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**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, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 000-54785

INTEGRITY APPLICATIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware

98-0668934

(State or other jurisdiction of
incorporation or organization)

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

19 Ha'Yahalomim Street
P.O. Box 12163
Ashdod, Israel

L3 7760049

(Address of principal executive offices)

(Zip Code)

972 (8) 675-7878

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 14, 2018, 8,864,612 shares of the Company's common stock, par value \$0.001 per share, were outstanding.

INTEGRITY APPLICATIONS, INC.

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INTEGRITY APPLICATIONS, INC.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

CONDENSED CONSOLIDATED BALANCE SHEETS

	US dollars (except share data)	
	September 30, 2018 (unaudited)	December 31, 2017
A S S E T S		
Current Assets		
Cash and cash equivalents	941,869	53,782
Accounts receivable, net	120,956	121,782
Inventories	894,678	957,349
Other current assets	122,130	94,137
Total current assets	2,079,633	1,227,050
Property and Equipment, Net	152,861	216,746
Long-Term Restricted Cash	47,975	39,562
Funds in Respect of Employee Rights Upon Retirement	177,384	185,570
Total assets	2,457,853	1,668,928
LIABILITIES, TEMPORARY EQUITY AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable	2,194,540	2,419,988
Other current liabilities	1,622,667	1,265,954
Total current liabilities	3,817,207	3,685,942
Long-Term Liabilities		
Long-Term Loans from Stockholders	173,485	182,767
Liability for Employee Rights Upon Retirement	177,384	185,570
Warrants with down-round protection	864,349	768,249
Total long-term liabilities	1,215,218	1,136,586
Total liabilities	5,032,425	4,822,528
Temporary Equity		
Convertible Preferred Stock of \$ 0.001 par value ("Preferred Stock"):		
10,000,000 shares of Preferred Stock authorized as of September 30, 2018 and December 31, 2017		
376 shares of Series A Preferred Stock issued and outstanding as of September 30, 2018 and December 31, 2017	221,152	221,152
15,031 shares of Series B Preferred Stock issued and outstanding as of September 30, 2018 and December 31, 2017	6,715,844	6,715,844
12,004 shares of Series C Preferred Stock issued and outstanding as of September 30, 2018 and December 31, 2017	6,484,337	6,484,337
Total temporary equity	13,421,333	13,421,333
Stockholders' Deficit		
Common Stock of \$ 0.001 par value ("Common Stock"):		
40,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 8,864,612 and 6,821,792 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively		
	8,866	6,824
Additional paid in capital	38,620,911	30,676,180
Accumulated other comprehensive income	151,045	110,675
Accumulated deficit	(54,776,727)	(47,368,612)
Total stockholders' deficit	(15,995,905)	(16,574,933)
Total liabilities, temporary equity and stockholders' deficit	2,457,853	1,668,928

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

INTEGRITY APPLICATIONS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	US dollars (except share data)			
	Nine-month period ended		Three-month period ended	
	September 30,		September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Revenues	43,582	125,881	94	20,900
Research and development expenses	1,818,814	1,833,841	534,223	635,478
Selling and marketing expenses	857,386	1,064,048	265,282	465,814
General and administrative expenses	2,894,553	5,124,048	811,695	1,567,970
Total operating expenses	5,570,753	8,021,937	1,611,200	2,669,262
Operating loss	(5,527,171)	(7,896,056)	(1,611,106)	(2,648,362)
Financing income, net	144,016	223,790	38,228	63,622
Loss for the period	(5,383,155)	(7,672,266)	(1,572,878)	(2,584,740)
Other comprehensive income:				
Foreign currency translation adjustment	40,370	52,360	4,740	(12,076)
Comprehensive loss for the period	(5,342,785)	(7,619,906)	(1,568,138)	(2,596,816)
Loss per share (Basic)	(0.96)	(1.40)	(0.31)	(0.44)
Loss per share (Diluted)	(0.96)	(1.40)	(0.31)	(0.44)
Common shares used in computing Basic income (loss) per share	7,745,275	6,207,844	8,249,442	6,386,772
Common shares used in computing Diluted income (loss) per share	7,745,275	6,207,844	8,249,442	6,386,772

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

INTEGRITY APPLICATIONS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

	US dollars (except share data)					Total Stockholders' deficit
	(unaudited)					
	Common Stock		Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	
Number of shares	Amount					
Balance as of January 1, 2018	6,821,792	6,824	30,676,180	110,675	(47,368,612)	(16,574,933)
Loss for the period					(5,383,155)	(5,383,155)
Other comprehensive income	-	-	-	40,370	-	40,370
Amounts allocated to Series D-1, D-2 and Series D-3 Warrants, net	-	-	1,983,502	-	-	1,983,502
Stock dividend on Series C Preferred Stock	364,451	364	892,905	-	(893,269)	-
Stock dividend on Series B Preferred Stock	456,365	456	1,118,094	-	(1,118,550)	-
Cash dividend on Series A Preferred Stock	-	-	-	-	(13,141)	(13,141)
Amounts allocated to issuance of Common Stock from Series D offering	1,206,444	1,206	2,373,230	-	-	2,374,436
Stock-based compensation	15,560	16	1,577,000	-	-	1,577,016
Balance as of September 30, 2018	<u>8,864,612</u>	<u>8,866</u>	<u>38,620,911</u>	<u>151,045</u>	<u>(54,776,727)</u>	<u>(15,995,905)</u>

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

INTEGRITY APPLICATIONS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	US dollars	
	Nine-month period ended September	
	30,	
	2018	2017
	(unaudited)	
Cash flows from operating activities:		
Loss for the period	(5,383,155)	(7,672,266)
Adjustments to reconcile (loss) for the period to net cash used in operating activities:		
Depreciation	58,789	50,341
Stock-based compensation	1,577,016	2,072,030
Change in the fair value of warrants with down-round protection	(251,790)	(273,733)
Linkage difference on principal of loans from stockholders	(1,266)	373
Changes in assets and liabilities:		
Decrease in accounts receivable	(5,590)	(18,748)
Increase in inventory	20,979	49,255
(Decrease) increase in other current assets	(31,717)	256,997
(Decrease) increase in accounts payable	(165,580)	235,138
Increase in other current liabilities	379,854	203,752
Decrease in liability for employee rights upon retirement	-	(10,148)
Net cash used in operating activities	<u>(3,802,460)</u>	<u>(5,107,009)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(3,505)	(19,467)
Increase in long-term restricted cash	<u>(10,164)</u>	<u>-</u>
Net cash used in investing activities	<u>(13,669)</u>	<u>(19,467)</u>
Cash flows from financing activities		
Cash dividend on Series A Preferred Stock	-	(5,143)
Proceeds allocated to Series C Preferred Stock, net of cash issuance expenses	-	3,598,254
Proceeds allocated to Series C Warrants, net of cash issuance expenses	-	1,780,963
Proceeds allocated to Common Stock from Series D offering, net of cash issuance expenses	2,563,839	-
Proceeds allocated to Series D Warrants, net of cash issuance expenses	<u>2,141,989</u>	<u>-</u>
Net cash provided by (used in) financing activities	<u>4,705,828</u>	<u>5,374,074</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(1,612)</u>	<u>65,274</u>
Increase in cash and cash equivalents	888,087	312,872
Cash and cash equivalents at beginning of the period	<u>53,782</u>	<u>148,836</u>
Cash and cash equivalents at end of the period	<u><u>941,869</u></u>	<u><u>461,708</u></u>

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

INTEGRITY APPLICATIONS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (cont.)

Supplementary information on financing activities not involving cash flows (unaudited):

During the nine months ended September 30, 2018, \$1,118,550 and \$893,269, representing the fair value of the shares of Common Stock to be issued to owners of Series B Preferred Stock and owners of Series C Preferred Stock, respectively, were recognized as stock dividends in the statement of changes in stockholders' deficit and was charged to accumulated deficit against additional paid in capital and Common Stock therein. The Company has not paid such dividends, plus interest at a rate of 9% per annum, as of the date of this filing.

During the nine months ended September 30, 2018, the Company accrued a cash dividend in the amount of \$13,141, in the aggregate, to be paid to holders of its Series A Preferred Stock. The Company has not paid such dividends, plus interest at a rate of 9% per annum, as of the date of this filing.

During the nine months ended September 30, 2018, \$347,890 representing the fair value of warrants issued as consideration for placement agent services was accounted for as warrants with down-round protection within long-term liabilities. Of these direct issuance expenses, \$158,487 was allocated to the Series D-1, D-2 and Series D-3 Warrants and was recorded as a reduction of additional paid in capital, and \$189,403 was allocated to the shares of common stock issued in the Series D offering and was recorded as a reduction of additional paid in capital.

