints by our competitors due to regulatory and other issues;
- the amount we spend on research and development; and
- changes in our strategy.

Although we are a Canadian company, a small number of our products are subject to U.S. export control and economic sanctions laws.

We have determined that some of our products are subject to U.S. export controls and may require a license from the U.S. Government prior to export to countries subject to economic sanctions. Although these products are manufactured in Canada, they incorporate U.S. origin components, and for that reason, they may be subject to U.S. controls.

As a result, we must monitor, on an on-going basis, the level of U.S. origin components contained in our products that may lead to more of our products being subject to U.S. controls. If we inadvertently violate U.S. export control and economic sanction laws, significant penalties that could include fines, termination of our ability to export our products, and/or referral for criminal prosecution may be imposed against us, our management, or other employees. These penalties may have a material adverse effect on our business, operating results, and financial condition.

We may not be able to compete effectively with larger, more established entities or their products, or with future organizations or future products, which could cause our sales to decline.

In-vitro diagnostics is a well-established field in which several competitors have substantially greater financial resources and larger, more established marketing, sales and service organizations than we do.

Our principal competitors in the human diagnostic market are Alere Inc. (Alere), Abbott Point of Care Inc. (Abbott), Mitsubishi Chemical Corporation (Mitsubishi), Roche Diagnostics (Roche), Siemens AG (Siemens), Becton Dickinson Corporation, and Quidel Corporation. Alere, Abbott and Roche have quantitative POC systems, and Mitsubishi and Siemens produce a small quantitative bench-top system, for the detection of some cardiac markers.

In addition, in various emerging markets such as China, there may be local competitors who sell only in that specific country. Some of these local competitors may be very strong competitors in their local markets due to factors which may include lower cost of production, stronger sales, marketing and distribution capabilities, less stringent quality standards and customer quality expectations, customer familiarity and preference for local suppliers and local government environments which may favor local companies and their products and/or may preferentially, or by statute, favor POC testing device manufacturers offering the lowest price.

In the biodefense testing market, our primary competitors are Alexeter Technologies LLC (Alexeter), Idaho Technology Inc., Cepheid Inc. (Cepheid) and Biofire Defense. Alexeter sells rapid on-site immunoassay tests that are read by an instrument and Cepheid and Biofire Defense have a polymerase chain reaction test system being sold in this marketplace.

In the environmental West Nile Virus testing market, our primary competitor is Medical Analysis Systems, Inc., which is wholly owned by Thermo Fisher Scientific, Inc. Medical Analysis Systems, Inc. markets and sells a product for the rapid detection of West Nile virus.

We believe the primary competitors in the POC Influenza A+B and RSV testing market are Binax, Inc., a division of Alere, Becton Dickinson Corporation and Quidel Corporation. Each of these companies has qualitative POC tests for the detection of Influenza A+B and RSV.

Many of our competitors have significantly larger product lines to offer and greater financial and other resources to acquire or develop new or competing technologies than we do. In addition, many of these competitors have large sales forces and well-established distribution channels and well-known brand names. In the event that we are not able to compete successfully in the marketplace, we may face limited adoption of our products by potential customers or erosion of current market share, which would seriously impede our ability to generate revenue.

Our business may be impacted by political events, war, terrorism, public health issues, natural disasters and other circumstances.

War, terrorism, geopolitical uncertainties, and other business interruptions have caused and could cause damage or disruption to international commerce and the global economy, and thus could have a material adverse effect on our Company, our suppliers, logistics providers, manufacturing vendors, and customers, including our channel partners. Our operations are subject to interruption by events beyond our control, which could decrease demand for our products, make it difficult or impossible to make and deliver products to our customers, including channel partners, or to receive components from our suppliers, and create delays and inefficiencies in our supply chain. Should any of these events occur, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to re-obtain market share or resume operations.

A larger-than-required and high cost facility lease and associated cash used to repay additional financial obligations associated with the facility will negatively impact our operating results and financial position.

In May 2007, we entered into an agreement to lease a multi-use, 46,000 square foot facility in Vancouver, British Columbia, Canada. Although we have recently brought our Reader manufacturing in-house, this facility, which we have occupied as our main operation center since 2008, is significantly larger than required for our near term production requirements. The excess space is difficult to sublease due to the current layout of the company's manufacturing operations and the significant availability of space in other buildings in the local real estate market. In addition to rental payments for the facility, we are obligated to repay with interest over the next 7.25 years the \$5.3 million balance due as of September 30, 2015 on the repayable leasehold improvement allowance.

We believe that the financial obligation associated with this facility lease and associated liabilities represent a total facilities cost significantly above the current real estate market prevailing lease rates. This factor, together with the excessive size of the facility, may adversely affect the company's financial performance.

