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**integrity**  
applications

102 Ha'Avoda Street, P.O. Box 432  
Ashkelon, Israel L3 78100  
(972) (8) 675-7878



Dear Stockholder,

2013 has gotten off to an exciting start for our company. Since the start of the year, we have:

- ✧ completed a significant financing transaction, providing much needed capital to fund our operations;
- ✧ made significant progress in our efforts to obtain CE Mark approval to market our GlucoTrack DF-F product candidate in the European Union; and
- ✧ received clearance for our common stock to be quoted on the OTC Bulletin Board and the OTC Link under the ticker symbol "IGAP."

### **Financing Transaction**

In March of 2013, we completed the sale of 6,300 units consisting of shares of our newly issued Series A 5% Convertible Preferred Stock and warrants to purchase shares of our common stock. After the payment of commissions and other expenses, we received net proceeds from this transaction of approximately \$5.3 million and currently have approximately \$5.0 million of cash and cash equivalents on hand. 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 approximately 22 months from the date of this letter.

### **Regulatory Developments**

In December of 2012, we submitted our CE Mark technical file to DEKRA Certification B.V. (successor by acquisition of Kema), our European notified body, in connection with our application to obtain CE Mark approval for the GlucoTrack DF-F. In March 2013 we submitted clinical evaluation data to the Notified body in further support of our CE Mark application. If the Notified Body accepts our technical file and clinical evaluation data as satisfactory, we anticipate receiving CE Mark approval to market and sell the GlucoTrack DF-F glucose monitoring device in certain European Union countries as early as the second quarter of 2013.

### **OTC Bulletin Board Quotation**

We are happy to report that, since April 9, 2013, our common stock has been cleared for a priced quotation on the OTC Bulletin Board and the OTC Link under the symbol "IGAP." Although there has been only very limited trading activity to date, we hope that this clearance will open up a potential source of liquidity for our shareholders. Of course, no assurance can be given that an active market will develop for our common stock or that a stockholder will ever be able to liquidate its shares of common stock without considerable delay, if at all.

### **What's Next For Integrity?**

We believe the remainder of 2013 will continue to be busy for us, as we work hard to create value for our stockholders. Specifically, we expect to continue in our efforts to seek a CE Mark for our GlucoTrack DF-F product candidate and will begin efforts to seek FDA approval which, if obtained, would allow us to market the GlucoTrack DF-F in the United States. We also expect to continue our efforts to prepare for the eventual commercialization of our product candidate, if

regulatory approval is received, negotiating with manufacturers and distributors in Israel and the far-east to seek to put in place arrangements for the manufacture and distribution of our product candidate if it is approved for sale.

Please accept our sincere thanks and appreciation for your continued support.

Very truly yours,

A handwritten signature in black ink, appearing to be 'Avner Gal', written in a cursive style.

**Avner Gal**

Chairman of the Board,

President and Chief Executive Officer

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

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 333-176415

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**INTEGRITY APPLICATIONS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

\_\_\_\_\_  
(State or other jurisdiction of  
incorporation or organization)

98-0668934

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

102 Ha'Avoda Street

P.O. Box 432

Ashkelon, Israel

\_\_\_\_\_  
(Address of principal executive offices)

L3 78100

\_\_\_\_\_  
(Zip Code)

Registrant's telephone number, including area code 972 (8) 675-7878

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common stock, par value \$.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

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Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

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

The aggregate market value of the voting stock held by non-affiliates is not determinable because there is no public trading market for our common stock, par value \$.001 per share.

As of March 15, 2013, 5,460,600 shares of our common stock, par value \$.001 per share, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

The registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for the 2013 annual meeting of shareholders is incorporated by reference in Part III of this Form 10-K to the extent stated herein.

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## GENERAL

Unless the context otherwise requires, the terms “we”, “our”, “ours” and “us”, refer to A.D. Integrity Applications, Ltd., an Israeli corporation (“Integrity Israel”), for all periods prior to July 15, 2010 and to Integrity Israel and Integrity Applications, Inc., a Delaware corporation (“Integrity U.S.”), on a combined basis, for all periods from and including July 15, 2010.

### CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K includes 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 or prospects. All statements other than statements of historical fact included in this Annual Report on Form 10-K, including statements regarding our future activities, events or developments, including such things as future revenues, 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,” “intend,” “anticipates,” or “propose,” and other similar words and phrases, are intended to identify forward-looking statements. The forward-looking statements made in this Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 in this Annual Report on Form 10-K under the caption “Risk Factors” beginning on page 26. We undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this report unless required by law.

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## PART I

### Item 1. Business.

#### Overview

Integrity is a development stage medical device company focused on the design, development and commercialization of non-invasive glucose monitoring devices for use by persons suffering from diabetes. 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 blood glucose monitor, the GlucoTrack DF-F glucose monitoring device, which is designed to help people with diabetes obtain blood glucose level readings without the pain, inconvenience, cost and difficulty of conventional (invasive) spot finger stick devices. The GlucoTrack DF-F utilizes a patented combination of ultrasound, electromagnetic and thermal technologies to obtain blood 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. Integrity Israel conducted pre-clinical trials involving over 7,000 readings from over 450 patients over the last seven years. Clinical data collected since 2009 at the Soroka University Medical Center in Be'er Sheva, Israel indicate a positive correlation between GlucoTrack DF-F readings and those obtained from conventional invasive devices. More specifically, a safety and performance clinical trial conducted on 135 subjects of various weights, ages, diabetes types and genders involved 6,275 measurements, of which 96.5% were within the clinically acceptable zones (zones A and B) of the Clarke Error Grid ("CEG"). Measurements are clinically acceptable, compared to a referenced invasive device, when the variance between the devices would have no worse than a benign effect on the patients. The results of these pre-clinical trials may not be indicative of future results due to their relatively small sample sizes.

In December 2012, we submitted our CE Mark technical file to DEKRA Certification B.V. (successor by acquisition of Kema), our European notified body (the "Notified Body"), in connection with our application to obtain CE Mark approval for the GlucoTrack DF-F. In March 2013 we submitted clinical evaluation data to the Notified body in further support of our CE Mark application. If the Notified Body accepts our technical file and clinical evaluation data as satisfactory, we anticipate receiving CE Mark approval to market and sell the GlucoTrack DF-F glucose monitoring device in certain European Union countries as early as April of 2013. We expect to begin clinical trials in the United States by late 2013 or early 2014, if our clinical trial protocol is approved by the U.S. Food and Drug Administration (the "FDA").

We have not yet generated any revenues from our operations and have incurred losses of \$15,289,826 from inception through December 31, 2012, stockholder's deficit of \$503,069 and cumulative negative operating cash flow of \$11,574,060. We are dependent upon external sources for financing our operations and there can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

We were incorporated in May 2010. On July 15, 2010, we completed a reverse triangular merger with Integrity Israel and Integrity Acquisition Corp. Ltd., an Israeli corporation and a wholly owned subsidiary of ours, pursuant to which Integrity Acquisition Corp. Ltd. merged with and into Integrity Israel and all of the stockholders and option holders of Integrity Israel became entitled to receive 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 received 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.

Our principal offices are located at 102 Ha'Avoda St., Ashkelon, Israel 78100 and our telephone number is 972-8-675-7878. Our website address is <http://www.integrity-app.com>; the reference to such website address does not constitute incorporation by reference of the information contained on the website and such information should not be considered part of this report. There is no relationship between us and Integrity Applications, Incorporated, the engineering and software services company based in Chantilly, Virginia.

## **Recent Corporate Developments**

### ***Preferred Stock and Warrant Issuance***

On March 13, 2013, we entered into a Securities Purchase Agreement with certain accredited investors (the "Unit Purchasers") pursuant to which, on March 13, 2013, we issued to the Unit Purchasers an aggregate of 6,300 Units, each consisting of (a) one share of our newly designated Series A 5% Convertible Preferred Stock, par value \$.001 per share (the "Preferred Stock"), convertible into shares of our common stock at an initial conversion price of \$5.80 per share, and (b) a warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of common stock issuable upon conversion of such share of Preferred Stock (each a "Warrant" and, collectively, the "Warrants"). The shares of Preferred Stock comprising the Units are convertible into an aggregate of 1,086,206 shares of common stock and the Warrants comprising the Units are exercisable for an aggregate of 1,086,206 shares of common stock, in each case subject to adjustment as described below. See "Item 5. Market for Registrant's Common Equity, Related Stockholder Matter and Issuer Purchases of Equity Securities - Recent Sale of Unregistered Securities" on page 54 below for a description of the material terms of the Preferred Stock and the Warrants.

The issuance and sale of the Units constituted the second and final closing of an offering of our securities in a private placement transaction. On November 19, 2012, we completed the first closing of the offering, pursuant to which we issued and sold an aggregate of 165,057 shares of common stock at a price of \$7.00 per share to certain accredited investors (the "First Closing Purchasers"). As previously disclosed, as a result of the conversion of the offering from an offering of Common Stock to an offering of Units, we agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will exchange the shares of common stock acquired by each First Closing Purchaser in the first closing for such number of Units equal to the aggregate purchase price paid by such First Closing Purchaser in the first closing, divided by \$1,000, in each case subject to the execution by the First Closing Purchaser of a consent to such modification.

In addition, as previously disclosed, we also agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will issue to the holders of the 1,295,535 shares of common stock issued by us at a price of \$6.25 per share pursuant to seven closings of a private placement (the "Previous Private Placement") held on December 16, 2010, December 30, 2010, January 31, 2011, March 31, 2011, April 29, 2011, May 31, 2011 and July 29, 2011, respectively, such number of shares of Common Stock as would reduce the per share purchase price paid by such holders for such shares from \$6.25 per share to \$5.80 per share, in each case subject to the execution by the holder of a consent to such modification.

Pursuant to a placement agent agreement between us and Andrew Garrett, Inc., the placement agent for the offering, at the closing of the sale of the Units we paid Andrew Garrett, Inc., as a commission, an amount equal to 7% of the aggregate sales price of the Units, plus 3% of the aggregate sales price as a management fee plus a non-accountable expense allowance equal to 3% of the aggregate sales price of the Units. In addition, pursuant to the placement agent agreement, we issued to Andrew Garrett, Inc., as partial consideration for its services as placement agent for the offering, warrants to purchase up to 217,240 shares of common stock. We will be required to issue to Andrew Garrett, Inc. warrants to purchase up to an additional 19,920 shares of common stock following the exchange of the shares of common stock issued to the First Closing Purchasers for Units. Half of such options are (or, when issued, will be) exercisable at an exercise price of \$5.80 per share, and the remainder of such options are (or, when issued, will be) exercisable at an exercise price of \$6.96 per share.