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

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

NOTE 1 – GENERAL

A. Integrity Applications, Inc. (the “Company”) was incorporated on May 18, 2010 under the laws of the State of Delaware. On July 15, 2010, Integrity Acquisition Corp. Ltd. (hereinafter: “Integrity Acquisition”), a wholly owned Israeli subsidiary of the Company, which was established on May 23, 2010, completed a merger with A.D. Integrity Applications Ltd. (hereinafter: “Integrity Israel”), an Israeli corporation that was previously held by the stockholders of the Company. Pursuant to the merger, all equity holders of Integrity Israel received the same proportional ownership in the Company as they had in Integrity Israel prior to the merger. Following the merger, Integrity Israel became a wholly-owned subsidiary of the Company. As the merger transaction constituted a structural reorganization, the merger has been accounted for at historical cost in a manner similar to a pooling of interests. Integrity Israel was incorporated in 2001 and commenced its operations in 2002. Integrity Israel, a medical device company, focuses on the design, development and commercialization of non-invasive glucose monitoring devices for use by people with diabetes.

B. Going concern uncertainty

Since its incorporation, the Company did not conduct any material operations other than those carried out by Integrity Israel. The development and commercialization of Integrity Israel’s product is expected to require substantial expenditures. Integrity Israel and the Company (collectively, the “Group”) have not yet generated significant revenues from operations, and therefore they are dependent upon external sources for financing their operations. As of September 30, 2018, the Group has incurred accumulated deficit of \$54,776,727, stockholder’s deficit of \$15,995,905 negative operating cash flows and negative working capital. Management considered the significance of such conditions in relation to the Group’s ability to meet its current and future obligations and determined that these conditions raise substantial doubt about the Group’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. During the nine months ended September 30, 2018, the Company raised funds in an aggregate amount of approximately \$4,705,828 (net of related cash expenses) through the issuance of 1,206,444 units (the “Series D Units”) each consisting of a) one share of Common Stock, Par Value \$0.001 b) a five year warrant to purchase, at an exercise price of \$4.50 per share, one share of Common Stock; c) a five year warrant to purchase, at an exercise price of \$5.75 per share, one share of Common Stock; and d) a five year warrant to purchase, at an exercise price of \$7.75 per share, one share of Common Stock.

Until such time as the Group generates sufficient revenue to fund its operations (if ever), the Group plans to finance its operations through the sale of equity or equity-linked securities and/or debt securities and, to the extent available, short term and long-term loans. There can be no assurance that the Group will succeed in obtaining the necessary financing to continue its operations as a going concern.

C. Risk factors

As described in Note 1A and Note 1B above, the Group has a limited operating history and faces a number of risks and uncertainties, including risks and uncertainties regarding continuation of the development process, demand and market acceptance of the Group’s products, the effects of technological changes, competition and the development of products by competitors. Additionally, other risk factors also exist, such as the ability to manage growth and the effect of planned expansion of operations on the Group’s future results and the availability of necessary financing. In addition, the Group expects to continue incurring significant operating costs and losses in connection with the development of its products and marketing efforts. The Group has not yet generated material revenues from its operations to fund its activities and therefore is dependent on the receipt of additional funding from its stockholders and/ or new investors in order to continue its operations.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 1 – GENERAL (cont.)

D. Use of estimates in the preparation of financial statements

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to (i) the fair value estimate of the warrants with down-round protection, (ii) the allocation of the proceeds and the related issuance costs of the Series D Units, (iii) the going concern assumptions, (iv) measurement of stock based compensation, and (v) determination of net realizable value of inventory.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A. Basis of presentation

Accounting Principles

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with our consolidated financial statements and related notes contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2018. The unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the SEC related to interim financial statements. As permitted under those rules, certain information and footnote disclosures normally required or included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The financial information contained herein is unaudited; however, management believes all adjustments have been made that are considered necessary to present fairly the results of the Company’s financial position and operating results for the interim periods. All such adjustments are of a normal recurring nature.

The results for the nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period or for any future period.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiary. Significant intercompany balances and transactions have been eliminated in consolidation.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (cont.)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

B. Warrants with down-round protection

The Company has determined its derivative warrant liability with respect to the remaining Series A Warrants and warrants issued to its placement agent as part of the Series A Unit offering, the Series B Unit offering, Series C Unit offering and the Series D Unit offering to be a Level 3 fair value measurement and has used the option pricing model (“OPM”) to calculate its fair value. Because the warrants contain a down round protection feature, the probability that the exercise price of the warrants would decrease as the stock price decreased was incorporated into the valuation calculations.

The changes in the fair value of the Level 3 liability are as follows (in US dollars):

	Warrants with down-round Protection	
	September 30,	
	2018	2017
	(unaudited)	
Balance, Beginning of the period	768,249	681,970
Warrants issued as consideration for placement services	347,890	359,650
Change in fair value Warrants with Down-Round Protection	(251,790)	(273,733)
Balance, End of period	864,349	767,887

The key inputs used in the fair value calculations were as follows:

	September 30,	
	2018	2017
Dividend yield (%)	-	-
Expected volatility (%) (*)	56.59	56.59
Risk free interest rate (%)	1.31	0.92
Expected term of options (years)	1.25-4.86	0.45-4.83
Exercise price (US dollars)	4.50 - 7.75	4.50, 7.75
Share price (US dollars) (**)	2.45	2.38
Fair value (US dollars)	0.04-0.80	0.02-0.74

(*) Due to the low trading volume of the Company’s Common Stock, the expected volatility was based on a sample of 254 companies operating in the Healthcare Products industry.

(**) The Common Stock price, per share reflects the Company’s management’s estimation of the fair value per share of Common Stock as of September 30, 2018 and 2017. In reaching its estimation for such periods, management considered, among other things, a valuation prepared by a third-party valuation firm following the issuance of the Series D Units and the Series C Units, as applicable to each reporting period.

The below chart reflects the Fair Value for each of the warrants with down-round protection that were outstanding as of September 30, 2018 in US dollars, except for Total quantity.

	Andrew Garrett, Inc. (“AGI”) -			Placement Agent - Series D
	Series A	AGI - Series B	AGI - Series C	
Total quantity	364,071	566,897	844,605	520,356
Exercise price	4.5	4.5, 7.75	4.5, 7.75	4.5, 5.75, 7.75
Fair value	0.17	0.04 – 0.19	0.18 – 0.65	0.41 – 0.80

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (cont.)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

C. Revenue recognition

The company recognize revenues from sales of the GlucoTrack® model DF-F and personal ear-clips (“PECs”) when control is transferred to the customer and collectability is probable.

D. Reclassified Amounts

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications did not have material effect on the reported results of operations, shareholder’s deficit or cash flows.

E. Recently issued accounting pronouncements

1. Accounting Standard Update 2014-09, “Revenue from Contracts with Customers”

Commencing January 1, 2018 the Company adopted Accounting Standard Update 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU 2014-09”).

ASU 2014-09 outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2014-09 also requires entities to disclose sufficient information, both quantitative and qualitative, to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

An entity should apply the amendments in ASU 2014-09 using one of the following two methods: 1. Retrospectively to each prior reporting period presented with a possibility to elect certain practical expedients, or, 2. Retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. If an entity elects the latter transition method, it also should provide certain additional disclosures.

During 2016, the FASB issued several Accounting Standard Updates (“ASUs”) that focus on certain implementation issues of the new revenue recognition guidance including Narrow-Scope Improvements, Practical Expedients and technical corrections.

In accordance with an amendment to ASU 2014-09, introduced by Accounting Standard 2015-14, “Revenue from contracts with Customers – Deferral of the Effective Date”, for a public entity, the amendments in ASU 2014-09 became effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period (the first quarter of fiscal year 2018 for the Company).

Since the company did not report significant revenues, the adoption of ASU 2014-09 did not have a significant impact on its consolidated financial statements. See also NOTE 2C above.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

2. Accounting Standard Update (ASU) No. 2017-11, “Earnings Per Share”

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”).

Among others, Part I of ASU 2017-11 simplifies the accounting for certain financial instruments with down round features, which is a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Current accounting guidance creates cost and complexity for organizations that issue financial instruments with down round features by requiring, on an ongoing basis, fair value measurement of the entire instrument or conversion option.

ASU 2017-11 require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity.

ASU 2017-11 also addresses navigational concerns within the FASB Accounting Standards Codification related to an indefinite deferral available to private companies.

The provisions of the new ASU related to down rounds are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 (fiscal 2019 for the Company). Early adoption is permitted for all entities.

The Company is evaluating the impact of ASU 2017-11 on its financial statements. Although this process has not been completed, managements believes that its provisions might impact the accounting of the financial instruments issued by the Company that include down-round protection. See also NOTE 2B above.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

3. Accounting Standard Update 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued Accounting Standard Update 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07). ASU 2018-07 aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions.

Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 will be measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the goods has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share-based payment awards will be measured at the grant date.

With respect to awards with performance conditions, ASU 2018-07 concludes that, consistent with the accounting for employee share-based payment awards, an entity will consider the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions.