Should there be a downturn in our business or the markets in which we compete, we may not achieve maximum utilization of our facility. As a result, we may then seek an alternative use for all or a portion of the property or seek to sub-lease some or all of our property. We may experience unanticipated decreases in productivity and other losses due to inefficiencies relating to any such transition, or delays in obtaining any required approvals or clearances from regulatory agencies related to the validation of any new manufacturing facilities. For instance, the scale-up of manufacturing at our planned facility could result in lower than expected manufacturing output and higher than expected product costs.

Sole-source suppliers provide some of our raw materials. In the event a sole-sourced raw material became unavailable, there may be a delay in obtaining an alternate source, and the alternate source may require significant development to meet product specifications. It is also possible that we may not be able to locate an acceptable alternate source on a timely basis, or at all. Consequently, we may face difficulty in manufacturing, or be entirely unable to manufacture, some of our products.

Single-source suppliers provide some key components, in particular antibodies, used in the manufacture of our products. We do not have supply agreements with all of our single-sourced suppliers. We are currently negotiating supply agreements for some of the key reagents that we use. Although we maintain inventories of some key components, including antibodies, any loss or interruption in the supply of a sole-sourced component or raw material would have a material adverse effect on our ability to manufacture these products until a new source of supply is qualified and, as a result, may temporarily or even permanently prevent us from being able to sell our products. Given the nature of variations in biological raw materials, a new supply source of antibodies may require considerable time and resources to develop manufacturing procedures to meet the required product performance levels for commercial sale. Additionally, it may require us to enter into supply agreements on commercially reasonable terms with the new suppliers to ensure supply or there could be a material adverse effect on our ability to manufacture product for commercial sale.

Interruption in the supply of any sole-sourced component or raw material would likely have a material adverse effect on our profit margins, our ability to develop and manufacture products on a timely and competitive basis, and the timing of market introductions and subsequent sales of products.

We rely significantly on third party manufacturers for some components of our products and rely on third party manufacturers of certain equipment necessary for us to scale-up our internal capacity to manufacture products. If these third party manufacturers experience difficulties, our ability to serve various markets with our products may be significantly restricted.

All of our test kits, or Kits, and our portable fluorescence readers, or Readers, are currently produced in-house. Some of the components of our Readers are assembled by third party manufacturers. To meet the projected demand for our products, we will require additional equipment to scale up our manufacturing processes. Some of this equipment will require customization that may increase the lead-time from the supplier. If demand for our products significantly exceeds forecasts, or manufacturing equipment is unable to be delivered to us on schedule, we may not be able to meet customer requirements.

Some components of our instruments face obsolescence pressure. If we are not able to secure enough of these components or design and receive any required regulatory approvals for replacement components to meet our future demands, our ability to serve various markets may be significantly restricted or eliminated.

As component manufacturers manage their product lifecycles, some critical components used in the manufacturing of our Readers may become unavailable resulting in delays in production or lead to the inability to manufacture our instrument as currently designed. In some cases, we are able to secure sufficient quantities of the components prior to their obsolescence to continue manufacturing until replacement components can be sourced or designed and the required regulatory approvals are received. Should these safety stocks of older components or product design updates for replacement components prove insufficient, we may experience significant delays in production or the potential inability to manufacture our instrument as currently designed may occur. As a result, we may not be able to meet customer requirements, and that could have a material adverse effect on future sales.

To the extent we are able to enter into collaborative arrangements or strategic partnerships, we will be exposed to risks related to those collaborations and partnerships.

We are currently party to a collaboration agreement and related supply agreement with Joinstar. The success of the collaboration agreement and the timing of our receipt of the development milestones is dependent on our and Joinstar's success in the co-development of components and assays to be run on a new immunoassay analyzer developed by Joinstar. In addition, since marketing and distribution of the co-developed assays will be the responsibility of Joinstar, we are dependent on the success of their marketing efforts under the supply agreement.

The collaboration with Joinstar could subject us to a number of risks, including the risk that:

- We may not be able to control the amount and timing of resources that Joinstar will devote to the co-development and marketing of the assays;
- Joinstar may experience financial difficulties or technical difficulties in the development of their new immunoassay analyzer; and
- Significant changes in a Joinstar's business strategy may adversely affect their willingness or ability to complete their obligations under our agreements.

We may not be able to adequately protect our technology and proprietary rights, and third parties may claim that we infringe on their proprietary rights. If we cannot protect our technology, companies with greater resources than us may be able to use our technology to make products that directly compete with ours. Additionally, third parties claiming that we infringe on their proprietary rights may be able to prevent us from marketing our products or force us to enter into license agreements to do so. Both situations may negatively impact our ability to generate revenues, cash flows and earnings.