## **Market Opportunity**

### ***Diabetes***

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize the hormone insulin. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. Normally, the pancreas provides control of blood glucose levels by secreting the hormone insulin to decrease blood glucose levels when concentrations are too high. In people with diabetes, blood glucose levels fluctuate between very high levels, a condition known as hyperglycemia, and very low levels, a condition known as hypoglycemia. Hyperglycemia can lead to serious long-term complications, such as blindness, kidney disease, nervous system disease, amputations, stroke and cardiovascular disease. Hypoglycemia can lead to confusion, loss of consciousness or death.

Diabetes is typically classified into two major groups: Type 1 and Type 2. Type 1 diabetes is characterized by the body's inability to produce insulin, resulting from destruction of the insulin producing cells of the pancreas. Individuals with Type 1 diabetes must rely on frequent insulin injections in order to regulate and maintain blood glucose levels. Type 1 diabetes is frequently diagnosed during childhood or adolescence, although disease onset can occur at any age. Type 2 diabetes, the more common form of diabetes, is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Type 2 diabetes is associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity and race or ethnicity. Depending on the severity of Type 2 diabetes, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels.



According to the Diabetes Atlas (Fifth Edition) published by the International Diabetes Federation in 2011, an estimated 366 million adults aged from 20 to 79 worldwide, or 8.3% of the world's adult population, were estimated to suffer from diabetes in 2011 (not including those persons who suffer from impaired glucose tolerance ("IGT") or gestational diabetes, diabetic conditions first arising during pregnancy). The International Diabetes Federation estimates that this number will grow to approximately 552 million adults worldwide, or 8.3% of the adult population in "high income" countries and 9.0% of the adult population in "low income" countries, in 2030, and that by 2030 the number of adults suffering from diabetes will have increased by 90.5% in Africa, 83.1% in the Middle East and North Africa, 69.3% in Southeast Asia, 59.0% in South and Central America, 42.5% in the Western Pacific, 35.8% in North America and the Caribbean and 21.6% in Europe, over such regions' respective 2011 levels. According to a statement made by the President of the International Diabetes Federation at a press briefing at the European Association for the Study of Diabetes in September 2011, as of the time of such presentation, an estimated 366 million people suffered from diabetes and approximately 4.6 million deaths were attributable to diabetes annually.

The CDC, in its 2011 National Diabetes Fact Sheet, estimated that in the United States alone, more than 25.8 million people, or 8.3% of the population, suffered from diabetes in 2010. According to the National Diabetes Education Program, approximately 5-10% of the diabetes population had Type 1 diabetes at the time of measurement.

According to the National Diabetes Education Program, about 75% of all newly diagnosed cases of Type 1 diabetes in the United States occur in juveniles younger than 18 years of age. In addition, according to the National Diabetes Education Program, Type 2 diabetes is occurring with increasing frequency in young people. The increase in prevalence is related to an increase in obesity amongst children. According to the 2007-2008 National Health and Examination Survey, approximately 16% of children and teens were overweight, about double the number two decades before.

The CDC, in its 2011 National Diabetes Fact Sheet, estimated that the direct medical costs and indirect expenditures attributable to diabetes in the United States were \$174 billion in 2007, an increase of \$42 billion since 2002. Of this amount, the CDC estimated that approximately \$116 billion were direct medical costs. In 2011, the International Diabetes Federation estimated that worldwide healthcare expenditures to treat diabetes and prevent its complications would total at least \$465 billion in 2011, including \$201 billion in the United States alone, and \$595 billion worldwide in 2030. According to a May 2010 special report by Pharmalive.com, a leading publisher of market research in medical markets, the market for self-monitoring glucose tests was estimated to be approximately \$8 billion in 2010.

## *Glucose Monitoring*

Blood glucose levels can be affected by many factors, including the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption and changes in the effects of insulin in the body. Given the many factors that affect blood glucose levels, maintaining glucose within a normal range can be difficult. Diabetics generally manage their blood glucose levels by administering insulin or ingesting carbohydrates throughout the day to maintain blood glucose within normal ranges. Normal ranges in diabetics vary from person to person. In order to maintain blood glucose levels within normal ranges, diabetics must first measure their blood glucose levels so that they can make the proper therapeutic adjustments. As adjustments are made, additional blood glucose measurements may be necessary to gauge the individual's response to the adjustments. More frequent testing of blood glucose levels provides patients with information that can be used to better understand and manage their diabetes. Testing of blood glucose levels is usually done before meals, after meals and before going to sleep. Diabetics who take insulin usually need to test more often than those who do not take insulin.

The outcome of clinical data supports the recommendation that frequent monitoring of blood glucose levels is an important component of effective diabetes management. The Diabetes Control and Complications Trial, consisting of patients with Type 1 diabetes, and the 1998 UK Prospective Diabetes Study, consisting of patients with Type 2 diabetes, demonstrated that patients who intensely managed blood glucose levels delayed the onset and slowed the progression of diabetes-related complications. In the Diabetes Control and Complications Trial, a major component of intensive management was monitoring blood glucose levels at least four times per day using conventional spot finger stick blood glucose meters. The Diabetes Control and Complications Trial demonstrated that intensive management reduced the risk of complications by 76% for eye disease, 60% for nerve disease and 50% for kidney disease. However, the Diabetes Control and Complications Trial also found that intensive management led to a two- to three-fold increase in the frequency of hypoglycemic events. In the December 2005 edition of the *New England Journal of Medicine*, the authors of a peer-reviewed study concluded that intensive diabetes therapy has long-term beneficial effects on the risk of cardiovascular disease in patients with Type 1 diabetes. The study showed that intensive diabetes therapy reduced the risk of cardiovascular disease by 42% and the risk of non-fatal heart attack, stroke or death from cardiovascular disease by 57%. However, despite evidence that intensive glucose management reduces the long-term complications associated with diabetes, the American Diabetes Association reported in a 2001 issue of its publication *Diabetes Care* that up to 67% of patients with diabetes fail to routinely monitor their glucose levels.

Spot finger stick devices are the most prevalent devices for blood glucose monitoring. These devices require inserting a strip into a glucose meter, taking a blood sample with a finger stick and placing a drop of blood on the test strip that yields a single point in time blood glucose measurement. Despite continued developments in the field of blood glucose monitors, the routine measurement of glucose levels remains invasive, painful, inconvenient, difficult and costly. This has resulted in a sub-optimal measurement regimen for many diabetics.

The FDA has approved continuous glucose monitoring system (CGMS) devices for blood glucose monitoring, when prescribed by a doctor. Continuous glucose monitoring system devices use sensors inserted under the skin to check glucose levels in interstitial fluid. The sensor stays in place for several days to a week and then must be replaced. A transmitter sends information about glucose levels via radio waves from the sensor to a pager-like wireless monitor. According to the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health, continuous glucose monitoring device users must check blood samples with a conventional glucose meter to calibrate the continuous glucose monitoring systems devices, and because currently approved continuous glucose monitoring systems are not as accurate as standard blood glucose meters, users should confirm glucose levels with a meter before changing treatment.

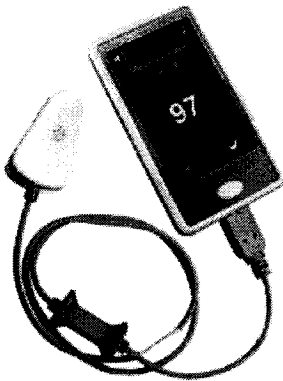
To our knowledge, there are currently no available devices that are cleared or approved for use in either the United States or the European Union for spot or continuous non-invasive blood glucose measurement. The FDA has previously approved a single non-invasive product for glucose trend analysis, the GlucoWatch®, so long as the device was used with conventional finger stick glucose monitoring devices. However, the device is no longer available commercially.

We believe that a significant market opportunity exists for a reliable, inexpensive, non-invasive blood glucose measurement device and that such a device could greatly increase compliance with blood glucose measurement recommendations and help many diabetics better manage their disease, providing significant benefits to both patients and payors.

### **The Product**

Our non-invasive blood glucose monitor, the GlucoTrack DF-F, utilizes a patented combination of ultrasound, electromagnetic and thermal technologies to obtain blood glucose measurements in less than one minute via a small sensor that is clipped onto one's earlobe and connected to a handheld control and display unit. See Figure A, below.

**Figure A**

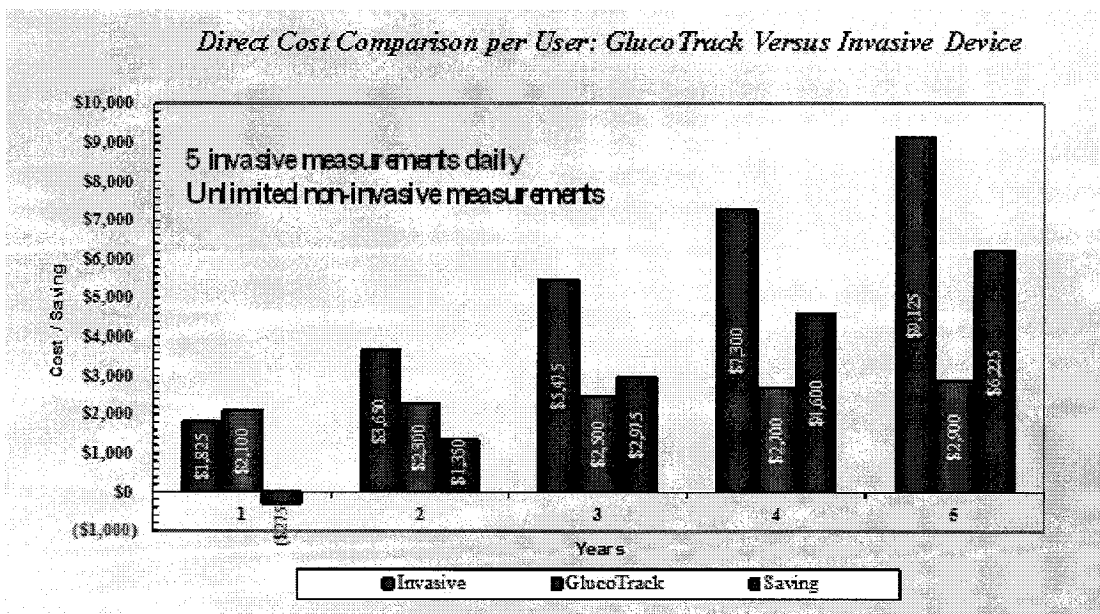


We believe that the GlucoTrack DF-F addresses the expressed, currently unmet needs of the diabetic market as it removes or diminishes two of the most significant barriers to the recommended frequent monitoring of blood glucose by diabetics:

- pain, as the GlucoTrack DF-F is a truly non-invasive device; and
- cost, as, despite the relatively high upfront cost of purchasing a GlucoTrack DF-F, we anticipate that the total cost of purchasing a device and purchasing replacement ear clips every six months (anticipated to be the only recurring cost, other than recalibration costs, which are expected to be minimal) over the useful life of the device will be significantly lower than the cost of purchasing single use glucose sticks over that same period. See Figure B and the accompanying footnotes for a direct cost comparison of the GlucoTrack DF-F and conventional (invasive) spot finger stick devices.