ASU 2018-07 also requires that the classification of equity classified nonemployee share-based payment awards will continue to be subject to the requirements of Topic 718 unless the award was modified after the goods has been delivered, the service has been rendered, any other conditions necessary to earn the right to benefit from the instruments have been satisfied, and the nonemployee is no longer providing goods or services. This eliminates the requirement to reassess classification of such awards upon vesting.

In addition, ASU 2018-07 includes certain Non-public Entity-Specific Amendments.

ASU 2018-07 is effective for Public entities in annual periods beginning after 15 December 2018, and interim periods within those years (first quarter of 2019 for the Company). Early adoption is permitted, including in an interim period, but not before an entity adopts the new revenue guidance (which was adopted by the Company in its interim financial statements for 2018).

An entity should only remeasure liability-classified awards that have not been settled by the date of adoption and equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date.

The Company is evaluating the impact of ASU 2018-07 on its financial statements.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 3 – RECENT EVENTS

1. During the first nine months of 2018, we received aggregate net proceeds of approximately \$4.7 million (net of related cash expenses), from the issuance and sale in a private placement transaction of 1,206,444 Series D Units. As of September 30, 2018, the Series D Warrants (issued on December 1, 2017 and on the first nine months of 2018) are exercisable for an aggregate of 3,902,667 shares of Common Stock, in each case subject to adjustment in certain circumstances.

Pursuant to a placement agent agreement (the “Placement Agent Agreement”) with the placement agent, the Company paid the placement agent, as a commission, an amount equal to 10% of the aggregate sales price of the Series D Units sold in each closing, plus a non-accountable expense allowance equal to 3% of the aggregate sales price of the Series D Units sold in such closing. In addition, pursuant to the Placement Agent Agreement, in connection with the closings in the first nine months of 2018, the Company is required to issue to the placement agent: (a) 5-year warrants to purchase up to 241,289 shares of Common Stock at an exercise price of \$4.50 per share, (b) 5-year warrants to purchase up to 120,644 shares of Common Stock at an exercise price of \$5.75 per share, and (c) 5-year warrants to purchase up to 120,644 shares of Common Stock at an exercise price of \$7.75 per share. The terms of such warrants are substantially similar to the Series D Warrants except that the warrants issued to the placement agent are exercisable on a cashless basis and include full ratchet anti-dilution protection. The total fair value of the Series D warrants that the Company is required to issue to the placement agent in connection with the 2018 issuances is \$347,890.

On February 15, 2018 and April 1, 2018, we issued ten-year non-qualified stock options to various employees, for the purchase of 767,500 and 15,000 shares of Common Stock at an exercise price of \$4.50 per share, with three-year quarterly vesting commencing on the first quarter after the effective date. The total fair value of the stock options is \$762,210 and \$14,897, respectively.

2. On March 23, 2018, the Company held its 2018 Special Meeting of Stockholders. At the Meeting, the Company’s stockholders voted on the proposal to approve and ratify the increase of the total number of shares authorized for issuance under the Company’s Compensation Plan to 7,000,000 shares, including an amendment to the Incentive Plan on April 7, 2017 to increase from 1,000,000 shares to 5,625,000 shares and another amendment on February 15, 2018 to increase from 5,625,000 shares to 7,000,000 shares.
3. After months of protracted negotiations with our China distributor we finally reached an impasse on several critical issues and decided that it would be in the best interests of the Company to terminate the existing agreements with such distributor due to various breaches of the distributor. On May 14, 2018, the Company sent notices to the distributor regarding the Company’s intention to terminate the agreement unless the breaches are cured within 30 days. On June 6, 2018, the Company received a response from the distributor denying all the allegations of breaches. On June 25, 2018, the Company sent a formal written notice to the distributor to terminate the agreement, effective immediately, to which the distributor responded on July 20, 2018 continuing to deny all the allegations of breaches. Notwithstanding the distributor’s denials, we are of the belief that the agreement has been terminated. The distributor played a critical role in assisting the Company to obtain regulatory approval by the China Food and Drug Administration (“CFDA”) for the GlucoTrack® model DF-F. As a result of the breaches of the distributor and the termination of such relationship, the Company may likely be unable to re-submit the file to the CFDA for the current product for a period of up to five years. While the Company is of the opinion that such termination will have little adverse effect on its future business opportunities in China, as it believes that it should be able to file applications with the CFDA for its next generation products through another distributor in China, there can be no assurance that the Company will be successful in this endeavor. If we were unable to partner with another distributor in China on terms mutually agreed upon by us and receive CFDA clearance to sell its future products in China, we would not have the ability to distribute our products in China and accordingly our business potential could be materially adversely affected.

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (cont.)

NOTE 4 – INVENTORIES

	US dollars	
	<u>September 30, 2018</u>	<u>December 31, 2017</u>
	(unaudited)	
Raw materials	13,522	12,734
Work in process	1,569,981	1,556,256
Finished products	67,309	144,493
	<u>1,650,812</u>	<u>1,713,483</u>
Less – provision for slow moving inventory	(756,134)	(756,134)
	<u>894,678</u>	<u>957,349</u>

NOTE 5 – OTHER CURRENT LIABILITIES

	US dollars	
	<u>September 30, 2018</u>	<u>December 31, 2017</u>
	(unaudited)	
Employees and related institutions	239,415	336,783
Accrued expenses	1,383,252	929,171
	<u>1,622,667</u>	<u>1,265,954</u>

NOTE 6 – FINANCING INCOME, NET

	US dollars		US dollars	
	<u>Nine-month period ended</u>		<u>Three-month period ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
	(unaudited)		(unaudited)	
Israeli CPI linkage difference on principal of loans from stockholders	1,266	(373)	(697)	(347)
Exchange rate differences	(14,410)	(30,154)	(8,789)	(12,960)
Change in fair value of warrants with down round protection	251,790	273,733	91,762	82,658
Interest expenses on credit from banks and other	(11,853)	(19,416)	(5,551)	(5,729)
Late fee penalty of dividend payments	(82,777)	-	(38,497)	-
	<u>144,016</u>	<u>233,790</u>	<u>38,228</u>	<u>63,622</u>

INTEGRITY APPLICATIONS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (cont.)

NOTE 7 – LOSS PER SHARE

In periods of net loss, basic loss per share is computed by dividing net loss for the period after consideration of the effect of dividends on preferred stock by the weighted average number of shares outstanding during the period.

The loss and the weighted average number of shares used in computing basic and diluted loss per share for the nine and three month periods ended September 30, 2018 and 2017 are as follows:

	US dollars		US dollars	
	Nine-month period ended September 30,		Three-month period ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Loss for the period	(5,383,155)	(7,672,266)	(1,572,878)	(2,584,740)
Cash dividend on Series A Preferred Stock	(13,141)	(19,243)	(4,171)	(12,529)
Stock dividend on Series B Preferred Stock	(1,118,550)	(609,582)	(533,229)	(117,914)
Stock dividend on Series C Preferred Stock	(893,269)	(370,325)	(425,836)	(93,751)
Loss for the period attributable to common stockholders	(7,408,115)	(8,671,416)	(2,536,114)	(2,808,934)

	US dollars		US dollars	
	Nine-month period ended September 30,		Three-month period ended September 30,	
	2018	2017	2018	2017
Number of shares:				
Common shares used in computing basic income (loss) per share	7,745,275	6,207,844	8,249,442	6,386,772
Common shares used in computing diluted income (loss) per share	7,745,275	6,207,844	8,249,442	6,386,772
Total weighted average number of common shares related to outstanding convertible Preferred Stock, options and warrants excluded from the calculations of diluted income (loss) per share (*)	26,938,336	20,304,950	28,470,324	23,378,950

(*) All outstanding convertible Preferred Stock, stock options and warrants have been excluded from the calculation of the diluted net loss per share for all the reported periods, because the effect of the common shares issuable as a result of the exercise or conversion of these instruments was determined to be anti-dilutive.

NOTE 8 – SUBSEQUENT EVENTS

On October 2, 2018, John Graham notified the Company of his resignation as CEO and Chairman of the Company for personal reasons, to be effective as of October 31, 2018. David Podwalski was appointed as President and Chief Operating Officer of the Company by its Board, effective October 9, 2018, and is appointed as a Director effective as of October 31, 2018 to fill the vacancy to be created by Mr. Graham's resignation.

Effective November 1, 2018, the Board approved an increase in David Podwalski's annual base salary to \$275,000; and the Board will re-evaluate his bonus payout as part of the annual compensation review at its January 2019 Board meeting, with new goals to be effective January 1, 2019. With respect to his \$70,000 salary due in arrears, \$50,000 shall be issued in RSUs, based on the price of the conversion of the outstanding preferred stock, and \$20,000 shall be paid in cash as soon as practicable; and he shall be granted an addition 75,000 stock options with a three year term and three year vesting schedule with an exercise price based upon the price for the conversion of the existing preferred stock.