The success of our technology and products is highly dependent on our intellectual property portfolio, for which we have sought protection through a variety of means, including patents (both issued and pending) and trade secrets, see "Intellectual Property". There can be no assurance that any additional patents will be issued on existing or future patent applications or on patent applications licensed from third parties. Even when such patents have been issued, there can be no assurance that the claims allowed will be sufficiently broad to protect our technologies or that the patents will provide protection against competitive products or otherwise be commercially valuable. No assurance can be given that any patents issued to or licensed to us will not be challenged, invalidated, infringed, circumvented or held unenforceable. In addition, enforcement of our patents in foreign countries will depend on the attitudes, laws and procedures in those foreign jurisdictions. Monitoring and identifying unauthorized use of our technologies or licensed technologies may prove difficult, and the cost of litigation to enforce our IP may impair our ability to guard adequately against such infringement. If we are unable to successfully defend our intellectual property, third parties may be able to use our technology to commercialize products that compete with ours. Further, defending intellectual property can be a very costly and time-consuming process. The costs and delays associated with such a defense, even if successful, may negatively impact our financial position.

There are many patent claims in the area of lateral flow immunoassays and some patent infringement lawsuits have occurred amongst parties, other than ourselves, with respect to patents in this area. Our commercial success may depend upon our products not infringing on any intellectual property rights of others and upon no such claims of infringement being made. In the event that a third party was able to substantiate a claim against us, it could result in us not being able to sell our products in certain markets or at all. Further, as a result we may be required to enter into license agreements with said third parties on terms that would negatively impact our ability to conduct our business. Even if such claims were found to be invalid, the dispute process would likely have a materially adverse effect on our business, results of operations and prospects. To date, to the best of our knowledge, there have been no threats of litigation, legal actions or other claims made against any of our intellectual property. Although we attempted to identify patents that pose a risk of infringement, there is no assurance that we have identified all U.S. and foreign patents that present such a risk.

In addition to patent protection, we also rely on trade secrets, proprietary know-how and technological advances which we seek to protect, in part, through confidentiality agreements with our collaborative partners, employees and consultants. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that the trade secrets and proprietary know-how will not otherwise become known or be independently discovered by others, which could negatively impact our ability to compete in the marketplace.

To continue developing new products or enhance existing ones, we may need to obtain licenses to certain technologies and rights from third parties, and such licenses may not be available on acceptable terms, or at all. If our product development efforts are hindered, we may face considerable challenges competing in the market place with our existing products or be unable to introduce new products.

Although we believe we are able to conduct our business based on our current intellectual property portfolio, there is a risk that additional non-core technology licenses may be required in the development of new products or to enhance the performance characteristics of our existing products. We believe that such licenses would generally be available on a non-exclusive basis; however, there is no guarantee that they will be available on acceptable terms, or at all. If we are unable to license any required non-core technology, it may impede our product development capabilities, which may put us at a competitive disadvantage in the market place and negatively affect our ability to generate revenue or profits.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries, including China, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We depend on our key personnel, the loss of whose services could adversely affect our business.

We are highly dependent upon the members of our management and scientific staff, who could leave Response at any time. The loss of these key individuals could impede our ability to achieve our business goals. Our Chief Executive Officer and Senior Vice President of Worldwide Sales and Marketing resigned during the third quarter of 2014 and our General Manager in China resigned during the first quarter of 2015. The Board consequently promoted a senior executive to Chief Operating Officer and then to Chief Executive Officer during the second quarter of 2015. In addition, after a successful candidate search, we hired a new general manager for our China office during the third quarter of 2015. The Board continues to work closely and support the remaining management team and believes this team has the potential to effectively lead the company's recovery and future growth. There can be no assurance however that the current management team can continue to improve operations and achieve strong targeted future growth due to the substantial workload facing the small leadership team.

We face competition for qualified employees from numerous industry and academic sources, and there can be no assurance that we will be able to retain our key managers and other qualified personnel on acceptable terms. We currently do not have key person insurance in place on any of our key employees. In the event that we are unable to retain key personnel, and recruit qualified key personnel on favorable terms, we may not be able to successfully manage our business operations, including sales and marketing activities, product research and development and manufacturing. As a consequence, we may not be able to effectively develop and manufacture new products, negotiate strategic alliances or generate sufficient revenue growth from existing products.

Compliance with changing regulations and standards for accounting, corporate governance and public disclosure may result in additional expenses.

To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with evolving regulations and standards for accounting. These investments may result in increased general and administrative expenses and a diversion of management time and attention from strategic revenue generating and cost management activities. If we fail to maintain effective internal controls and procedures for financial reporting, or the SEC requirements applicable to these, we could be unable to provide timely and accurate financial information and therefore be subject to investigation by the SEC, and civil or criminal sanctions. Additionally, ineffective internal control over financial reporting would place us at increased risk of fraud or misuse of corporate assets and could cause our stockholders, lenders, suppliers and others to lose confidence in the accuracy or completeness of our financial reports.

Management is required to determine if material weaknesses exist in our internal control over financial reporting.