We estimate that, over a five-year period, a GlucoTrack DF-F user could save an average of \$6,405 when compared to the cost of a conventional invasive blood glucose monitoring system, while also taking advantage of the benefits of more frequent blood glucose testing. See Figure B, below.

Figure B



The direct cost comparison assumes (i) a single invasive measurement costs \$1.00; (ii) the average user of an invasive device takes five measurements daily; (iii) the average retail price for the GlucoTrack DF-F is \$2,000 (including one personal ear clip); and (iv) the personal ear clip is replaced every six months at a cost of \$100. The direct cost comparison excludes recalibration costs, which are expected to be approximately \$70, in total, over a five year period.

Despite the fact that the overall costs associated with owning and using a GlucoTrack DF-F device are expected to be substantially lower than the cost of purchasing and using single use invasive devices over an extended period of time, as demonstrated in Figure B above, the significant initial purchase price of a GlucoTrack device might present a barrier to adoption of the GlucoTrack system by patients. In light of this fact, we are considering options to lessen the initial financial burden associated with purchasing a GlucoTrack device, including leasing devices to users. In addition, we intend to seek reimbursement approval for the GlucoTrack device from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. There can be no assurance that such third party-payors will provide reimbursement coverage for the GlucoTrack or, if so, whether such reimbursement coverage will be adequate. See “Risk Factors - If GlucoTrack DF-F or our future product candidates, if any, fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability” on page 27 of this report.

Instead of directly measuring the glucose level of a user’s blood, as conventional spot finger stick devices do, the GlucoTrack DF-F uses a small, non-invasive sensor that is clipped onto a user’s earlobe to obtain certain body measurements using three technologies, which are then analyzed using a proprietary algorithm on a small, handheld control and display unit. Within one minute, the GlucoTrack DF-F will produce a blood glucose measurement that can be simultaneously audibly announced and displayed on the control unit, as well as recorded on internal flash memory. The two units of the device (main unit and personal ear clip) are connected through a multi-wire flexible cable. When and if we develop a continuous measurement model, we plan for this connection to be wireless.

The primary statistical tools used to evaluate the performance of GlucoTrack DF-F to date are CEG analysis and Mean Absolute Relative Difference (“MARD”). The CEG analysis was developed by Dr. William Clarke and his team from the University of Virginia as a universal tool for assessing the accuracy of glucose monitors and is currently used (and has been used for more than two decades) widely all over the world as the industry-standard analytical tool to assess such accuracy. The purpose of the CEG is to assess measurement error from a clinical point of view, i.e. the statistical difference in the readings and the impact of any error on the patient. The CEG is a plot of all data pairs categorized into five discrete zones: A (clinically accurate reading), B (the decision based on the reading is benign or no treatment is given), C (the decision based on the reading leads to normal glucose levels being overcorrected), D (the decision based on the reading results in a failure to treat high and low levels) and E (the decision based on the reading results in an erroneous treatment decision). The A and B zones are the most clinically desirable zones and the D and E zones are the least clinically desirable zones. For example, a pair of data points at 200 mg/dl for the reference device compared to 280 mg/dl for the unit under testing are within zone B despite the significant difference between the two while measurements of 50 mg/dl for the reference device compared to 110 for the unit under testing are in zone D because of the possible failure to treat a low level of glucose. Devices with a higher combined A and B percentage (closer to 100%) and lower combined D and E percentage (closer to 0) are considered to have better performance. MARD is an error calculation tool that measures the average relative difference between the unit under testing and the reference measurements, on a percentage basis. While CEG is a specific tool to evaluate clinical risk due to errors in measuring glucose, MARD is a common statistical tool, subtracting the measurement value of a measurement of a specific subject with respect to a tested device from the measurement value of that subject’s measurement from a reference device and then taking the absolute value of the result. The last step is to calculate the mean of these absolute values to obtain MARD. MARD is a common statistical index that is used to compare a set of paired measurements coming from two devices or systems in order to evaluate the bias between the two.

CEG analysis of data from the safety and performance clinical trial conducted by Integrity Israel in 2012 at the Soroka University Medical Center showed that GlucoTrack DF-F had 96.5% of the data in the combined A and B zones, with approximately 42.8% in the A zone, 53.7% in the B zone, 1.9% in the C zone, 1.6% in the D zone and 0% in the E zone. MARD for the study was approximately 30%. We believe that the results of the Soroka University study show that GlucoTrack DF-F accurately and reliably measured blood glucose readings using the same calibration set.

A full explanation of the different CEG zones is set forth below in Figure C:

**Figure C**

<b>Zone</b>	<b>Description</b>	<b>Definition of Risk</b>	<b>Risk</b>
A	Clinically accurate, would lead to correct treatment decisions	No effect on clinical action	None
B	Would lead to benign decisions or no treatment	Altered clinical action, little or no effect on clinical outcome	Slight
C	Would lead to overcorrection of normal glucose levels	Altered clinical action, likely to affect clinical outcome	Moderate
D	Would lead to failure to detect & treat high or low glucose levels	Altered clinical action, could have significant medical risk	Significant
E	Would lead to erroneous treatment decisions	Altered clinical action, could have dangerous consequences	Dangerous

Since the GlucoTrack DF-F non-invasive measurement does not directly measure glucose levels in the blood, but rather measures a series of physiological characteristics that correlate with glucose levels, each patient must be calibrated by using a reference to a measurement obtained from an invasive device. Calibration consists of comparing each individual patient’s physiological measurements by GlucoTrack DF-F to the measurements from the invasive device under different circumstances over a defined period (such as fasting and after eating). Our pre-clinical and safety and performance clinical trials to date have indicated that recalibration is necessary as infrequently as once every six months, while to our knowledge, competing products require recalibration significantly more frequently. However, to date, in informal discussions with the FDA, the FDA has indicated that initially it would require recalibration of the GlucoTrack DF-F every month, but has not yet indicated what standards will be used for clearance. Recalibration of the device would be accomplished in the same manner as the initial calibration of the device, by comparing the readings obtained from the GlucoTrack DF-F against measurements obtained using an invasive device. We expect that the initial calibration and the first one or two recalibrations would be completed by experienced clinicians in a clinical setting, and all other recalibrations after the initial one or two recalibrations would be completed by the patient in his or her home or another location of his or her choosing. We expect that, subject to FDA and other regulatory approval, eventually the GlucoTrack will require only an initial calibration upon use of a new PEC (replaced every 6 months) and will not require recalibration.

A CEG analysis of the GlucoTrack DF-F conducted for up to 6 months after calibration, but without re-calibration for each patient, demonstrates that calibration of the GlucoTrack DF-F remains valid for the period tested with only a very slight degradation in the accuracy level during the last month. Therefore, we anticipate that, subject to regulatory approval, the GlucoTrack DF-F may ultimately be used without recalibration for as long as 6 months (the expected time between replacement of ear clips).

Part of the safety and performance clinical trial was conducted as a home simulation, to test the performance of the GlucoTrack DF-F while the device was operated by the patients themselves in a home-like environment and in the absence of direct clinical supervision. In this study, the performance of the GlucoTrack DF-F was monitored for 41 participants, with each subject performing the measurement procedure him or herself in the clinic on 4 to 19 days over a period of one to six months, yielding an aggregate of 1,629 data points. The GlucoTrack readings from patients in this group were compared with readings from an invasive glucose monitoring device, which served as the reference for calibration and comparison of measurements. In this home simulation, the GlucoTrack DF-F had 96% of the data in the combined A and B of the CEG zones, with approximately 41.1% in the A zone, 55% in the B zone, 2.2% in the C zone, 1.7% in the D zone and 0% in the E zone. The MARD for the home simulation was approximately 31%.

Within the last few years, continuous glucose monitoring system devices have been introduced into the market. Currently, three different brands have obtained FDA clearance to market, and are selling, continuous glucose monitoring system devices in the US and EU markets. These brands are sold by Medtronic-MiniMed, Abbott and Dexcom. Continuous glucose monitoring system devices are invasive devices, in which a needle is inserted under the skin (either in the abdomen or the upper arm) and measures interstitial fluid. Although we cannot predict what standards will be employed by applicable regulatory authorities as we seek a CE Mark and FDA clearance, the results achieved by the GlucoTrack DF-F in our safety and performance clinical trial conducted in 2012 were similar to the results obtained from the continuous glucose monitoring system devices that have been introduced to the market, as of the time of their introduction.

The three different technologies used by GlucoTrack DF-F, ultrasound, electromagnetic and thermal, simultaneously measure three independent criteria. As indicated in the Soroka University study, these three measurements (criteria) are combined together by a unique (on line) algorithm to produce an acceptable measurement of a user's blood glucose level.

The technologies operate as follows:

- **Ultrasound:** The GlucoTrack DF-F uses ultrasound technology to measure the change of speed of sound through the earlobe, which is impacted by the glucose concentration in the capillary blood vessels.
- **Electromagnetic:** The GlucoTrack's DF-F's electromagnetic technology uses a measurement of conductivity to measure the change in tissue impedance, which is a function of glucose concentration. The GlucoTrack DF-F's electromagnetic technology analyzes criteria similar to those analyzed by conventional invasive devices, such as spot finger stick devices, but does so in a non-invasive manner.
- **Thermal:** The GlucoTrack DF-F's thermal technology uses heat transfer characteristics of the tissue, which are influenced by glucose concentration.