The Board also approved that no later than December 31, 2018, the Company shall pay to John Graham his salary arrears as follows: (i) \$320,000 in RSUs based on the price of the conversion of the existing preferred stock, and (ii) \$61,335 to be paid in cash; and all of his existing options shall expire on January 30, 2019, if not exercised by that date

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

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. These forward looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies and prospects. All statements other than statements of historical fact included in this Quarterly Report on Form 10-Q, including statements regarding our future activities, events or developments, including such things as future revenues, capital raising and financing, product development, clinical trials, regulatory approval, market acceptance, responses from competitors, capital expenditures (including the amount and nature thereof), business strategy and measures to implement strategy, competitive strengths, goals, expansion and growth of our business and operations, plans, references to future success, projected performance and trends, and other such matters, are forward-looking statements. The words "believe," "expect," "anticipate," "intend," "estimate," "plan," "may," "will," "could," "would," "should" and other similar words and phrases, are intended to identify forward-looking statements. The forward-looking statements made in this Quarterly Report on Form 10-Q are based on certain historical trends, current conditions and expected future developments as well as other factors we believe are appropriate in the circumstances. These statements relate only to events as of the date on which the statements are made and we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. All of the forward-looking statements made in this Quarterly Report on Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to or effects on us or our business or operations. Whether actual results will conform to our expectations and predictions is subject to a number of risks and uncertainties that may cause actual results to differ materially. Risks and uncertainties, the occurrence of which could adversely affect our business, include the risks identified under the caption "Risk Factors" included in our annual report on Form 10-K for the year ended December 31, 2017. The following discussion should be read in conjunction with the condensed consolidated financial statements and the notes thereto included in Item 1 of this Quarterly Report on Form 10-Q.

Overview

Incorporated in Delaware in May 2010, we are a medical device company focused on the design, development and commercialization of non-invasive glucose monitoring devices for use by people with diabetes and pre-diabetics. On July 15, 2010, we completed a reverse triangular merger with Integrity Israel and Integrity Acquisition, an Israeli corporation and a wholly owned subsidiary of ours, pursuant to which Integrity Acquisition merged with and into Integrity Israel and all of the stockholders and option holders of Integrity Israel received shares and options in us in exchange for their shares and options in Integrity Israel (the "Reorganization"). Following the Reorganization, the former equity holders of Integrity Israel were entitled to the same proportional ownership in us as they had in Integrity Israel prior to the Reorganization. As a result of the Reorganization, Integrity Israel became a wholly owned subsidiary of ours. We operate primarily through Integrity Israel.

Integrity Israel was founded in 2001 with a mission to develop, produce and market non-invasive glucose monitors for home use by diabetics. We have developed a non-invasive glucose monitor, the GlucoTrack® model DF-F glucose monitoring device, which is designed to help people with diabetes and pre-diabetics obtain glucose level readings without the pain, inconvenience, cost and difficulty of conventional (invasive) spot finger stick devices. The GlucoTrack® model DF-F utilizes a patented combination of ultrasound, electromagnetic and thermal technologies to obtain glucose measurements in less than one minute via a small sensor that is clipped onto one's earlobe and connected to a small, handheld control and display unit, all without drawing blood or interstitial fluid.

In June 2013, we received the initial Conformité Européene (CE) Mark (indicating the conformity of the Company's product with health, safety, and environmental protection standards for products sold within the European Economic Area) approval for the GlucoTrack® model DF-F non-invasive glucose monitoring device from DEKRA Certification B.V., our European notified body (the "Notified Body"), which is an entity that has been accredited by a member state of the European Union ("EU") to assess whether a product to be placed on the market meets certain preordained standards.

This original approval required that the device be re-calibrated every 30 days, with each such re-calibration taking between 2.5 and 3 hours to complete. In March 2014, we received CE Mark approval for six months' calibration validity of the same device. This approval eliminates the need for monthly re-calibrations and enables the calibration process to be conducted only when the sensor is replaced, once every 6 months. We believe that this is a significant feature of the GlucoTrack® model DF-F. On August 31, 2015, we received a further approval from the Notified Body for improvements to the GlucoTrack® model DF-F to simplify and shorten the initial calibration process for the device (from approximately 2.5 hours to approximately half an hour). All these improvements enhance the competitiveness of the device and its commercial viability. In addition, we received approval from the Notified Body on the updated intended use for the device, which expands the intended user population to include not only Type 2 diabetics, but also people suffering from pre-diabetes conditions, which we believe represents a material expansion of the potential market for the device. In December 2015, we received approval from the Notified Body for further improvements to the GlucoTrack® model DF-F that increase the accuracy and efficacy of the device. As a result of these incremental, but important, enhancements to the performance of the device we believe that the product is ready for commercial launch in specific market segments.

Receipt of the CE Mark allows us to market and sell the GlucoTrack® model DF-F glucose monitoring device in EU member countries that have adopted the European Medical Device Directive (the "MDD") without being subject to additional national regulations with regard to demonstration of performance and safety. However, although the MDD is applicable throughout the EU, in practice it does not ensure uniform regulation throughout the EU. Accordingly, member countries may apply and enforce the MDD's terms differently, and certain EU member countries may request or require performance and/or safety data in addition to the MDD's requirements from time to time, on a case-by-case basis. The CE Mark also permits the sale in countries that have an MDD Mutual Recognition Agreement with the EU. This would include some countries in South East Asia as well as Latin America opening new potential markets for us on a global basis.

Safety and quality are non-negotiables in the medical devices industry. Regulatory requirements are increasingly stringent throughout every step of a product's life cycle, including service and delivery. It becomes more often that organizations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do. ISO 13485 is an internationally agreed upon standard that sets out the requirements for a quality management system specific to the medical devices industry. On February 19, 2016, we received an extension of our ISO 13485:2003 certificate and Annex II certification from the EU. The ISO 13485:2003 certification signifies that we have met the standards required for company-wide implementation of device quality management systems. The scope of the certification is design, development, manufacture and service of non-invasive glucose monitoring systems for home use. Annex II also addresses quality control systems. The certification allows us to self-certify certain modifications and changes and simplifies some of the reporting to and review by the relevant Notified Body. This can shorten the CE-mark review process of future GlucoTrack® model DF-F enhancements or revisions, including software updates and other improvements of the device that do not affect the intended use and/or safety performance. The ISO 13485:2003 and Annex II certifications enable us to potentially reduce the time to market for product sales on new, enhanced or modified GlucoTrack® model DF-F devices.

The GlucoTrack® model DF-F has not yet been approved for commercial sale in the United States. On August 10, 2015, we submitted pre-submission documents to the U.S. Food and Drug Administration (the "FDA") in connection with our proposed future application for FDA approval of our U.S. clinical trial protocol. The pre-submission documentation was submitted to the FDA in order to obtain the FDA's guidance regarding the U.S. regulatory pathway for the GlucoTrack® model DF-F, the proper approach to refining the trial protocol and preparing the pre-marketing application. On October 19, 2015, we met with the FDA to discuss the pre-submission documents, including the approach to and details of the clinical trial protocol for the GlucoTrack® model DF-F. On May 10, 2016, we submitted a pre-submission supplement (including clinical trial protocol) to the FDA which reflects the feedback received from the FDA at our October 2015 meeting. On July 18, 2016, we completed a teleconference with the FDA to further discuss our pre-submission supplement. At the end of this discussion, we received verbal confirmation from the FDA that clinical trials of the GlucoTrack® model DF-F constitute non-significant risk device studies, which allows the trials to proceed without an Investigational Device Exemption (IDE) application. Such trials are assessed by the FDA and not considered to present a potential for serious risk to the health, safety or the welfare of subjects. We expect that the regulatory pathway would be that of a *de novo* 510k, requiring a clinical trial design based on feedback from the agency. The initiation of clinical trials in the USA is subject to raising adequate financing to fund the clinical program through completion. If we are unable to raise additional capital of at least \$10 million, we do not expect to commence such clinical trials.

Clinical trials conducted in Germany by Pfutzner Science & Health Institute, GmbH, headed by Prof. Dr. Andreas Pfutzner, on subjects with Type 2 diabetes and pre-diabetics, as well as at Soroka University Medical Center, Beer-Sheva, Israel, demonstrated favorable results, which were presented on November 10, 2016 by the Company at the 16th annual Diabetes Technology Meeting (DTM), Bethesda, MD in an invited presentation. Most notably, the presentation included data validating that GlucoTrack's accuracy has increased significantly. Results from the trials show 99.7% of the study data points within the clinically accepted A and B zones of the Consensus Error Grid (which is a new tool for evaluating the accuracy of a blood glucose meter) (Type 2), 99.3% of the study data points were within the clinically accepted A and B zones of the Clarke Error Grid (which is a tool used to quantify the clinical accuracy of blood glucose estimates generated by meters as compared to a reference value), 17.0% Mean Absolute Relative Difference, and 12.9% Median Absolute Relative Difference. In addition, the German trial concluded that the data confirms the performance of the GlucoTrack® among its intended users, including pre-diabetic patients.