We are required to maintain internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes. If we fail to maintain effective internal controls over financial reporting and disclosure controls and procedures, our business and results of operations could be harmed, we may be unable to report properly or timely the results of our operations and investors may lose faith in the reliability of our financial statements. Ineffective internal control over financial reporting may also increase the risk of, or result in, fraud or misuse of our corporate assets. As a consequence, the market price of our securities may be harmed. In addition, our current or former officers, directors and employees, may be subject to investigation by the SEC or Canadian securities regulators, and civil or criminal sanctions, or shareholder lawsuits, any of which could result in a significant expense whether directly or indirectly through the Company's statutory or contractual obligations to indemnify such persons, and require significant investments of management time, which may prevent management from focusing its efforts on our business operations.

We may be subject to breaches of our information technology systems, which could cause substantial harm to our business.

We maintain significant proprietary information and manage personal data and confidential information about our employees and customers. Although cybersecurity and the continued development and enhancement of our controls, processes and practices designed to protect our systems, computers, software, data and networks from attack, damage or unauthorized access are a high priority for us, this may not successfully protect our systems against all vulnerabilities, including technologies developed to bypass our security measures. In addition, outside parties may attempt to fraudulently induce employees or customers to disclose sensitive information in order to gain access to our secure systems and networks.

As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. Further, because the techniques used to gain access to, or sabotage, systems often are not recognized until launched against a target, we may be unable to anticipate the correct methods necessary to defend against these types of attacks. Any actual breach, the perceived threat of a breach or a perceived breach, could cause our customers to cease doing business with us, subject us to lawsuits, regulatory fines or other action or liability, which would harm our business, financial condition and results of operations.

We may be subject to product liability claims, which may adversely affect our operations.

We may be held liable or incur costs to settle liability claims if any of the products we sell cause injury or are found unsuitable. Although we currently maintain product liability insurance, we cannot be assured that this insurance is adequate, and, at any time, it is possible that such insurance coverage may cease to be available on commercially reasonable terms, if at all. A product liability claim could result in liability to us greater than our total assets or insurance coverage. Moreover, product liability claims could have an adverse impact on our business even if we have adequate insurance coverage.

Manufacturing risks and inefficiencies may adversely affect our ability to produce products and could reduce our gross margins and increase our research and development expenses.

We are subject to manufacturing risks, including our manufacturing experience with newer products and processes, which may hinder our ability to scale-up manufacturing. Additionally, unanticipated acceleration or deceleration of customer demand may lead to manufacturing inefficiencies. We must manufacture our products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining acceptable product quality and manufacturing costs. Significant additional resources, implementation of additional automated and semi-automated manufacturing equipment and changes in our manufacturing processes and organization have been, and are expected to continue to be, required for scale-up to meet increasing customer demand, and this work may not be affordable and/or successfully or efficiently completed.

In addition, although we expect some of our newer products and products under development to share production attributes with our existing products, production of these products may require the development of new manufacturing technologies and expertise. It may not be possible for us, or any other party, to manufacture these products at a cost or in quantities to make these products commercially viable.

Manufacturing and quality problems have arisen and may arise in the future as we attempt to scale-up our manufacturing capacity to meet potentially higher future sales growth and implement automated and semi-automated manufacturing methods. We rely on third parties for the manufacture of much of our automated and semi-automated manufacturing equipment. Consequently, implementation of automated and semi-automated manufacturing methods may not be achieved in a timely manner or at a commercially reasonable cost, or at all. In addition, we continue to make investments to improve our manufacturing processes and to design, develop and purchase manufacturing equipment that may not yield the improvements that we expect. Unanticipated acceleration and deceleration of customer demand for our products has resulted, and may continue to result, in inefficiencies or constraints related to our manufacturing, which has harmed, and may in the future harm, our gross margins and overall financial results. Such inefficiencies or constraints may also result in delays, lost potential product sales or loss of current or potential customers due to their dissatisfaction.

We may not be able to effectively and efficiently manage the planned growth of our operations and, as a result, we may find ourselves unable to effectively compete in the marketplace with our products resulting in lost revenue, poor operational performance, and sustained losses.

We anticipate growth in the scope of the operating and financial systems and the geographic area of operations as new products are developed and commercialized. This growth will result in increases in responsibilities for both existing and new management personnel. Managing growth effectively will require us to continue to implement and improve operational, financial and management information systems, and to successfully attract, hire on favorable terms, develop, motivate and manage employees. This growth may require additional locations and new capital equipment. If we are unable to successfully manage and finance our expansion, we may experience an inability to take advantage of new sales opportunities, poor employee morale, an inability to attract new employees and management, an inability to generate adequate financial and other relevant reports, poor quality control and customer service and difficulty managing our operating expenses and working capital. As a consequence, we may find ourselves unable to compete effectively in the market place with our products leading to loss of revenue and poor operational performance, including sustained losses.

The research and development of our products carries substantial technical risk. We may not be able to successfully commercialize future products. As a consequence, our ability to expand our product portfolio to generate new revenue opportunities may be severely limited.