The GlucoTrack DF-F does not directly measure the glucose level concentration in the blood. Rather, it measures several physiological phenomena which are correlated with the glucose level. In order to correlate between the measured signal and the glucose level, a translation is needed. This translation is accomplished through the individual calibration of the device by reference to a measurement obtained from an invasive device.

Non-invasive devices (under different stages of development) generally require frequent recalibration. For example, GlucoWatch, a single non-invasive product for glucose trend analysis that was previously approved for sale by the FDA, but which is no longer available commercially, required recalibrations approximately every 13 hours. The main reasons for calibration are that tissue parameters generally fluctuate in the area of the measurement, and are sensitive to the location of the sensor and the impact of potential disturbances. For various reasons, including the results of our safety and performance clinical trial, we believe that the GlucoTrack DF-F will have significantly less need for recalibration (if at all), with recalibration initially required just once a month and possibly less frequently later. Disturbances are less frequent in the earlobes, where the GlucoTrack DF-F takes its measurements. Utilizing three channels simultaneously reduces the noise contribution in the measurement. In addition, the personal ear clip contains sensors to help users attach the device to the proper part of the ear lobe.

The GlucoTrack does not use any optical method (either Infra Red (IR) or Near Infra Red (NIR) technology), which we understand are being used by other developers of noninvasive blood glucose measurement devices. We believe that optical technologies are less reliable than the GlucoTrack's combination of ultrasound, electromagnetic and thermal technologies due to inherent physiological limitations with optical technology. More specifically, optical technology is based on dispersion of a beam that is analyzed by spectrometric methods. As such devices are non-invasive, the beam passes through other components in the finger tip, such as skin, bone, muscle and fat tissue, which interfere with the measurements. Generally, most of these interferences have been overcome, but not the epidermis, primarily due to roughness, pigmentation and perspiration, which act like lenses in optical wavelengths.



Unlike conventional spot finger stick devices, which require single-use glucose test strips, the GlucoTrack DF-F requires no short term disposables. We believe that the personal ear clip that accompanies each GlucoTrack DF-F will need to be replaced only once every six months, although regulatory authorities may require that replacement occur more frequently. Since there is no additional cost or pain involved with each blood glucose measurement using the GlucoTrack DF-F, we believe that users of our device would be encouraged to take multiple blood glucose measurements per day, significantly increasing compliance with blood glucose measurement recommendations and helping diabetics better manage their disease. More frequent testing of blood glucose levels may provide a patient with information that can be used to determine optimal timing and dosage for corrective treatments such as insulin, and can also direct a patient to seek a clinical analysis or detailed testing and diagnosis. We believe that the GlucoTrack DF-F's non-invasive advantages will hold particular appeal for classes of users that require special care, including premature infants (through a separate GlucoTrack device which we may develop in the future), children and the elderly.

We intend to eventually develop a family of GlucoTrack devices, including a device for night time usage (which would provide advance warnings of potential hypoglycemic episodes); a continuous measurement device; a driver alert device; a basic model to be used in poorer countries; a device for use in pediatric incubators; and a device for people with pre-diabetes. The current GlucoTrack device, or DF-F, measures glucose levels at discrete times as desired by the user, known as spot measurement. We intend that next generation models of GlucoTrack will include both spot and continuous measurements of glucose levels. We also intend to develop accessories for GlucoTrack, including belt holders, desktop stands and software applications for data processing and analysis. Certain models of the device will include a USB port to allow offline analysis of downloaded data. All of the above models will be derivative of the technologies currently used by the DF-F model. The modifications involve mostly engineering changes as opposed to development. Notwithstanding the foregoing, there is no assurance that we will be successful in developing or engineering any of these models or accessories.

The GlucoTrack DF-F has not yet been cleared or approved for commercial sale in the United States, the European Union or any other jurisdiction. See "Government Regulation - Regulation of the Design, Manufacture and Distribution of Medical Devices" below for a discussion of the approval process for commercial sale. There can be no assurance that approval for commercial sale in any jurisdiction will be obtained.

#### **Manufacturing**

We do not have commercial manufacturing facilities and do not intend to build commercial manufacturing facilities of our own in the foreseeable future. We intend to enter into agreements with various third parties for the formulation and manufacture of our products. We build prototypes of GlucoTrack devices for testing, including for limited use in clinical testing, using parts manufactured by subcontractors and assembling them in our Ashkelon, Israel offices. We intend to enter into agreements with third-party manufacturers for the manufacture of prototypes for certain GlucoTrack devices. These suppliers and their manufacturing facilities must comply with FDA and applicable foreign regulations (including ISO 13485), current quality system regulations, which include current good manufacturing practices, and to the extent laboratory analysis is involved, current good laboratory practices.

## **Sales & Marketing**

We do not have dedicated sales or marketing personnel yet, because neither the GlucoTrack DF-F nor other GlucoTrack devices are approved for commercial sale. In order to commercialize the GlucoTrack DF-F, if it is approved for commercial sale, we intend to collaborate with third parties with established sales and marketing operations in the medical device industry to market and sell the GlucoTrack DF-F to point of sale end users or for personal use. However, there can be no assurance that we will be able to enter into distribution agreements on terms acceptable to us or at all. We have signed an agreement with a leading chain of private diabetes clinics in South Africa to purchase GlucoTrack DF-F devices, pending approval for commercial sale by that chain's headquarters, which will depend on performance of the device in clinical trials. The agreement requires tests of a few devices by the clinics (no FDA or CE Mark approval is required in this particular country) as a prerequisite for sales. If the device is approved by the chain, then it will purchase devices directly from us for sale directly to its patients, without the need for third-party marketing or sales. If the device is approved by the chain's headquarters, this chain will have an annual obligation during the first year to purchase a minimum of 10,000 units at a price of \$835 per unit. Minimum obligations for the second and following years are subject to mutual agreement. There is no assurance that any sales will be made pursuant to this agreement. We anticipate that we will begin sales efforts in various jurisdictions as the GlucoTrack DF-F receives commercial approval in such jurisdictions.

## **Government Regulatory**

Healthcare is heavily regulated in the United States by federal, state and local governments, and by similar authorities in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country. The laws and regulations affecting healthcare change regularly, thereby increasing the uncertainty and risk associated with any healthcare-related venture. The United States government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly and adversely affect reimbursement for healthcare products such as GlucoTrack DF-F devices. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for GlucoTrack, if it is approved or cleared for sale, or our future products, if any. These include changes that may reduce reimbursement or payment rates for such products and changes that may be proposed or implemented by the current administration or Congress. We cannot predict, however, if any proposal that has been or will be considered will be adopted or what effect any such legislation will have on us.

In the United States, the federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Food, Drug, and Cosmetic Act, as well as other relevant laws; (ii) the Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General, which enforces various laws aimed at curtailing fraudulent or abusive practices including, by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude health care providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights which administers the privacy and security aspects of the Health Insurance Portability and Accountability Act of 1996. All of the aforementioned are agencies within the Department of Health and Human Services. Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs under, among other laws, the Veterans Health Care Act of 1992, the Public Health Service within HHS under the Public Health Service Act, the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under the Medicaid program and their internal laws regulating all healthcare activities.

***Regulation of the Design, Manufacture and Distribution of Medical Devices***

Any product that we develop must receive all relevant regulatory clearances or approvals, as the case may be, before it may be marketed in a particular country. In the United States, under Section 201(h) of the Food, Drug, and Cosmetic Act, a medical device is an article which, among other things, is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals. We believe that GlucoTrack devices will be classified as medical devices and subject to regulation by numerous agencies and legislative bodies, including the FDA and its foreign counterparts. Devices are subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution. The FDA classifies medical devices into one of three classes. Class I devices are relatively simple and can be manufactured and distributed with general controls. Class II devices are somewhat more complex and require greater scrutiny. Class III devices are new and frequently help sustain life.

In the United States, a company generally can obtain permission to distribute a new device in two ways – through a so-called “510(k)” premarket notification application or through a Section 515 premarket approval application. The 510(k) submission applies to any device that is substantially equivalent to a device first marketed prior to May 28, 1976 or to another device marketed after that date, but which was substantially equivalent to a pre-May 28, 1976 device. These devices are either Class I or Class II devices. Under the 510(k) submission process, the FDA will issue an order finding substantial equivalence to a predicate device (pre-May 28, 1976 or post-May 28, 1976 device that was substantially equivalent to a pre-May 28, 1976 device) and permitting commercial distribution of that device for its intended use. A 510(k) submission must provide information supporting its claim of substantial equivalence to the predicate device. The FDA permits certain low risk medical devices to be marketed without requiring the manufacturer to submit a premarket notification. In other instances, the FDA may require that a premarket notification not only be submitted, but also be accompanied by clinical data. If clinical data from human experiments are required to support the 510(k) submission, these data must be gathered in compliance with investigational device exemption regulations for investigations performed in the United States. The FDA review process for premarket notifications submitted pursuant to section 510(k) should take about 90 days, but it can take substantially longer if the agency has concerns, and there is no guarantee that the agency will clear the device for marketing, in which case the device cannot be lawfully distributed in the United States. If the FDA finds that the device subject to the premarket notification is substantially equivalent to a proper predicate device, then the agency may “clear” that device for marketing. These devices are not “approved” by the FDA. There is no guarantee, however, that the agency will deem the device subject to the 510(k) process, as opposed to the more time-consuming, resource intensive and problematic PMA process described below.

The more comprehensive premarket approval process applies to a new device that either is not substantially equivalent to a pre-May 28, 1976 product or is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices and can only be marketed following approval of a premarket approval application (PMA). For example, most implantable devices are subject to the premarket approval application approval process. Two steps of FDA approval generally are required before a company can market a product in the U.S. that is subject to Section 515 premarket approval application approval, as compared to a Section 510(k) clearance. First, a company must comply with investigational device exemption regulations in connection with any human clinical investigation of the device; however those regulations permit a company to undertake a clinical study of a “non-significant risk” device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. If there is any doubt as to whether a device is a “non-significant risk” device, companies normally seek prior approval from the FDA. Normally, clinical studies of new diagnostic products are conducted in tandem with a cleared or approved device and treatment decisions are based on the results from the existing diagnostic device. In such a setting, the FDA may well consider the clinical trial as one not posing a significant risk. However, FDA action is always uncertain and dependent on the contours of the design of the clinical trial and the device and there is no assurance that the FDA would consider any proposed clinical trial as one posing a non-significant risk. Moreover, before undertaking any clinical trial, the company sponsoring the trial and the investigator conducting the trial are required by federal law to seek and obtain the approval of institutional review boards. An institutional review board weighs the risks and benefits of a proposed trial to ensure the human subjects are not exposed to unnecessary risk and reviews the informed consent form to ensure that it meets federal requirements and accurately describes the risks and benefits, if any, of the clinical trial. IRB review occurs annually and annual re-approval is required. University medical centers as well as other entities maintain and operate institutional review boards. Second, the FDA must review a company’s premarket approval application, which contains, among other things, clinical information acquired under the investigational device exemption. The FDA will approve the premarket approval application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The premarket approval process takes substantially longer than the 510(k) process.