In the second half of 2017 we conducted a strategic review of our previous commercial activities. We established a cross-functional task force with the goal of reviewing the current commercial performance in all countries and identifying the critical success factors (CSF's) necessary for successful commercialization. The CSF's that were determined to be most important to our future commercial success include: 1) selecting the right distribution partners within countries that have knowledge and experience in diabetes, the appropriate capabilities and proven performance in the sales, marketing, and customer service in support of medical devices, and a commitment to investing the appropriate resources required for a successful launch and building of the business; 2) segmenting and targeting the right customers including key opinion leaders, treating physicians, and diabetes nurses within the healthcare provider communities as well as those patient groups that will benefit most from the use of a non-invasive device; 3) revising the cost structure for GlucoTrack® so that it will be more affordable on a monthly basis for patients; and 4) working with government authorities and health insurance companies to achieve full or partial reimbursement for GlucoTrack® within covered medical plans.

We have started the implementation of this new commercial program by selecting two countries where we will pilot this approach as our proof-of-concept; the Netherlands and Israel. These countries were chosen based on the relatively smaller size of these marketplaces that will allow us to be able to rapidly assess our performance and make adjustments as necessary. On December 22, 2017 we signed an exclusive distribution agreement with a new partner in the Netherlands (MediReva B.V.) and are underway with launch preparations for 2018. We have been working closely with our new distributor and have accomplished: product and disease area training across the organization; segmentation of the local target audiences including key opinion leaders, treating physicians, and diabetes nurses. We received our first order of 30 units from MediReva and this has been shipped and received in their warehouse. The most important aspect of our launch preparations are the discussions being held with many health insurance companies. Approval of full or partial reimbursement by the health insurance companies will be a key factor in enabling us to achieve significant sales volume. We are currently working with several of these companies to initiate pilots with GlucoTrack® before the end of this year as the first step towards reimbursement approval.

We have been in negotiations with a new strategic partner for Israel with the goal of identifying a new distributor to replace the previous distributor where we terminated our distribution agreement due to a lack of performance over the last two years. At the same time, we have been in direct discussions with a potential new distributor with a Mutual NDA signed on May 31, 2018. In the meantime, we are exploring the use of direct-to-consumer web campaigns and direct-to-prescriber promotion to physicians and diabetes nurses to evaluate the potential of a direct commercial approach for Israel.

On July 3, 2018 we signed a new exclusive distribution agreement for GlucoTrack® with CuraTec Nordic for the Scandinavian countries (Denmark, Sweden, Norway, and Finland). We anticipate that they will be a strong partner due to their previous experience in diabetes, strong sales presence in all four countries, and established relationships with key opinion leaders. Launch preparations are underway to enter the markets in the fourth quarter of this year. On August 6, 2018 we received our first order of 100 units which will be delivered in mid-November and be available for the start of our commercialization in the Scandinavian countries.

On May 25, 2018 we signed a Mutual NDA with a potential distributor in Hungary. Discussions on a go-to-market strategy started during Q3 and will continue during Q4.

On July 18, 2018 we signed a Mutual NDA with a potential distributor in Romania. Discussions on a go-to-market strategy started during Q3 and will continue during Q4.

On July 25, 2018 we signed a Mutual NDA with a potential distributor in Japan. On September 12, 2018 we signed a Mutual NDA with a second potential distributor in Japan. Discussions on a go-to-market strategy started during Q3 and will continue during Q4.

In the meantime, we have assessed the performance of all of our current distributors in Europe and Asia. A number of these agreements have been terminated given that they did not perform in the past and had minimal or no sales over the course of 2017. We are also initiating discussions with our distributors in the remaining countries to focus on changes needed to address the CSF's for future success with implementation plans foreseen in the second half of 2018.

On October 2, 2018, John Graham notified the Company of his resignation as CEO and Chairman of the Company for personal reasons. to be effective as of October 31, 2018. David Podwalski was appointed as President and Chief Operating Officer of the Company by its Board, effective October 9, 2018, and is appointed as a Director effective as of October 31, 2018 to fill the vacancy created by Mr. Graham's resignation.

Effective November 1, 2018, the Board approved an increase in David Podwalski's annual base salary to \$275,000; and the Board will re-evaluate his bonus payout as part of the annual compensation review at its January 2019 Board meeting, with new goals to be effective January 1, 2019. With respect to his \$70,000 salary due in arrears, \$50,000 shall be issued in RSUs, based on the price of the conversion of the outstanding preferred stock, and \$20,000 shall be paid in cash as soon as practicable; and he shall be granted an addition 75,000 stock options with a three year term and three year vesting schedule with an exercise price based upon the price for the conversion of the existing preferred stock.

The Board also approved that no later than December 30, 2018, the Company shall pay to John Graham his salary arrears as follows: (i) \$320,000 in RSUs based on the price of the conversion of the existing preferred stock, and (ii) \$61,335 to be paid in cash; and all of his existing options shall expire on January 30, 2019, if not exercised by that date

We do not own commercial manufacturing facilities and do not intend to build commercial manufacturing facilities of our own in the foreseeable future. We currently utilize a third-party manufacturer in Israel to manufacture the GlucoTrack® model DF-F. Moreover, in July 2014, we entered into a manufacturing agreement with Wistron Corp. (“Wistron”), a Taiwanese entity and the manufacturing arm of Acer Inc. Pursuant to such agreement, Wistron has agreed to mass produce and service, on a non-exclusive basis, the GlucoTrack® model DF-F and any future products, if any, introduced by us. Pursuant to such agreement, Wistron has also agreed to provide full turn-key manufacturing services for the GlucoTrack® model DF-F, including components procurement, unit assembly, device integration, testing, packaging and delivery to customers (distributors). In November 2015, we sent a delegation to Wistron’s main production facility in Taiwan to, among other things, inspect the readiness of Wistron’s production line for the GlucoTrack® model DF-F. Wistron has produced a small pilot batch and recently produced a second pilot batch of the GlucoTrack® model DF-F device. Following the receipt of an official clearance from the Taiwanese authorities on January 11, 2017 and the successful completion of a GMP (Good Manufacturing Practice) audit by the local regulatory authorities in July 2017, the production line for the GlucoTrack® model DF-F is now operational. We intend to utilize the services of both Wistron and the Israeli third-party manufacturer to produce the GlucoTrack® model DF-F.

In support of the commercialization effort, we intend to conduct further post-market clinical trials, as well as publish scientific and clinical studies, case studies, and white papers. To that end, we have engaged with a leading clinic in Germany, Pfutzner Science & Health Institute, GmbH, headed by Prof. Dr. Andreas Pfutzner, to conduct additional clinical trials on subjects with Type 2 diabetes and pre-diabetics. We anticipate adding additional sites in Europe.

In September 2016, we had a booth at the 52nd annual conference of the European Association for Study of Diabetes (EASD) in Munich.

In December 2016, we had a poster at the 9th Annual World Congress on Prevention of Diabetes and its Complications (WCPD, in Atlanta, GA). This Congress provided the Company with an opportunity to showcase GlucoTrack® model DF-F as a tool to fight diabetes and its complications, as well as using GlucoTrack® model DF-F as a tool to assist pre-diabetics.

In February 2017, the Company presented at the 10th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2017) in Paris, France. The Company presented key findings including (1) the latest generation GlucoTrack® algorithm, which compensates for the tissue-lagging effect relative to blood glucose changes post-meal intake, significantly improves GlucoTrack® accuracy at different post-prandial (post-meal) states, and equalizes accuracy for pre- and post-meal glucose readings; (2) GlucoTrack® clinical accuracy as measured by Consensus Error Grid (CEG) showed 100% of the pre-prandial readings in the A+B zones, and 98.2% of the post-prandial readings in the A+B zones; (3) GlucoTrack® Model DF-F demonstrates consistent glucose measurement repeatability between different GlucoTrack® devices and on each earlobe of the same subject; (4) the repeatability of different GlucoTrack® devices is similar at all tested glucose ranges and post-prandial time periods; and (5) the GlucoTrack® mean precision absolute relative difference (PARD) of 8.2% is equivalent or better than the independently reported PARD values of commercially available continuous glucose monitoring systems.

On June 12, 2017, we announced new data demonstrating the clinical performance of GlucoTrack®, further supporting its suitability for people with type 2 diabetes across various medication regimes. The data was recently presented at the American Diabetes Association's (ADA) 77th Scientific Sessions in San Diego, CA.

In September 2017, we presented key findings at the European Association for the Study of Diabetes Congress (EASD) in Lisbon, Portugal. The study evaluated GlucoTrack®'s accuracy in 172 adults with type 2 diabetes who were prescribed one or more medications for major medical conditions associated with diabetes. The experiment stratified participants into five medication groups, focusing on anti-cholesterolemia, anti-hypertension, anti-thrombotic, and anti-diabetic (prolonged duration and short and mixed duration) medications. The study demonstrated that the use of these common concomitant medications in diabetes had no effect on the performance of GlucoTrack®. We also had a display booth at this conference that was well attended by hundreds of treating physicians and diabetes nurses.