Our future growth will depend upon, among other factors, our ability to afford and to successfully develop new products and to make product improvements to meet evolving market needs. Although we believe that we have the scientific and technical resources available, future products will nevertheless be subject to the risks of failure inherent in the development of products based on innovative technologies and our ability to fund the timely development of new products. Any specific new product in research and development may face technical challenges that may significantly increase the costs to develop that product, cause delays to commercialization or prevent us from commercializing that product at all. Additionally, our currently constrained financial resources may limit our ability to develop new products and technologies. Although we expect to continue to expend resources on research and development efforts, to enhance existing products and develop future ones, we are unable to predict whether research and development activities will result in any commercially viable products. There can be no assurance that we will be able to successfully develop future products and tests. This would prevent us from introducing new or improved products in the marketplace, could allow for competing products to capture additional market shares and would negatively impact our ability to grow our revenues and become profitable.

Our Company is organized under the laws of British Columbia, Canada, and certain of our directors and officers and substantially all of our assets are located outside of the United States, which may make enforcement of United States judgments against us difficult.

We are organized under the laws of British Columbia, Canada, substantially all of our assets are located outside of the United States and certain members of our directors and officers are residents outside of the United States. Currently, we only maintain a permanent place of business within the United States, for our wholly owned U.S. subsidiary, Response Point Of Care, Inc. As a result, it may be difficult for U.S. investors to affect service of process, or enforce within the United States any judgments obtained against us or those officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. In addition there is uncertainty as to whether the courts of Canada would recognize, or enforce, judgments of United States courts obtained against us, or our directors and officers, predicated upon the civil liability provisions of the securities laws of the United States, or any state thereof; or be competent to hear original actions brought in Canada against us, or our directors and officers, predicated upon the securities laws of the United States, or any state thereof.

Valuation of stock-based payments, which we are required to perform for purposes of recording compensation expense under FASB – ASC 718 "Compensation - Stock Compensation", involves significant assumptions that are subject to change and difficult to predict.

On January 1, 2006, we adopted FAS 123(R), which is now codified as FASB ASC 718 Compensation – Stock Compensation, which requires that we record compensation expense in the statement of income for stock-based payments, such as stock options, using the fair value method. As long as stock-based awards are utilized as part of our compensation strategy, the requirements of ASC 718 have had, and will continue to have, a material effect on our future financial results reported under Generally Accepted Accounting Principles, and make it difficult for us to accurately predict our future financial results.

For instance, estimating the fair value of stock-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. Our stock-based payments have characteristics significantly different from those of freely traded options, and changes to the subjective input assumptions of our stock-based payment valuation models can materially change our estimates of the fair values of our stock-based payments. In addition, the actual values realized upon the exercise, expiration, early termination, or forfeiture of stock-based payments might be significantly different than our estimates of the fair values of those awards as determined at the date of grant.

ASC 718 could also adversely impact our ability to provide accurate guidance on our future financial results as assumptions that are used to estimate the fair value of stock-based payments are based on estimates and judgments that may differ from period to period. For instance, we may be unable to accurately predict the timing, amount, and form of future stock-based payments to employees or directors. We may also be unable to accurately predict the amount and timing of the recognition of tax benefits associated with stock-based payments as they are highly dependent on the exercise behavior of our employees, and the price of our stock relative to the exercise and fair value of each outstanding stock option.

For those reasons, among others, ASC 718 may create variability and uncertainty in the compensation expense we will record in future periods, potentially negatively impacting our ability to provide accurate financial guidance. This variability and uncertainty could further adversely impact our stock price, and increase our expected stock price volatility as compared to prior periods.

RISKS RELATED TO OUR INDUSTRY

Products in the biomedical industry, including ours, may be subject to government regulation. Obtaining government approvals can be costly and time consuming. Any failure to obtain necessary regulatory clearances will restrict our ability to sell those products and impede our ability to generate revenue.

As we operate in the biomedical industry, some of our products are subject to a wide variety of government regulation (federal, state, and municipal) within the United States, China and in other international jurisdictions. For example, Health Canada, the FDA, the CFDA and comparable regulatory agencies in other countries impose substantial pre-market approval requirements on the introduction of medical products, through lengthy and detailed clinical testing programs and other costly and time consuming procedures. Satisfaction of these requirements is expensive and can take a long period of time depending upon the type, complexity, and novelty of the product. All medical devices manufactured for sale in the United States and Canada, regardless of country of origin, must be manufactured in accordance with Good Manufacturing Practices specified in regulations under the Federal Food, Drug, and Cosmetic Act. These practices control the product design process as well as every phase of production from incoming receipt of raw materials, components, and subassemblies to product labeling, tracing of consignees after distribution, and follow-up and reporting of complaint information. Both before and after a product is commercialized, we have ongoing responsibilities under the regulations of Health Canada, the FDA, the CFDA and other agencies. Noncompliance with applicable laws and the requirements of Health Canada, the FDA, the CFDA and other agencies can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals, and criminal prosecution. Health Canada, the FDA, the CFDA and other agencies have the authority to request recall, repair, replacement, or refund of the cost of any device manufactured or distributed by us. The FDA and CFDA also administer certain controls over the import and export of medical devices to and from the United States and China respectively. The U.S. Clinical Laboratory Improvement Acts of 1988 also affects our medical products. This law is intended to assure the quality and reliability of all medical testing in the United States regardless of where tests are performed. The regulations require laboratories performing clinical tests to meet specified standards in the areas of personnel qualification, administration, and participation in proficiency testing, patient test management, quality control, quality assurance, and inspections.