We believe that the GlucoTrack DF-F device will be classified as a Class III device that will be subject to the premarket approval application process and require human clinical trials, although that may not be true with other products mentioned in this report. We currently anticipate that we will submit the protocol for U.S. clinical trials of the GlucoTrack DF-F to the FDA by the second half of 2013. Following approval of the clinical trial protocol for the GlucoTrack DF-F by the FDA, we intend to conduct clinical trials of the GlucoTrack DF-F device at one or two locations in the U.S. We have commenced negotiations for such locations.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA approval. These differences may affect the efficiency and timeliness of international market introduction of GlucoTrack DF-F. For countries in the European Union, or EU, medical devices must display a CE mark before they may be imported or sold and must comply with the requirements of the European Medical Device Directive (the "MDD") or the Active Implantable Medical Device Directive. Integrity anticipates that the GlucoTrack devices will be subject to the MDD. Compliance with the MDD and obtaining a CE Mark involve obtaining International Organization for Standardization, or ISO, 13485 certification, an internationally recognized quality system, and approval of the product's technical file by a notified body that is recognized by applicable authorities of an EU Member State.

We selected the Notified Body as the notified body for our CE Mark application. In December 2012, we submitted our technical file to the Notified Body in connection with our application to obtain CE Mark approval for the GlucoTrack DF-F model non-invasive glucose monitoring device. In March 2013 we submitted clinical evaluation data to the Notified body in further support of our CE Mark application. If the Notified Body accepts our Technical File and clinical evaluation data as satisfactory, we anticipate receiving CE Mark approval to market and sell the GlucoTrack DF-F glucose monitoring device in certain European Union countries as early as April 2014. We currently anticipate receiving the CE Mark no earlier than April of 2013 and FDA approval at least a year and a half thereafter; however, there can be no assurance that either such approval will be obtained within such time frames, or at all. We may also seek regulatory approval to market the GlucoTrack devices in foreign countries that do not rely on the CE Mark. To date, the only non-CE Mark jurisdiction which we have identified as an intended target market for our products is South Africa. Based on guidance published by the South African Ministry of Health, we do not believe that regulatory approval is required to market the GlucoTrack DF-F in South Africa. To the extent that we seek to market our devices in other non-CE Mark countries in the future, we will be required to comply with the applicable regulatory requirements in each such country. Such regulatory requirements vary by country and may be onerous. As a result, no assurance can be given that we will be able to satisfy the regulatory requirements to sell our products in any such country.

Even when a clinical study has been approved or cleared by the FDA or a notified body or deemed approved, the study is subject to factors beyond a manufacturer's control, including, but not limited to the fact that the institutional review board at a given clinical site might not approve the study, might decline to renew approval which is required annually, or might suspend or terminate the study before the study has been completed. Also, the interim results of a study may not be satisfactory, in which case the sponsor may terminate or suspend the study on its own initiative or the FDA or a notified body may terminate or suspend the study. There is no assurance that a clinical study at any given site will progress as anticipated; there may be an insufficient number of patients who qualify for the study or who agree to participate in the study, or the investigator at the site may have priorities other than the study. Also, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA or a notified body that the product is safe and effective, a prerequisite for FDA approval of a PMA, or substantially equivalent in terms of safety and effectiveness to a predicate device, a prerequisite for clearance under 510(k). Even if the FDA or a notified body approves or clears a device, it may limit its intended uses in such a way that manufacturing and distributing the device may not be commercially feasible.

After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval or require changes to a device, its manufacturing process or its labeling or additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the premarket approval application process is not permitted to make changes to the device which affect its safety or effectiveness without first submitting a supplement application to its premarket approval application and obtaining FDA approval for that supplement. In some instances, the FDA may require clinical trials to support a supplement application. A manufacturer of a device cleared through a 510(k) submission must submit another premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Any change in the intended uses of a premarket approval application device or a 510(k) device requires an approval supplement or cleared premarket notification. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

#### ***Recently Enacted Health Care Reform Legislation***

Congress recently passed health care reform legislation, known as the Patient Protection and Affordable Care Act. The President signed the measure into law on March 23, 2010 and on March 30, 2010, the President signed into law a reconciliation bill that modifies certain provisions of the same. These two laws are jointly referred to as the "Affordable Care Act" or "ACA."

The principal aim of the reform legislation as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The law's most far-reaching changes do not take effect until 2014, including a requirement that most Americans carry health insurance. The consequences of these significant coverage expansions on the sales of our products is unknown and speculative at this point, although the ACA and certain state initiatives may compel private insurers to reduce coverage or reimbursement for various items and services, including medical devices of the type that we contemplate distributing.

The enacted legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer will have to pay an excise tax (or sales tax) in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. The tax applies to all medical devices, including our products and product candidates. The ACA also provides for increased enforcement of the fraud and abuse regulations previously mentioned.

In June, 2012, the United States Supreme Court upheld most of the provisions of the Affordable Care Act. While Federal regulatory agencies are moving forward with implementation of the provisions of the Affordable Care Act, Congress is attempting to pass legislation which would reverse the Affordable Care Act. Furthermore, various health insurance reform proposals are also emerging at the state level. Due to the unsettled nature of these reforms and the numerous steps required to implement them, we cannot predict to what extent (if at all) Congress will succeed in limiting or reversing the Affordable Care Act, whether (and if so, what) additional health insurance reforms will be implemented at the federal or state level and/or the effect that any future legislation or regulation will have on our business.

On August 2, 2011, President Obama and the U.S. Congress enacted the Budget Control Act of 2011 to increase the federal government's borrowing authority (the so-called "debt ceiling") and reduce the federal government's projected operating deficit. To implement this legislation, President Obama and members of the U.S. Congress have proposed various spending cuts and tax reform initiatives, some of which could result in changes (including substantial reductions in funding) to Medicare, Medicaid or Medicare Advantage Plans. Under the agreement reached to allow the federal government to raise the debt ceiling in August, a twelve-member, bipartisan committee was given a deadline of November 23, 2011 to develop recommendations for reducing the federal budget deficit by a total of at least \$1.2 trillion over ten years. However, the committee was not able to agree on a plan and, therefore, \$1.2 trillion in automatic spending cuts, including a two-percent reduction in Medicare payments to dialysis facilities were expected to take effect on January 1, 2013. CMS has notified dialysis providers that the reductions are expected to be seen in reimbursements beginning April 1, 2013. These measures and any future federal legislation relating to the debt ceiling or deficit reduction could have a material adverse effect on us.

### ***Reimbursement***

We anticipate that sales volumes and prices of the GlucoTrack DF-F and any other products we commercialize will depend in large part on the availability of reimbursement from third-party payors. Third-party payors include governmental programs such as Medicare and Medicaid, private insurance plans and workers' compensation plans. These third-party payors may deny reimbursement for a product or therapy if they determine that the product was not medically appropriate or necessary. Also, third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payors must also approve coverage for new or innovative devices before they will reimburse health care providers who use the products. Even though a new product may have been cleared for commercial distribution, it may find limited demand for the device until reimbursement approval has been obtained from governmental and private third-party payors.

Inasmuch as a percentage of the projected patient population that could potentially benefit from the GlucoTrack DF-F is elderly, Medicare would likely be a potential source of reimbursement. Medicare is a federal program that provides certain hospital and medical insurance benefits to persons age 65 and over, certain disabled persons, persons with end-stage renal disease and those suffering from Lou Gehrig's Disease. In contrast, Medicaid is a medical assistance program jointly funded by federal and state governments and administered by each state pursuant to which benefits are available to certain indigent patients. The Medicare and Medicaid statutory framework is subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare and Medicaid.

Medicare reimburses for medical devices in a variety of ways depending on where and how the device is used. However, Medicare only provides reimbursement if CMS determines that the device should be covered and that the use of the device is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor (formerly called carriers and fiscal intermediaries) or a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS. There are new statutory provisions intended to facilitate coverage determinations for new technologies under the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, §§ 731 and 942, but it is unclear how these new provisions will be implemented. Coverage presupposes that the device has been cleared or approved by the FDA and, further, that the coverage will be no broader than the approved intended uses of the device (i.e., the device's label) as cleared or approved by the FDA, but coverage can be narrower. In that regard, a narrow Medicare coverage determination may undermine the commercial viability of a device.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for respective devices. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations. A key component in the reimbursement decision by most private insurers will be whether the GlucoTrack DF-F is reimbursed by virtue of a national coverage determination by CMS. We may negotiate contracted rates for the GlucoTrack DF-F with private insurance providers for the purchase of the GlucoTrack DF-F by their members pending a coverage determination by CMS. Our inability to obtain a favorable coverage determination for the GlucoTrack DF-F may adversely affect our ability to market the GlucoTrack DF-F and thus, the commercial viability of the product. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. Distributors expressly support the reimbursement process and, depending on the distribution agreement and geographic area, may assume responsibility for the process.



We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. Furthermore, deficit reduction and austerity measures in the United States and abroad may put further pressure on governments to limit coverage of, and reimbursement for, our products. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition. Until reimbursement or insurance coverage is established, patients will have to bear the financial cost of GlucoTrack. Third-party coverage may be particularly difficult to obtain while the GlucoTrack DF-F is not approved by the FDA as a replacement for existing single-point finger stick devices.

Until a reimbursement code is achieved, in order to reduce out of pocket expenses for users and increase the number of devices sold, we have considered potentially implementing a leasing program in the United States and Europe under which we would offer to lease devices to end users for periods of one, two or three years. The required lease payment per month is expected to be similar to the current monthly cost for invasive measurement devices, although there would be no limitation on the number of measurements a patient can perform per day. In this approach, the device will pay for itself in a shorter time.