In February 2018, the Company presented at the 11th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2018) in Vienna, Austria. The Company presented data on the performance of a non-invasive glucose monitoring device (GlucoTrack®) with regard to accuracy and precision. Device accuracy data was presented for 37 people with type 2 diabetes using the consensus error grid analysis for type 2 diabetes and measuring the median absolute relative difference (ARD). The results showed that 99.6% of 257 measurements were in zones A and B of the Consensus error grid, with 90.3% of the measurements in zone A, the mean and median ARD were 17.2% and 12.9%, respectively, and at various glucose levels, mean PARD ranged from 7.7%-8.7%. Data was also presented on sensor to sensor precision in 20 people with type 2 diabetes where ~19 simultaneous measurements using two GlucoTrack® devices, one on each earlobe. The results show that GlucoTrack® is highly accurate with sensor-to-sensor precision is comparable to that of CGMs (GlucoTrack: 8.1%, Dexcom G4: 7.3%, Freestyle Navigator: 9.6%).

We have not yet generated any material revenues from our operations and, as of September 30, 2018, have incurred an accumulated deficit of \$54,776,727, stockholders' deficit of \$15,995,905 and negative operating cash flows. We currently have no material sources of recurring revenue and therefore are dependent upon external sources for financing our operations. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. As a result, substantial doubt exists regarding our ability to continue as a going concern.

Recent Developments

During the first nine months of 2018, we received aggregate net proceeds of approximately \$4.7 million (net of related cash expenses), from the issuance and sale in a private placement transaction of 1,206,444 Series D Units. As of September 30, 2018, the Series D Warrants (issued on December 1, 2017 and on the first nine months of 2018) are exercisable for an aggregate of 3,902,667 shares of Common Stock, in each case subject to adjustment in certain circumstances.

Pursuant to a placement agent agreement (the “Placement Agent Agreement”) with the placement agent, the Company paid the placement agent, as a commission, an amount equal to 10% of the aggregate sales price of the Series D Units sold in each closing, plus a non-accountable expense allowance equal to 3% of the aggregate sales price of the Series D Units sold in such closing. In addition, pursuant to the Placement Agent Agreement, in connection with the closings in the first nine months of 2018, the Company is required to issue to the placement agent: (a) 5-year warrants to purchase up to 241,289 shares of Common Stock at an exercise price of \$4.50 per share, (b) 5-year warrants to purchase up to 120,644 shares of Common Stock at an exercise price of \$5.75 per share, and (c) 5-year warrants to purchase up to 120,644 shares of Common Stock at an exercise price of \$7.75 per share. The terms of such warrants are substantially similar to the Series D Warrants except that the warrants issued to the placement agent are exercisable on a cashless basis and include full ratchet anti-dilution protection. The total fair value of the Series D warrants that the Company is required to issue to the placement agent in connection with the 2018 issuances is \$347,890.

On March 23, 2018, the Company held its 2018 Special Meeting of Stockholders. At the Meeting, the Company’s stockholders voted on the proposal to approve and ratify the increase of the total number of shares authorized for issuance under the Company’s Compensation Plan to 7,000,000 shares, including an amendment to the Incentive Plan on April 7, 2017 to increase from 1,000,000 shares to 5,625,000 shares and another amendment on February 15, 2018 to increase from 5,625,000 shares to 7,000,000 shares.

We recently laid out our strategic priorities in terms of product enhancements and a future generation of products. As a result of the review of our corporate strategy, we have decided to concentrate our research and development activities around 4 main strategic pillars:

1. Wireless Connectivity

We have developed a wireless module (“WLM”) with embedded Bluetooth Low-Energy (BLE), which enables the transmission of measurement data captured by the GlucoTrack® model DF-F to a cloud-based server or a smart device. We expect this module and the related applications to facilitate viewing of glucose related data and correlate it closely with lifestyle choices made by the users, be that dietary choices or activity-based choices, among other things. The wireless module will also facilitate sharing, viewing and analysis of GlucoTrack® measurements and profile by clinicians and others caregivers.

2. Digital Health Applications

We intend to develop smart device applications (“Apps”) to facilitate the interaction of users with GlucoTrack® DF-F and the glucose data collected. We intend to develop Apps that support the management of Type 2 diabetics and pre-diabetic patients by provided immediate feedback and insights as to the glucose measurements. The goal is to provide relevant information to guide patients to change behavior and improve the management of their condition. The Apps are expected to have a user-directed capability to connect with third party healthcare providers (physicians, dieticians, and nurse practitioners), in order to receive professional guidance based on the accumulated information ultimately leading to improved management of the condition and better disease outcomes.

3. Accuracy

While the accuracy of the GlucoTrack® DF-F is sufficient for the management of Type 2 diabetics and pre-diabetic patients (and approved as such by the EU authorities), we strive to further improve the product in future iterations and maximize its potential by expanding the addressable market, e.g. into Type 1 diabetes. The research projects include further improving the algorithms involved in computing our glucose measurement data, as well as deeper research on the existing sensing technologies to improve sensitivity. The ultimate goal being to eventually commercialize a non-invasive device for all types of diabetics.

4. Miniaturization

The objective of this project is to reduce the existing device to a simple, aesthetically designed, wireless ear-clip which would measure glucose and communicate the results seamlessly to any other platform whether through a wireless connection to the cloud or a Bluetooth connection to a smart device such as a smartphone, tablet or computer. As a result, the current handheld display would be eliminated completely. The result would be a user- friendly, inconspicuous measuring device for the management of diabetes and pre-diabetes. With a significantly cheaper cost to manufacture than our current device. Simultaneously we will be working to further simplify the calibration process eventually enabling self-calibration.

After months of protracted negotiations with our China distributor we finally reached an impasse on several critical issues and decided that it would be in the best interests of the Company to terminate the existing agreements with such distributor due to various breaches of the distributor. On May 14, 2018, the Company sent notices to the distributor regarding the Company's intention to terminate the agreement unless the breaches are cured within 30 days. On June 6, 2018, the Company received a response from the distributor denying all the allegations of breaches. On June 25, 2018, the Company sent a formal written notice to the distributor to terminate the agreement, effective immediately, to which the distributor responded on July 20, 2018 continuing to deny all the allegations of breaches. Notwithstanding the distributor's denials, we are of the belief that the agreement has been terminated. The distributor played a critical role in assisting the Company to obtain regulatory approval by the China Food and Drug Administration ("CFDA") for the GlucoTrack® model DF-F. As a result of the breaches of the distributor and the termination of such relationship, the Company may likely be unable to re-submit the file to the CFDA for the current product for a period of up to five years. While the Company is of the opinion that such termination will have little adverse effect on its future business opportunities in China, as it believes that it should be able to file applications with the CFDA for its next generation products through another distributor in China, there can be no assurance that the Company will be successful in this endeavor. If we were unable to partner with another distributor in China on terms mutually agreed upon by us and receive CFDA clearance to sell its future products in China, we would not have the ability to distribute our products in China and accordingly our business potential could be materially adversely affected.

Significant Accounting Policies

Our consolidated financial statements are prepared in accordance with U.S. GAAP. In connection with the preparation of our financial statements, we are required to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosures. We base our assumptions, estimates and judgments on historical experience, current trends and other factors that management believes to be relevant at the time our consolidated financial statements are prepared. On a regular basis, management reviews the accounting policies, assumptions, estimates and judgments to ensure that our financial statements are presented fairly and in accordance with U.S. GAAP. However, because future events and their effects cannot be determined with certainty, actual results could differ from our assumptions and estimates, and such differences could be material.

Our significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, of the Notes to the Consolidated Financial Statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2017. Our management believes that, as for the financial statements for the periods included in this report, the going concern assessment and assumptions relate to (i) the fair value estimate of the warrants with down-round protection, (ii) the allocation of the proceeds and the related issuance costs of the Series D Units, (iii) measurement of stock based compensation, and (iv) determination of net realizable value of inventory are considered as critical accounting policies. However, due to the early stage of operations of the Company, there are no other accounting policies that are considered to be critical accounting policies by management.

Going Concern Uncertainty

The development and commercialization of our product will require substantial expenditures. We have not yet generated any material revenues and have incurred a substantial accumulated deficit and negative operating cash flows. We currently have no sources of recurring revenue and are therefore dependent upon external sources for financing our operations. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. Management's plans concerning these matters are described in Note 1B to our Annual Report on Form 10-K for the year ended December 31, 2017. (See also Note 1B to our interim financial statements for the period ended September 30, 2018). As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in our Annual Report on Form 10-K for year ended December 31, 2017. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Recently Issued Accounting Pronouncements

1. Accounting Standard Update 2014-09, “Revenue from Contracts with Customers”

Commencing January 1, 2018, the Company adopted Accounting Standard Update 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU 2014-09”).