Sales and pricing of medical products, including ours, are affected by third-party reimbursement. Depending on our manufacturing costs, we may not be able to profitably sell our products at prices that would be acceptable to customers affected by third party reimbursement programs. Consequently, we may have difficulty generating revenue from these customers, resulting in reduced profit margins and potential operating losses.

Third party payers can indirectly affect the pricing and, therefore, the relative attractiveness of our products by regulating the maximum amount of reimbursement provided for testing services. These third party payers increasingly challenge prices paid for medical products, and the cost effectiveness of such products due to global pressure on healthcare costs. If the reimbursement amounts for testing services are decreased in the future, it may decrease the amount that physicians and hospitals are able to charge patients for such services and therefore the prices that we, or our distributors, can charge for our products. Consequently, our ability to generate revenue and/or profits may be negatively impacted for both existing and new products.

Significant uncertainty exists as to the reimbursement potential of newly cleared health care products, if any. The reimbursement amounts paid by third-party payers on existing medical products can be reduced at any time. There can be no assurance that products will be considered cost effective, or that reimbursement from third party payers will be available, or, if available, that reimbursement will not be limited, thereby adversely affecting our ability to sell products or sell our products at a profit.

Our business is substantially dependent on market acceptance of our products. As well, our environmental and biodefense business is affected by industry, governmental and public perceptions of these products in general. Failure to obtain or retain market acceptance for some or all of our products would have a negative impact on our revenue and ability to operate profitably.

The commercial success of our clinical tests is highly dependent upon the acceptance and adoption of the tests by the medical community. The medical community tends to be very conservative with regards to adopting new technologies and products. Often substantial data and evidence supporting product performance is required to generate market acceptance. If we are unsuccessful in generating market acceptance, our ability to generate revenue and hence profits would be severely limited.

The commercial success of our environmental and biodefense tests is dependent upon their acceptance by the public safety community and government funding agencies as being useful and cost effective. In addition, the purchase of our biodefense products in the United States (our largest potential market) by the public safety community is highly dependent on the availability of federal and state government funds dedicated to "homeland security". In the event that homeland security funds became unavailable for use (to purchase our products or otherwise) or the release of such funds was significantly delayed, it would have a negative effect on our ability to generate revenue or profits.

Federal, state and foreign regulations regarding the manufacture and sale of medical devices continue to evolve and are constantly subject to change. We cannot predict what regulations may come into effect in the future and what impact, if any; such regulatory changes may have on our business.

A majority of our sales are through distributors in foreign markets who sell our products or modifications of our products in their local country markets. Sales through these distributors in these markets are usually subject to the regulators in those markets. Frequently our distributors are responsible for obtaining and maintaining regulatory approval in their territories and are thus subject to all of those requirements. In the future, should we elect to build our own sales and marketing operations in certain countries outside the US, we would be subject to extensive regulations in each of those countries. We may not be successful in such new initiatives.

If products in the biodefense testing industry and other environmental testing segments, including ours, become subject to government legislation in the future, obtaining necessary government approvals may be very costly and time consuming. Failure to obtain government approvals will restrict our ability to sell our products and impede our ability to generate revenue.

In the biodefense and West Nile Virus testing markets, there is currently an absence of regulatory checks and balances and there is significant market uncertainty and misinformation. While we believe it is likely that future regulatory requirements in these markets will come into effect, the form and substance of these regulations remain highly uncertain. The effect of government regulations may be to prevent or to delay marketing and pricing of any new products for a considerable or indefinite period or to require additional studies prior to approval. Federal, state and foreign regulations, or lack thereof, regarding the sale of environmental testing devices are subject to change. We cannot predict the impact, if any, such changes may have on our business.

We operate primarily selling through distributors in highly competitive markets, with continual developments in new technologies and products. Some of our competitors have significantly greater resources than we do. Others, while having fewer resources than we do, may nevertheless have a very strong market or other leadership position in a specific local market where we or our distributors compete. We or our distributors may not be able to compete successfully based on many factors, including product price or performance characteristics, sales and marketing effort or customer support capabilities. An inability to successfully compete could lead to us having limited prospects for establishing market share or generating revenues.

The diagnostic industry is characterized by extensive research efforts, ongoing technological progress and intense competition. There are many public and private companies, including well-known diagnostic companies, engaged in marketing and developing products for the markets we have targeted. Many of these companies have substantially greater financial, technical and human resources than we do, including direct sales in countries in which we are selling our products. While we are in the process of establishing our distribution networks in the United States and China, our competitors may be more successful in convincing potential customers to adopt their products over ours and hence gain greater market share. Competitors with greater financial resources may also have an advantage when dealing with suppliers, particularly sole source suppliers providing antibodies or unique reagents. Additionally, they may develop technologies and products that are more effective than any products developed by us, or that would render our technologies and products obsolete or non-competitive.