#### ***Anti-Fraud and Abuse Rule***

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties that can materially affect us. These federal laws include, by way of example, the following:

- The anti-kickback statute (Section 1128B(b) of the Social Security Act) prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other governmental programs;
- The physician self-referral prohibition (Ethics in Patient Referral Act of 1989, as amended, commonly referred to as the Stark Law, Section 1877 of the Social Security Act), which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians (or their immediate family members) have ownership interests or with which they have certain other financial arrangements;
- The anti-inducement provisions of the Civil Monetary Penalties Law (Section 1128A(a)(5) of the Social Security Act), which prohibit providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program;

- The False Claims Act (31 U.S.C. § 3729 et seq.), which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment to the federal government (including the Medicare and Medicaid programs); and
- The Civil Monetary Penalties Law (Section 1128A of the Social Security Act), which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment and/or denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from the Medicare and other government programs.

Many states have adopted or are considering legislative proposals similar to the federal fraud and abuse laws, some of which extend beyond the Medicare and Medicaid programs, to prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted or are considering legislative proposals to increase patient protections, such as limiting the use and disclosure of patient specific health information. These state laws also impose criminal and civil penalties similar to the federal laws.

In the ordinary course of their business, medical device manufacturers and suppliers have been and are subject regularly to inquiries, investigations and audits by federal and state agencies that oversee these laws and regulations. Recent federal and state legislation has greatly increased funding for investigations and enforcement actions, which have increased dramatically over the past several years. This trend is expected to continue. Private enforcement of healthcare fraud also has increased due in large part to amendments to the civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. These whistleblower suits by private persons, known as qui tam relators, may be filed by almost anyone, including present and former patients or nurses and other employees, as well as competitors. HIPAA, in addition to its privacy provisions, created a series of new healthcare-related crimes.

As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on a supplier's liquidity and financial condition. An investigation into the use of a device by physicians may dissuade physicians from recommending that their patients use the device. This could have a material adverse effect on our ability to commercialize the GlucoTrack DF-F.

### ***The Privacy Provisions of HIPAA***

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates “covered entities,” such as healthcare providers, insurers and clearinghouses, and regulates “business associates,” with respect to the privacy of patients’ medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA and, owing to changes in the law, it is uncertain, based on our current business model, whether we would be a business associate. Nevertheless, we will likely be contractually required to physically safeguard the integrity and security of any patient information that we receive, store, create or transmit. If we fail to adhere to our contractual commitments, then our physician, hospital or insurance customers may be subject to civil monetary penalties, which could adversely affect our ability to market our devices. Recent changes in the law wrought by the HITECH Act provisions of the American Recovery and Reinvestment Act of 2009 increase the duties of business associates and covered entities with respect to protected health information that thereby subject them to direct government regulation, increasing its compliance costs and exposure to civil monetary penalties and other government sanctions. While the new law does not alter the definition of a business associate, it makes it more likely that covered entities with whom we are likely to do business will require us to enter into business associate agreements.

### **Intellectual Property**

We believe that intellectual property is important to our business and to the medical device industry overall. We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our intellectual property and proprietary rights.

We understand the importance of obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in large part on our ability to file for and obtain patent protection of our principal products and procedures, to defend existing or future patents, to maintain trade secrets and to operate without infringing upon the proprietary rights of others.

We have obtained an issued patent for “A Method of Monitoring Glucose Level” in the United States, Europe, Australia, Canada, China, India, Israel, Japan, Mexico, the Philippines, Russia, South Africa and South Korea. This patent expires in 2024 in the United States and 2023 or 2024 in most other jurisdictions. One additional patent application is awaiting examination in Brazil.

We have also obtained an issued patent in the United States for an invention entitled “Device For Non-Invasively Measuring Glucose.” The issued United States patent expires in April 2031.

During 2011 and 2012, we filed additional patent applications in the U.S. Europe, Australia, Brazil, Canada, Chile, China, India, Israel, Japan, Russia, South Africa, South Korea and Taiwan, and covering the technologies related to the GlucoTrack® measurement process, as well as the combination of the three technologies used in the GlucoTrack® device.

Regarding the Personal Ear Clip and its structure, we have filed a utility patent application and a design application in Israel. We are in the process of preparing and filing additional design applications in the US, Europe, China and elsewhere. In due course US and PCT utility patent applications will be filed, based on the Israeli application, and then National Stage applications in the key countries.

We have obtained trademark registrations for GlucoTrack in the United States, Europe and fifteen other countries, including Australia, Brazil, Chile, China, India, Indonesia, Israel, Japan, Mexico, New Zealand, Russia, South Africa, South Korea, Taiwan and Turkey, and have trademark applications pending for GlucoTrack in Canada and Venezuela.

An additional application is pending in the US to register the trademark "JUST CLIP IT!"

Patent protection is highly uncertain and involves complex legal and factual questions and issues. The patent application and issuance process can be expected to take several years and entail considerable expense. There can be no assurance that patents will issue as a result of any applications or that any patents resulting from such applications or our existing patents will be sufficiently broad to afford protection against competitors with similar or competing technology. Patents that we obtain may be challenged, invalidated or circumvented, or the rights granted under such patents may not provide us with any competitive advantages.

We believe that our patents and products do not and will not infringe patents or violate proprietary rights of others, although it is possible that our existing patent rights may not be valid or that infringement of existing or future patents or proprietary rights may occur. Litigation may be necessary to defend or enforce our patent rights or to determine the scope and validity of the proprietary rights of others. Defense and enforcement of patent claims can be expensive and time consuming, even in those instances in which the outcome is favorable, and could result in the diversion of substantial resources and management time and attention from our other activities. An adverse outcome could subject us to significant liability to third parties, require us to obtain licenses from third parties, alter our products or processes, or require that we cease altogether any related research and development activities or product sales.

### **Competition**

The market for blood glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions. Four companies, Roche Diagnostics, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, currently account for substantially all of the worldwide sales of self-monitored glucose testing systems. These competitors' products use a meter and disposable test strips to test blood obtained by pricking the finger or, in some cases, the palm or forearm.

In addition, other companies are developing or marketing minimally invasive or noninvasive glucose testing devices and technologies that could compete with our devices. There are also a number of academic and other institutions involved in various phases of technology development regarding blood glucose monitoring devices. We believe that the majority of noninvasive blood glucose monitors in development require frequent calibrations (from a few hours to a few days, compared to GlucoTrack, which is expected to require recalibration on a monthly basis initially and perhaps less frequently as the device is used). Among the companies developing noninvasive glucose testing devices are Echo Therapeutics, Inc., GlucoLight, C8 MediSensors (which recently received CE Mark approval but has not announced any completed sales at this time) and Grove Instruments. Cygnus, a company subsequently acquired by Johnson & Johnson, obtained FDA approval and a CE Mark in 2001 for a noninvasive trend analysis device that was marketed under the name GlucoWatch Biograpgher, however, the device is no longer commercially available. Other companies developing continuous measurement devices, based on minimally invasive methods, such as implants or subdermal needles include Medtronic, Inc., Abbot Laboratories and Dexcom, Inc.

Some of our competitors are either publicly traded or are divisions of publicly-traded companies, and they enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

Some of our other competitors also enjoy these competitive advantages. As a result, we cannot assure that we will be able to compete effectively against these companies or their products.

To our knowledge, a summary of potential competitors with non-invasive products in development is set forth below:

**Figure D**

	<u>Company</u>	<u>Product</u>	<u>Technology</u>	<u>Calibration</u>	<u>Type of Measurement</u>	<u>Technology Description</u>
1.	Echo Therapeutics (MA, USA)	Symphony	UltraSound	Daily calibration	Continuous	Needle-free skin permeation and non-invasive, continuous transdermal glucose biosensor (device attached to skin).
2.	Freedom Meditech (MA, USA)		Optical Polarimetry (in front of the eye)		Spot; Screening	Non-invasive direct measurement of glucose levels in front of the eye via optical polarimetry.
3.	C-8 MediSensors (CA, USA)	HG1-c	Raman spectroscopy	"No calibration"	Continuous	Through a device strapped to a patient's abdomen by a wide belt, continuously measures glucose levels by measuring the "Raman" effect of the permeation of light through glucose cells in the body.
4.	GlucoLight (PA, USA)		Optical Coherence Tomography (OCT)		Continuous	Hospital-based monitor monitors blood glucose level using Optical Coherence Tomography, a form of imaging technology which uses a disposable patch affixed to the patient's skin to measure the presence of glucose.
5.	Grove Instruments (MA, USA)	GI-200	Optical Bridge		Spot	Optical bridge uses 3 diode lasers in the NIR spectrum and one in the visible spectrum to measure glucose.
6.	AiMedics (Australia)	HypoMon	Skin Bio-Sensors		Continuous	Uses skin sensors strapped to a patient's chest to continuously measure the patient's glucose levels as they sleep. Used for Type 1 patients aged 10 to 25 years.
7.	Cybiocare (Quebec, Canada)	OHD	Optical		Continuous	Through a device strapped to a patient's arm, continuously measures glucose levels by using infrared light to detect hypoglycemia in the patient.

**Employees**

As of December 31, 2012, we had nineteen full-time employees and thirteen part-time employees. None of our employees are represented by a collective bargaining agreement.