ASU 2014-09 outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2014-09 also requires entities to disclose sufficient information, both quantitative and qualitative, to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

An entity should apply the amendments in ASU 2014-09 using one of the following two methods: 1. Retrospectively to each prior reporting period presented with a possibility to elect certain practical expedients, or, 2. Retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. If an entity elects the latter transition method, it also should provide certain additional disclosures.

During 2016, the FASB issued several ASUs that focus on certain implementation issues of the new revenue recognition guidance including Narrow-Scope Improvements, Practical Expedients and technical corrections.

In accordance with an amendment to ASU 2014-09, introduced by Accounting Standard 2015-14, “Revenue from contracts with Customers – Deferral of the Effective Date”, for a public entity, the amendments in ASU 2014-09 became effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period (the first quarter of fiscal year 2018 for the Company).

Since the Company did not report significant revenues, the adoption of ASU 2014-09 did not have a significant impact on its consolidated financial statements.

2. Accounting Standard Update (ASU) No. 2017-11, “Earnings Per Share”

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”).

Among others, Part I of ASU 2017-11 simplifies the accounting for certain financial instruments with down round features, which is a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Current accounting guidance creates cost and complexity for organizations that issue financial instruments with down round features by requiring, on an ongoing basis, fair value measurement of the entire instrument or conversion option.

ASU 2017-11 require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity.

ASU 2017-11 also addresses navigational concerns within the FASB Accounting Standards Codification related to an indefinite deferral available to private companies.

The provisions of the new ASU related to down rounds are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 (fiscal 2019 for the Company). Early adoption is permitted for all entities.

The Company is evaluating the impact of ASU 2017-11 on its financial statements. Although this process has not been completed, management believes that its provisions might impact the accounting of the financial instruments issued by the Company that include down-round protection.

3. Accounting Standard Update 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued Accounting Standard Update 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07). ASU 2018-07 aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions.

Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 will be measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share-based payment awards will be measured at the grant date.

With respect to awards with performance conditions ASU 2018-07 concludes that, consistent with the accounting for employee share-based payment awards, an entity will consider the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions.

ASU 2018-07 also requires that the classification of equity classified nonemployee share-based payment awards will continue to be subject to the requirements of Topic 718 unless the award was modified after the good has been delivered, the service has been rendered, any other conditions necessary to earn the right to benefit from the instruments have been satisfied, and the nonemployee is no longer providing goods or services. This eliminates the requirement to reassess classification of such awards upon vesting.

In addition, ASU 2018-07 includes certain Non-public Entity-Specific Amendments

ASU 2018-07 is effective for Public entities in annual periods beginning after December 15, 2018, and interim periods within those years (first quarter of 2019 for the company). Early adoption is permitted, including in an interim period, but not before an entity adopts the new revenue guidance (which was adopted by the Company in its interim financial statements for 2018).

An entity should only remeasure liability-classified awards that have not been settled by the date of adoption and equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date.

The Company is evaluating the impact of ASU 2018-07 on its financial statements.

Results of Operations

The following discussion of our operating results explains material changes in our results of operations for the nine-month period ended September 30, 2018 compared with the same period ended September 30, 2017. The discussion should be read in conjunction with the financial statements and related notes included elsewhere in this report.

Nine Months ended September 30, 2018 compared to Nine Months ended September 30, 2017

Revenues

During the nine-month period ended September 30, 2018, we had revenues of \$43,582 from orders for our GlucoTrack® model DF-F glucose monitoring device and personal ear-clip (“PEC”) that are replaced every six months, as compared with \$125,881 for the prior-year period. The decrease in revenues is due to the fact that during the first quarter of 2017 we received an initial order from a customer in Hong Kong.

We recognize revenues from sales of the GlucoTrack® model DF-F and PECs when control is transferred to the customer and collectability is probable.

Research and development expenses

Research and development expenses were \$1,818,814 for the nine-month period ended September 30, 2018, as compared to \$1,833,841 for the prior-year period. The decrease is attributable the completion of the clinical trials performed at the Soroka Facility in the first quarter of 2018 and the decrease in our cost of revenues which is in line with the decrease in revenues offset by the stock based compensation issued to all employees during the first quarter of 2018 and the continued development of the WLM.

Research and development expenses consist primarily of salaries and other personnel-related expenses, including materials, travel expenses, clinical trials and other expenses. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect research and development expenses to increase during the remainder of 2018 and beyond, primarily due to hiring additional personnel and developing our product line, as well as improvement of the GlucoTrack® model DF-F; however, we may adjust or allocate the level of our research and development expenses based on available financial resources and based on our commercial needs including the FDA registration process, specific requirements from customers, development of new GlucoTrack® models and others.

Selling and marketing expenses

Selling and marketing expenses were \$857,386 for the nine-month period ended September 30, 2018, as compared to \$1,064,048 for the prior-year period. The decrease is attributable the reduction in our business development personnel during the first quarter of 2018 and the reduction in the number of trade shows we have participated in 2018 offset by the stock based compensation issued to all employees during the first quarter of 2018.

Selling and marketing expenses consist primarily of salaries, travel expenses and other related expenses. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect selling and marketing expenses to increase during the remainder of 2018 and beyond as we continue our focus on marketing and sales of the GlucoTrack® model DF-F; however, we may adjust or allocate the level of our marketing based on available financial resources and based on our commercial needs including the FDA registration process, specific requirements from customers, development of new GlucoTrack® models and others.

General and administrative expenses

General and administrative expenses were \$2,894,553 for the nine-month period ended September 30, 2018, as compared to \$5,124,048 for the prior-year period. The decrease is primarily attributable to severance paid to our former Chairman and CEO and former CFO of approximately \$162,000 as well as stock based compensation in the amount of \$152,000 during the nine months ending September 30, 2017. In addition, the decrease is attributable to a one time signing bonus of \$412,500 and a \$225,000 guaranteed bonus for 2017 including employer payroll taxes, stock based compensation in the amount of approximately \$1,399,000 paid to our new Chairman and CEO, recruiting fees of \$195,000 and the related professional fees associated with the changes in management paid during the nine months ending September 30, 2017.

General and administrative expenses consist primarily of professional services, salaries, travel expenses and other related expenses for executive, finance and administrative personnel, including stock-based compensation expenses. Other general and administrative costs and expenses include facility-related costs not otherwise included in research and development costs and expenses, and professional fees for legal and accounting services. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect selling, general and administrative expenses to increase during the remainder of 2018 and beyond.

Financing income, net

Financing income, net was \$144,016 for the nine-month period ended September 30, 2018, as compared to \$223,790 for the prior-year period. The change is primarily attributable to changes in fair market value adjustments relating to our warrants with down-round protection. In accordance with U.S. GAAP, we mark the warrants to market on a quarterly basis based on the fair value estimate derived by using an option pricing model, with the changes in fair value recognized as finance expense or income, as applicable, in our consolidated statement of operations. The decrease in the estimated fair value of our warrants with down-round protection during the nine-month period ended September 30, 2018 and 2017 amounted to \$251,790 and \$273,733, respectively, resulting primarily from the decrease in the expected term of warrants and the changes in the estimated expected volatility. In addition, the Company recorded an expense in the amount of \$82,777 related to the late fee penalty resulting from the non-issuance of dividend payments at the required time.

Net Loss

Net loss was \$5,383,155 for the nine-month period ended September 30, 2018, as compared to \$7,672,266 for the prior-year period. The decrease in net loss is attributable primarily to the decrease in our general and administrative expenses, as described above.

Three Months ended September 30, 2018 compared to Three Months ended September 30, 2017

Revenues

During the three-month period ended September 30, 2018, we had revenues of \$94 from orders for our GlucoTrack® model DF-F glucose monitoring device and PEC that are replaced every six months, as compared with \$20,900 for the prior-year period.

We recognize revenues from sales of the GlucoTrack® model DF-F and PECs when control is transferred to the customer and collectability is probable

Research and development expenses

Research and development expenses were \$534,223 for the three-month period ended September 30, 2018, as compared to \$635,478 for the prior-year period. The decrease is attributable the completion of the clinical trials performed at the Soroka Facility in the first quarter of 2018 and the decrease in our cost of revenues which is in line with the decrease in revenues offset by the stock based compensation issued to all employees during the first quarter of 2018 and the continued development of the WLM.

Research and development expenses consist primarily of salaries and other personnel-related expenses, including materials, travel expenses, clinical trials and other expenses. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect research and development expenses to increase during the remainder of 2018 and beyond, primarily due to hiring additional personnel and developing our product line, as well as improvement of the GlucoTrack® model DF-F; however, we may adjust or allocate the level of our research and development expenses based on available financial resources and based on our commercial needs including the FDA registration process, specific requirements from customers, development of new GlucoTrack® models and others.

Selling and marketing expenses

Selling and marketing expenses were \$265,282 for the three-month period ended September 30, 2018, as compared to \$465,814 for the prior-year period. The decrease is attributable the reduction in our business development personnel during the first quarter of 2018 and the reduction in the number of trade shows we have participated in 2018.