In addition, in various emerging markets such as China, there may be local competitors who sell only in that specific country. Some of these local competitors may be very strong competitors in their local markets due to factors, which may include lower cost production, stronger sales, marketing and distribution capabilities, customer familiarity and preference for local suppliers and local government environments, which may favor local companies and their products.

In addition to the specific competitive risks from rapid diagnostic manufacturers that we face in the market for our tests, we face intense competition in the general market for diagnostic testing including companies making laboratory-based tests and analyzers, and clinical reference laboratories. Currently, the majority of diagnostic tests prescribed by physicians and other healthcare providers are performed by independent clinical reference laboratories and hospital-based laboratories using automated testing systems. Therefore, in order to achieve market acceptance for our products, we will be required to demonstrate that our products provide clinical benefit and are cost-effective and time saving alternatives to automated tests traditionally used by clinical reference laboratories or hospital-based laboratories.

Companies operating in our industry may be impacted by potential healthcare reform, including decreased reimbursement for our product's use. Such healthcare reform may include pricing restrictions on medical products, including ours, that may restrict our ability to sell our products at a profit.

Healthcare reform bills that have been before the United States Congress and government officials in other countries contemplate changes in the structure, financing, and delivery of healthcare services. These and any future healthcare reforms may have a substantial impact on the operations of companies in the healthcare industry worldwide, including us. Such reforms could include product pricing restrictions, excise taxes, or additional regulations governing the usage of medical products. No assurances can be given that any such proposals, or other current, or future, legislation in the United States, or other countries, will not adversely affect our product development and commercialization efforts, results of operations, or financial condition. At this time, we are unaware of any recent legislation or pending legislative proposals that will materially negatively affect our business.

The impact of consolidation of several major competitors in the market for immunoassay testing is difficult to predict and may harm our business.

The market for immunoassay-based diagnostic testing is rapidly changing as a result of consolidation in the industry. There have been many acquisitions in the medical diagnostics market including several by Alere, which helped the company expand its presence in the market for rapid diagnostic tests used in hospitals and doctors' offices. Siemens and Alere both have significant existing businesses in diagnostics and/or related markets for healthcare equipment and services. It is unclear how these completed, or future, acquisitions will impact the competitive landscape for our products, or for hospital-based diagnostic testing in general. However, because these competitors sell a broad range of product offerings to our prospective hospital customers, and because of the substantially greater financial resources and more established marketing, sales, and service organizations that they each have, we believe there is greater risk that these new consolidated competitors may offer discounts as a competitive tactic, or may hold other competitive advantages as a result of their ability to sell to a broader menu of important hospital infrastructures, for equipment and information systems, on a combined, or bundled basis.

Our business and industry is affected by seasonality, including governmental budget cycles. We may not be able to successfully scale up operations to meet demand during peak seasonal periods or scale down operations during periods of low demand, which could result in lost revenue and/or reduced manufacturing efficiencies, negative cash flows and losses.

Our operating results may fluctuate from quarter to quarter due to many seasonal factors. Many of our prospective customers are government related organizations at a federal, state/provincial or municipal level. Consequently, our sales may be tied to government budget and purchasing cycles. Sales may also be slower in the traditional vacation months, could be accelerated in the first or fourth calendar quarters by customers whose annual budgets are about to expire (especially affecting purchases of our test Readers), may be distorted by unusually large Reader shipments from time to time, or may be affected by the timing of customer cartridge ordering patterns. Seasonality may require us to invest significantly in additional resources including equipment, labor, and inventory to meet demand during peak seasonal periods. There can be no assurance that we will be successful in putting in place the resources to meet anticipated demand, which could lead to lost revenue opportunities. If we cannot scale down our operations and expenses sufficiently during periods of low demand for our products, we may experience significantly negative cash flow and operating losses. If we are unable to adequately forecast seasonal activity, we may experience periods of inventory shortages or excesses that would negatively impact our working capital position.

RISKS RELATED TO OUR COMMON STOCK

As we have a large number of warrants and stock options outstanding, our shareholders will experience dilution from these options and warrants in the event that they are exercised.

As of September 30, 2015, we had outstanding stock options to purchase an aggregate of 1,287,631 shares, at exercise prices between \$0.72 and \$8.20, warrants to purchase an aggregate of 5,067,134 shares at exercise prices between \$1.00 and \$3.58, and 112,489 restricted share units, which in total represents 39% of our fully diluted outstanding share capitalization at that date. To the extent that these outstanding options and warrants are exercised, considerable dilution to the interests of our shareholders will occur.

The price of our common stock may be volatile, and a shareholder's investment in our common stock could suffer a decline in value.