## Item 1A. Risk Factors.

*An investment in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the following risk factors. If any of these risks actually occur, our business, financial condition and results of operations could be materially harmed. In addition, risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, financial condition and results of operations. If this were to happen, the value of our common stock could decline significantly and you could lose all or part of your investment.*

***A former stockholder of Integrity Israel who is entitled to receive shares in our company, subject to the fulfillment of certain requirements, has challenged our and Integrity Israel's position that certain rights he had in Integrity Israel terminated upon the Reorganization.***

Integrity Israel is party to a loan and investment agreement with Dimri, pursuant to which Dimri loaned Integrity Israel a principal amount of New Israeli Shekel ("NIS") 1,440,000, subject to linkage differences in Israel (\$385,748 based on an exchange rate of 3.733 NIS/dollar in effect on December 31, 2012). In connection with such loan, Dimri received shares of common stock representing 25% of Integrity Israel's ordinary shares at such time. Under the Dimri agreement, certain rights in Integrity Israel were granted to Dimri, including an anti-dilution provision that provided that Dimri's holdings in Integrity Israel would not be diluted below 18% of Integrity Israel's issued capital shares as a result of any investment in Integrity Israel, subject to the fulfillment of certain requirements. On the date of the Reorganization, Dimri owned 18% of Integrity Israel's ordinary shares and, therefore, upon the completion of the Reorganization, Dimri was entitled to receive 18% of the shares of common stock of the Company outstanding on such date in exchange for his shares in Integrity Israel, subject to the fulfillment of certain requirements. We believe, based on the advice of Israeli counsel, that, given Dimri no longer owns shares in Integrity Israel as a result of the Reorganization, rights attached to the shares in Integrity Israel no longer exist in Integrity Israel and do not and have never existed in us. However, Dimri has refused to acknowledge or agree to the termination of these rights and has challenged our position. On June 23, 2011, Dimri appealed to the District Court of HaMerkaz District in Petah Tikva, Israel, requesting the court to appoint an arbitrator to decide the dispute between Integrity Israel, the founders of Integrity Israel and Dimri (HPB 40754-06-11). On December 26, 2011, an arbitrator was appointed in this matter. On March 20, 2012, Dimri submitted a statement of claim to the arbitrator and pled for a declaratory judgment against Integrity Israel and the Founders of Integrity Israel. Dimri claimed that its rights under the loan and investment agreement, Integrity Israel's Articles of Association and two other internal agreements entered into among the Founders of Integrity Israel are valid and in effect. Dimri also pled for an injunction requiring the founders of Integrity Israel to transfer shares of our Common Stock held by them to Dimri, from time to time, in such amounts necessary so that Dimri's holdings in us would not be diluted below 18% of our issued share capital at any time. The defendants in the arbitration submitted a statement of defense on May 28, 2012 and Dimri submitted a reply on June 14, 2012. At a preliminary session held on June 19, 2012, the arbitrator suggested that the parties meet with him in order to examine whether a settlement can be reached. A meeting for this purpose had been set for August 27, 2012 but has been postponed by the arbitrator. After several postponements, Dimri submitted its affidavits on October 16, 2012. The defendants submitted their affidavits on February 7, 2013. Testimony and summary hearings have been set for June 2013.

As a condition to the Previous Private Placement, our founders, Avner Gal, Zvi Cohen, David Malka, Ilana Freger and Alex Reikhman, entered into an Irrevocable Undertaking of Indemnification with us pursuant to which, among other things, the founders agreed to indemnify us and hold us harmless from any adverse consequences (excluding the fees and costs of defending us) that result from Dimri's, or Dimri's successors' or assigns', enforcement of the anti-dilution rights granted to Dimri as described above. The founders' obligations under the Irrevocable Undertaking of Indemnification only obligate each founder to transfer up to such number of shares of our common stock that he or she owned as of the date of the Reorganization to Dimri or to us. The term of the Irrevocable Undertaking of Indemnification is three years (subject to extension if there is a pending action), provided that, after two years, any founder may sell or transfer up to twenty percent (20%) of his or her shares of common stock covered by the Irrevocable Undertaking of Indemnification so long as no action is pending by Dimri against us at the time of such sale and the sale price of the common stock is at least \$6.25 per share. No assurances can be made that the Irrevocable Undertaking of Indemnification will fully protect us or our stockholders from any adverse consequences of an action by Dimri to enforce its anti-dilution rights. In addition, Dimri may assert other rights that it had under the Investment Agreement, for which we are not indemnified.

Notwithstanding the indemnification by our founders, any such challenge by Dimri, or any other legal action, if any, brought by Dimri against us, Integrity Israel and/or the founders, could have a material adverse effect on us and our stockholders, including (i) significant costs and expenses that may be incurred in connection with any action, suit or other proceeding, (ii) potential dilution of the interests of our other stockholders if Dimri is successful in such challenge and the founders exhaust all of their shares in satisfaction of their indemnification obligations, resulting in an obligation of the Company to issue additional shares to Dimri, (iii) the impact that the loss of shares of common stock owned by Messrs. Gal and Malka, who are key employees of ours, as a result of their indemnification obligation would have on their commitment to us given the loss of a portion of their economic interests in us and (iv) if a court were to order Integrity Israel to issue shares to Dimri as part of a successful challenge, we would not wholly own Integrity Israel.

***We have a history of operating losses and do not expect to generate revenues or become profitable in the near future.***

We are a pre-clinical stage medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. We do not anticipate that we will generate revenue from the sale of products until at least early 2014. Our initial product, the GlucoTrack DF-F, has not been approved for marketing in the United States, the European Union or any other jurisdiction and may not be sold or marketed without FDA clearance or approval in the United States, the receipt of a CE Mark in the European Union or the receipt of regulatory approval in accordance with the applicable requirements of any other jurisdiction. We continue to incur research and development and general and administrative expenses related to our operations and the development of our first product. Our net losses for the years ended December 31, 2012 and 2011 were approximately \$2.8 million and \$2.4 million, respectively, and we had an accumulated deficit of approximately \$15.3 million as of December 31, 2012. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we prepare for and begin to commercialize the GlucoTrack DF-F, if it is approved. If the GlucoTrack DF-F and possibly other products fail in clinical trials or do not gain regulatory clearance or approval, or if the GlucoTrack DF-F does not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.



***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

Our independent registered public accounting firm noted in its report accompanying our financial statements for the fiscal year ended December 31, 2012 that we had suffered significant losses during the development stage, had a negative operating cash flow since inception and that the development and commercialization of our product is expected to require substantial expenditures. We have not yet generated any revenues from our operations to fund our activities, 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. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. Management's plans concerning these matters are described in Note 1B to our financial statements; however management cannot assure you that its plans will be successful in addressing these issues. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in our common stock.

***We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.***

Our cash on hand was approximately \$5.3 million as of March 13, 2013. 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 approximately 23 months from the date of this report. In order to fund our anticipated liquidity needs beyond such 23 month 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 may need to raise additional capital. Our future funding requirements will depend on many factors, including but not limited to:

- our need to expand research and development activities;
- the need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- the need to implement additional internal systems and infrastructure, including financial and reporting systems;

- the rate of progress and cost of our clinical trials;
- the costs associated with establishing commercialization capabilities, including a sales force if we distribute our product other than through distributors;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals; and
- the ability to maintain, expand and defend the scope of our intellectual property portfolio.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, or at all, we may have to delay, reduce the scope of or eliminate clinical trials or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. In addition to the dilution normally attendant to an equity offering, holders of our shares of common stock may experience additional dilution as a result of the anti-dilution provisions of the Preferred Stock. See “Item 5. Market for Registrant’s Common Equity, Related Stockholder Matter and Issuer Purchases of Equity Securities - Recent Sale of Unregistered Securities” on page 54 below.

*The agreements governing our outstanding preferred stock contain various covenants that limit our ability to take certain actions and our failure to comply with any of the covenants would have a material adverse effect on our business, financial condition and results of operations.*

The agreements governing our outstanding Preferred Stock contain a number of significant covenants that, among other things, limit our ability to incur indebtedness or liens, and repay, repurchase, pay dividends on or otherwise make distributions in respect of any shares of Common Stock or other securities junior to the Preferred Stock. Unless we receive a consent or a waiver from the holders of our Preferred Stock, these covenants may restrict our ability to take certain actions that we would have otherwise taken in the absence of these covenants and which may be in the best interests of Integrity and its shareholders. There can be no assurance that we will be able to receive a consent or waiver on acceptable terms, if at all. If we fail to comply with these covenants, we will be in default of the agreements governing our outstanding Preferred Stock, which would have a material adverse effect on our business, financial condition and results of operations.

***The recent worldwide economic crisis and market instability may materially and adversely affect the demand for our products, if and when approved, as well as our ability to obtain credit or secure funds through sales of our stock, which may materially and adversely affect our business, financial condition and ability to fund our operations.***

The recent worldwide economic crisis may reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our products, if and when they are approved. Such a delay could have a material adverse impact on our business, expected cash flows, results of operations and financial condition. Additionally, we have funded our operations to date primarily through private sales of securities, including common stock and other securities convertible into or exercisable for shares of our common stock. The recent economic turmoil and instability in the world's equity and credit markets may materially adversely affect our ability to sell additional securities and/or borrow cash. There can be no assurance that we will be able to raise additional working capital on acceptable terms or at all, and any failure to do so may materially adversely affect our ability to continue operations.

***Healthcare reforms, changes in healthcare policies, including recently enacted legislation reforming the U.S. healthcare system, and changes to third-party reimbursements for diabetes-related products may affect demand for our products and have a material adverse effect on our financial condition and results of operations.***

The United States government has in the past considered and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as the GlucoTrack DF-F. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures.

Congress passed health care reform legislation that the President signed into law on March 23, 2010 and March 30, 2010. The package signed into law is considered by some to be the most dramatic change to the country's health care system in decades. The principal aim of the law currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The law's most far-reaching changes do not take effect until 2014, including a requirement that most Americans carry health insurance. The consequences of these significant coverage expansions on the sale of our products is unknown and speculative at this point.

The enacted legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers like us. The legislation imposes an annual excise tax (or sales tax) on medical devices like ours, beginning with calendar year 2013. The taxes would be allocated based on our proportionate share of the prior-year's aggregate domestic gross receipts from medical device sales.

In addition to the new legislation discussed above, the effect of which cannot presently be quantified given its recent enactment, various healthcare reform proposals have also emerged at the state level. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for the GlucoTrack DF-F or other GlucoTrack products, if approved for sale, or our future products, if any. These include changes that may lower reimbursement rates for such products from what we might otherwise have obtained and changes that may be proposed or implemented by the current administration or Congress.

We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. In addition to the taxes imposed by the new federal legislation, any further expansion in government's role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and materially adversely affect our business, financial condition and results of operations.

***Our product research and development activities may not result in commercially viable products.***

Our current product candidate, the GlucoTrack DF-F, is in the early stages of development and, therefore, is prone to the risks of failure inherent in medical device product development. We will likely be required to undertake significant clinical trials to demonstrate to the FDA that the GlucoTrack DF-F is either safe and effective for its intended use or is substantially equivalent in terms of safety and effectiveness to an existing, lawfully marketed non-Section 515 premarket approval device. We may also be required to undertake clinical trials by non-U.S. regulatory agencies. Clinical trials are expensive and uncertain processes that may take years to complete. Failure can occur at any point in the process and early positive results do not ensure that the entire clinical trial will be successful. Product candidates in clinical trials may fail to show desired efficacy and safety traits despite early promising results. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after their product candidates demonstrated promising results at earlier points.