Selling and marketing expenses consist primarily of salaries, travel expenses and other related expenses. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect selling and marketing expenses to increase during the remainder of 2018 and beyond as we continue our focus on marketing and sales of the GlucoTrack® model DF-F; however, we may adjust or allocate the level of our marketing based on available financial resources and based on our commercial needs including the FDA registration process, specific requirements from customers, development of new GlucoTrack® models and others.

General and administrative expenses

General and administrative expenses were \$811,695 for the three-month period ended September 30, 2018, as compared to \$1,567,970 for the prior-year period. The decrease is primarily attributable to the reduction in stock based compensation paid to our former Chairman and CEO,

General and administrative expenses consist primarily of professional services, salaries, travel expenses and other related expenses for executive, finance and administrative personnel, including stock-based compensation expenses. Other general and administrative costs and expenses include facility-related costs not otherwise included in research and development costs and expenses, and professional fees for legal and accounting services. Subject to the receipt of additional funds to finance our operations (of which there can be no assurance), we expect selling, general and administrative expenses to increase during the remainder of 2018 and beyond.

Financing income, net

Financing income, net was \$38,228 for the three-month period ended September 30, 2018, as compared to \$63,622 for the prior-year period. The decrease in income is attributable to an expense in the amount of \$38,497 related to the late fee penalty resulting from the non-issuance of dividend payments at the required time.

Net Loss

Net loss was \$1,572,878 for the three-month period ended September 30, 2018, as compared to \$2,584,740 for the prior-year period. The decrease in net loss is attributable primarily to the decrease in our general and administrative expenses, as described above.

Liquidity and Capital Resources

As of November 14, 2018, cash on hand was approximately \$114,000. During 2018 we received aggregate net proceeds of approximately \$4.7 million (net of related cash expenses) from the issuance and sale of Series D Units. During the first nine months of 2018, we did not collect a material amount in cash proceeds from the fulfillment of orders for our improved GlucoTrack® model DF-F. While we expect to generate additional cash from sales, we do not anticipate that our income from operations will be sufficient to sustain our operations in the next 12 months. Based on our current cash burn rate, strategy and operating plan, we believe that our cash and cash equivalents will enable us to operate for a period of three months from the date of this report. In order to fund our anticipated liquidity needs beyond such period (or possibly earlier if our current cash burn rate, strategy or operating plan change in a way that accelerates or increases our liquidity needs), we will need to raise additional capital.

Messrs. Avner Gal and Zvi Cohen collectively loaned Integrity Israel NIS 176,000 (\$48,525 based on the same exchange rate) on May 15, 2002 pursuant to a board approval. Messrs. Nir Tarlovsky, Yitzhak Fisher and Asher Kugler loaned Integrity Israel NIS 336,300 (\$92,721 based on the same exchange rate) on March 16, 2004. These loans are not required to be repaid until the first year in which we realize profits in our annual statement of operations (accounting profit). At such time, the loans are to be repaid on a quarterly basis in an amount equal to 10% of our total sales in the relevant quarter, beginning on the quarter following the first year in which we realize profits in our annual statement of operations. The total amount to be repaid by us to each lender shall be an amount equal to the aggregate principal amount loaned by such lender to us, plus an amount equal to the product of the amount of each payment made by us in respect of such loan multiplied by the percentage difference between the Israeli Consumer Price Index on the date on which the loan was made and the Israeli Consumer Price Index on the date of such payment. However, notwithstanding the above-mentioned mechanism, we will not be required to repay the loans during any time when such repayment would cause a deficit in our working capital. Our Board of Directors is entitled to modify the repayment terms of these loans, so long as such modification does not discriminate against any particular lender, and provided that all payments must be allocated among the lenders on a pro-rata basis.

Integrity Israel is required to pay royalties to the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of the State of Israel at a rate ranging between 3-5% of the proceeds from the sale of the Company's products arising from the development plan up to an amount equal to \$93,300, plus interest at LIBOR from the date of grant. As of September 30, 2018, the contingent liability with respect to royalty payment on future sales equaled approximately \$33,166 excluding interest.

Net Cash Used in Operating Activities for the Nine-Month Periods Ended September 30, 2018 and September 30, 2017

Net cash used in operating activities was \$3,802,460 and \$5,107,009 for the Nine-month periods ended September 30, 2018 and 2017, respectively. Net cash used in operating activities primarily reflects the net loss for those periods of \$5,383,155 and \$7,672,266, respectively, increased by non-cash changes in fair value of warrants with down-round protection of \$251,790 and \$273,733, respectively. Net cash used in operating activities was also partially offset by changes in operating assets and liabilities in the aggregate amounts of \$197,946 and \$716,246, respectively.

Net Cash Used in Investing Activities for the Nine-Month Periods Ended September 30, 2018 and September 30, 2017

Net cash used in investing activities was \$13,669 and \$19,467 for the nine-month periods ended September 30, 2018 and 2017, respectively, and was used to purchase equipment (such as computers, research and development, and office equipment). In addition, we increased our balance of long-term restricted cash by \$10,164 to fund a deposit against credit card use.

Net Cash Provided by Financing Activities for the Nine-Month Periods Ended September 30, 2018 and September 30, 2017

Net cash provided by financing activities was \$4,705,828 and \$ 5,374,074 for the nine-month period ended, September 30 2018 and 2017, respectively. Cash provided by financing activities for the nine-month period ended September 30, 2018 reflected net capital raised from the issuance of Series D Units. Cash used in financing activities for the nine-month period ended September 30, 2017 reflected net capital raised from the issuance of Series C Units.

Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the “SEC”). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

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

Offering of Series D Units

On July 16, 2018, July 27, 2018 and August 10, 2018 the Company received aggregate gross proceeds of \$2,632,000 in the seventh, eighth and ninth closings of the private placement of its securities from 25 accredited investors. The Company issued to the investors an aggregate of 584,889 units of the Company (each a “Series D Unit”), each consisting of (a) one share of the Company’s Common Stock, (b) a five year warrant to purchase, at an exercise price of \$4.50 per share, one share of Common Stock, (c) a five year warrant to purchase, at an exercise price of \$5.75 per share, one share of Common Stock, and (d) a five year warrant to purchase, at an exercise price of \$7.75 per share, one share of Common Stock. These private placements were made under an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

Issuance of Non-Qualified Stock Options to Employees

On February 15, 2018 and April 1, 2018, we issued a ten-year non-qualified stock option to various employees, for the purchase of 767,500 and 15,000, respectively, shares of Common Stock at an exercise price of \$4.50 per share, with three-year quarterly vesting commencing on the first quarter after the effective date.

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit No.	Description
2.1	<u>Merger Agreement and Plan of Reorganization, dated as of May 25, 2010, by and among Integrity Applications, Inc., Integrity Acquisition Ltd. and A.D. Integrity Applications Ltd. (1)</u>
3.1	<u>Certificate of Incorporation of Integrity Applications, Inc. (1)</u>
3.2	<u>Certificate of Amendment to Certificate of Incorporation of Integrity Applications, Inc. (1)</u>
3.3	<u>Bylaws of Integrity Applications, Inc. (1)</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2	<u>Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	XBRL Instance Document (2)
101.SCH	XBRL Schema Document (2)
101.CAL	XBRL Calculation Linkbase Document (2)
101.LAB	XBRL Label Linkbase Document (2)
101.PRE	XBRL Presentation Linkbase Document (2)
101.DEF	XBRL Definition Linkbase Document (2)

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- (1) Previously filed as an exhibit to the Company's Registration Statement on Form S-1, as filed with the SEC on August 22, 2011, which exhibit is incorporated herein by reference.
- (2) Pursuant to Rule 402 of Regulation S-T, the interactive files on Exhibit 101 hereto are deemed not filed for purposes of Section 11 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under those sections, and are not part of any registration statement to which they relate.

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.

Dated: November 14, 2018

INTEGRITY APPLICATIONS, INC.

By: /s/ David Podwalski

Name: David Podwalski

Title: President and Chief Operating Officer
(Principal Executive Officer)

By: /s/ Sami Sassoun

Name: Sami Sassoun

Title: Chief Financial Officer
(Principal Accounting Officer)

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, David Podwalski, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2018 of Integrity Applications, Inc.;
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.

Date: November 14, 2018

By: */s/ David Podwalski*

David Podwalski
President and Chief Operating Officer

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Sami Sassoun, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2018 of Integrity Applications, Inc.;
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.

Date: November 14, 2018

By: */s/ Sami Sassoun*

*Sami Sassoun
Chief Financial Officer*

Exhibit 32.1

**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 Integrity Applications, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Podwalski, President and Chief Operating 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, as amended; 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/ David Podwalski*

David Podwalski
President and Chief Operating Officer

Dated: November 14, 2018

Exhibit 32.2

**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 Integrity Applications, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sami Sassoun, 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, as amended; 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/ Sami Sassoun*

Sami Sassoun
Chief Financial Officer

Dated: November 14, 2018