There has been significant volatility in the volume and market price of our common stock, and this volatility may continue in the future. This volatility may be caused by a variety of factors, including the lack of readily available quotations, the absence of consistent administrative supervision of "bid" and "ask" quotations, and generally lower trading volume. In addition, factors such as quarterly variations in our operating results, changes in financial estimates by securities analysts or our failure to meet our or their projected financial and operating results, litigation involving us, general trends relating to the medical device industry, actions by governmental agencies, national economic and stock market considerations, as well as other events and circumstances beyond our control, could have a significant impact on the future market price of our common stock and the relative volatility of such market price.

Because our common stock is considered a "penny stock," a shareholder may have difficulty selling shares in the secondary trading market.

Our common stock is subject to certain rules and regulations relating to "penny stock" (generally defined as any equity security that is not quoted on the Nasdaq Stock Market and that has a price less than US\$5.00 per share, subject to certain exemptions). Broker-dealers who sell penny stocks are subject to certain "sales practice requirements" for sales in certain nonexempt transactions (e.g., sales to persons other than established customers and institutional "accredited investors"), including requiring delivery of a risk disclosure document relating to the penny stock market and monthly statements disclosing recent price information for the penny stock held in the account, and certain other restrictions. For as long as our common stock is subject to the rules on penny stocks, the market liquidity for such securities could be significantly limited. This lack of liquidity may also make it more difficult for us to raise capital in the future through sales of equity in the public or private markets.

Because our common stock is not traded on a national securities exchange in the U.S., a U.S. shareholder's ability to sell shares in the secondary trading market may be limited.

Our common stock is currently listed for trading in Canada on the Toronto Stock Exchange. Our common stock is also quoted in the United States on the OTCQB. Shareholders may find it more difficult to dispose of or to obtain accurate quotations as to the price of our securities than if the securities were traded on a national securities exchange like The New York Stock Exchange, the NASDAQ Stock Market or the NYSE Amex LLC.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference
3.1	Certificate of Incorporation dated August 20, 1980.	Previously filed as an exhibit to, and incorporated herein by reference from, our Annual Report on Form 20-F for the year ended December 31, 2004, as filed on May 2, 2005.
3.2	Company Act Name Change dated October 15, 1991.	Previously filed as an exhibit to, and incorporated herein by reference from, our Annual Report on Form 10-K for the year ended December 31, 2011 as filed on March 29, 2012.
3.3	Articles of the Company dated April 10, 1997.	Previously filed as an exhibit to, and incorporated herein by reference from, our Registration Statement on Form 20-F filed on February 4, 2004.
4.1	Escrow Agreement dated July 29, 2004.	Previously filed as an exhibit to, and incorporated herein by reference from, our Annual Report on Form 20-F for the year ended December 31, 2004, as filed on May 2, 2005.
31.1	CEO's Certification required by Rule 13A-14(a) of the Securities Exchange Act of 1934	
31.2	CFO's Certification required by Rule 13A-14(a) of the Securities Exchange Act of 1934	
32.1	CEO's Certification of periodic financial reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, U.S.C. Section 1350	
32.2	CFO's Certification of periodic financial reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, U.S.C. Section 1350	
101	The following materials from Response Biomedical Corp.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) unaudited Consolidated Statements of Loss and Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014, (ii) unaudited Consolidated Balance Sheets as of September 30, 2015, (iii) audited Consolidated Balance Sheets as of December 31, 2014, (iv) unaudited Consolidated Statements of Shareholders' Deficit as of September 30, 2015 (v) unaudited Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (vi) unaudited Notes to Consolidated Financial Statements	

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Response Biomedical Corp.
(Registrant)

Date: November 12, 2015

/s/ Dr. Barbara R. Kinnaird
Dr. Barbara R. Kinnaird
Chief Executive Officer

Date: November 12, 2015

/s/William J. Adams
William J. Adams
Chief Financial Officer

CERTIFICATION PURSUANT TO
RULE 13A-14 OR 15D-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Barbara R. Kinnaird, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Response Biomedical Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 12, 2015

/s/ Dr. Barbara R. Kinnaird
Dr. Barbara R. Kinnaird
Chief Executive Officer

CERTIFICATION PURSUANT TO
RULE 13A-14 OR 15D-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William J. Adams, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Response Biomedical Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 12, 2015

/s/ William J. Adams

William J. Adams
Chief Financial Officer

CERTIFICATION PURSUANT TO
18 U.S.C SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Response Biomedical Corp. (the "Company") for the period ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Barbara R. Kinnaird, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Dr. Barbara R. Kinnaird
Dr. Barbara R. Kinnaird
Chief Executive Officer

Dated: November 12, 2015

CERTIFICATION PURSUANT TO
18 U.S.C SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Response Biomedical Corp. (the "Company") for the period ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William J. Adams, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ William J. Adams
William J. Adams
Chief Financial Officer

Dated: November 12, 2015