***The results of our limited pre-clinical trials and safety and performance clinical trial may not be indicative of future results, and our planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.***

Positive results from the limited pre-clinical trials and safety and performance clinical trial that we have conducted should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. These trials involved limited patient populations and there is no assurance that the experimental protocol or protocols, as the case may be, used in these informal trials will be methodologically similar to ones submitted to the FDA or any other regulatory body for its approval. Because of the sample size, possible variation in methodology, differences in exclusion/inclusion criteria, or differences in endpoints, the results of these pre-clinical trials may not be indicative of future results. We will likely be required to demonstrate through well-controlled clinical trials that the GlucoTrack DF-F or future product candidates, if any, are safe and effective for their intended uses. In the event that the FDA deems GlucoTrack DF-F to be a class II device, which we do not believe is likely at this point, then we would be required to demonstrate that it is substantially equivalent in terms of safety and effectiveness to a device lawfully marketed either through a premarket notification or prior to May 28, 1976.

Further, the GlucoTrack DF-F or our future product candidates, if any, may not be cleared or approved, as the case may be, even if the clinical data are satisfactory and support, in our view, its or their clearance or approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design or interpretation of the clinical data. In addition, any of these regulatory authorities may change requirements for the clearance or approval of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA approval. In addition, any of these regulatory authorities may also clear or approve a product candidate for fewer or more limited uses than we request or may grant clearance or approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-U.S. regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of the GlucoTrack DF-F or our future product candidates, if any.

***We are highly dependent on the success of our initial product candidate, the GlucoTrack DF-F, and cannot give any assurance that it will receive regulatory approval or clearance or be successfully commercialized.***

We are highly dependent on the success of our initial product candidate, the GlucoTrack DF-F. We cannot give any assurance that the FDA will permit us to clinically test the device, nor can we give any assurance that the clinical trials will be successful or that the GlucoTrack DF-F will receive regulatory clearance or approval or be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically-effective or cost-effective alternatives, failure in our sales and marketing efforts, or the failure to obtain positive coverage determinations or reimbursement. Any failure to obtain approval to conduct clinical trials, favorable clinical data, clearance or approval of or to successfully commercialize the GlucoTrack DF-F would have a material adverse effect on our business.

***If our competitors develop and market products that are more effective, safer or less expensive than GlucoTrack DF-F or our future product candidates, if any, our commercial opportunities will be adversely affected.***

The life sciences industry is highly competitive and we face significant competition from many medical device companies that are researching and marketing products designed to address the needs of persons suffering from diabetes. We are currently developing medical devices that will compete with other medical devices that currently exist or are being developed. Products that we may develop in the future are also likely to face competition from other medical devices and therapies. Some of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical device companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than us. Some of the medical device companies that we expect to compete with include Roche Diagnostics, a division of Roche; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; Bayer Corporation; Echo Therapeutics, Inc.; GlucoLight; C8 MediSensors, Grove Instruments; and Medtronic, Inc. In addition, many other universities and private and public research institutions are or may become active in research involving blood glucose measurement devices.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety, performance and reliability of our product candidates;
- the speed at which we develop product candidates;
- our ability to obtain prompt and favorable IRB review and approval at each of our clinical sites;
- our ability to commercialize and market any of our product candidates that may receive regulatory clearance or approval;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory clearances or approvals;
- appropriate coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to have partners manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than GlucoTrack DF-F or our future product candidates, if any, or that reach the market sooner than GlucoTrack DF-F or our future product candidates, if any, we may not achieve commercial success. In addition, the medical device industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive.

***Our product development activities could be delayed or stopped.***

We do not know whether our future clinical trials will begin on time, or at all, and whether ongoing and/or future clinical trials will be completed on schedule, or at all.

The commencement of future clinical trials could be substantially delayed or prevented by several factors, including:

- the failure to obtain sufficient funding to pay for all necessary clinical trials;

- limited number of, and competition for, suitable patients that meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- limited number of, and competition for, suitable sites to conduct the clinical trials, and delay or failure to obtain FDA approval, if necessary, to commence a clinical trial;
- delay or failure to obtain sufficient supplies of the product candidate for clinical trials;
- requirements to provide the medical device required in clinical trials at cost, which may require significant expenditures that we are unable or unwilling to make;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board approval or renewal of such approval to conduct a clinical trial at a prospective or accruing site, respectively.

The completion of clinical trials in connection with our application for FDA approval could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the institutional review board for any given site, or us. Any failure or significant delay in completing clinical trials for GlucoTrack or future product candidates, if any, could materially harm our financial results and the commercial prospects for our product candidates.

*The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of GlucoTrack DF-F or our future product candidates, if any.*

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive a clearance letter under the 510(k) premarket notification process or approval of a Section 515 premarket approval, from the FDA, depending on the nature of the device. We have not submitted an application or premarket notification for or received marketing clearance or approval for any of our product candidates. Obtaining approval of any premarket approval can be a lengthy, expensive and uncertain process. While the FDA normally reviews and clears a premarket notification in three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance that, even if a device is reviewed under the 510(k) premarket notification process, the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-premarket approval device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. In addition, failure to comply with FDA, non-U.S. regulatory authorities or other applicable U.S. and non-U.S. regulatory requirements may, either before or after product clearance or approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters or non-warning letters incorporating inspectional observations, i.e., so-called “untitled letter”;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory clearances or approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.



Regulatory approval of a premarket approval application, premarket approval application supplement or clearance pursuant to a 510(k) premarket notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive and may, especially in the case of the premarket approval application, take several years. The FDA also has substantial discretion in the medical device clearance or approval processes. Despite the time and expense exerted, failure can occur at any stage and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA clearance or approval varies depending on the medical device candidate, the disease or condition that the medical device candidate is designed to address, and the regulations applicable to any particular medical device candidate. The FDA can delay, limit or deny clearance or approval of a medical device candidate for many reasons, including:

- a medical device candidate may not be deemed safe or effective, in the case of a premarket approval application;
- a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed non-premarket approval device in the case of a 510(k) premarket notification;
- FDA officials may not find the data from the clinical trials sufficient;
- the FDA might not approve our third-party manufacturer's processes or facilities; or
- the FDA may change its clearance or approval policies or adopt new regulations.

***Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.***

We may encounter delays if we are unable to recruit and enroll and retain enough patients to complete clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Delays in patient enrollment are not unusual. Any such delays in planned patient enrollment may result in increased costs, which could harm our ability to develop products.

***Even if we obtain regulatory clearances or approvals for the GlucoTrack DF-F or our future product candidates, if any, the terms of clearances or approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.***

Once regulatory clearance or approval has been granted, the cleared or approved product and its manufacturer are subject to continual review. Any cleared or approved product may only be promoted for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities clear or approve GlucoTrack DF-F or our future product candidates, if any, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We, and the manufacturers of our products, if other than us, also will be required to comply with the FDA's Quality System Regulation, which includes requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which are publicly available. Further, regulatory agencies must approve our manufacturing facilities before they can be used to manufacture products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;

- adverse inspectional observations (Form 483), warning letters, or non-warning letters incorporating inspectional observations;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory clearances or approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.

In addition, the FDA and other non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we will likely not be permitted to market future product candidates and may not achieve or sustain profitability.

***Even if we receive regulatory clearance or approval to market the GlucoTrack DF-F or our future product candidates, if any, the market may not be receptive to our products.***

Even if GlucoTrack DF-F or our future product candidates, if any, obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- safety and efficacy of our product;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our product candidates, both in absolute terms and relative to alternative treatments; and
- availability of coverage and reimbursement from government and other third-party payors.

***If the GlucoTrack DF-F or our future product candidates, if any, fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.***

The coverage and reimbursement status of newly cleared or approved medical devices is uncertain, and failure to obtain adequate coverage and adequate reimbursement could limit our ability to market GlucoTrack DF-F or future product candidates, if any, and may inhibit our ability to generate revenue from GlucoTrack DF-F or our future product candidates, if any, that may be cleared or approved.

There is significant uncertainty related to the third-party coverage and reimbursement of newly cleared or approved medical devices. The commercial success of GlucoTrack DF-F or our future product candidates, if any, in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for GlucoTrack DF-F or our future product candidates, if any. These payors may conclude that our products are not as safe or effective as existing devices or that the overall cost of using one of our devices exceeds the overall cost of the competing device, and third-party payors may not approve GlucoTrack DF-F or our future product candidates, if any, for coverage and adequate reimbursement. Furthermore, deficit reduction and austerity measures in the United States and abroad may put further pressure on governments to limit coverage of, and reimbursement for, our products. The failure to obtain coverage and adequate reimbursement for GlucoTrack DF-F or our future product candidates, if any, or health care cost containment initiatives that limit or restrict reimbursement for such products may reduce any future product revenue.

***If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize GlucoTrack DF-F or our future product candidates, if any.***

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for GlucoTrack DF-F or our future product candidates, if any. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our senior management, particularly Avner Gal, could delay or prevent the development or commercialization of GlucoTrack DF-F or our future product candidates, if any. At present we maintain key man insurance on Mr. Gal, but do not have key man insurance policies with respect to any of our other employees. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing function. Although we currently have employment agreements with each of Messrs. Bar-Shalom, Gal and Malka, those agreements provide that they may be terminated by Mr. Bar Shalom, Gal or Malka, as applicable, upon 60, 180 or 90 days written notice to us, respectively.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among medical device and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

*If and when we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.*

As we advance the GlucoTrack DF-F or our future product candidates, if any, through research and development, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. We anticipate that, as our operations expand, we will need to manage additional relationships with such third parties. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

*We likely will rely on third parties to manufacture and supply our product candidates.*

We do not own or operate manufacturing facilities for clinical or commercial production of the GlucoTrack DF-F, other than a prototype lab. We have no experience in medical device manufacturing, and lack the resources and the capability to manufacture the GlucoTrack DF-F on a commercial scale. If our future manufacturing partners are unable to produce our products in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require. We expect to depend on third-party contract manufacturers for the foreseeable future.

The GlucoTrack DF-F does, and our future product candidates, if any, likely will require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and other non-U.S. regulatory authorities to ensure strict compliance with quality system regulations, including current good manufacturing practices and other applicable government regulations and corresponding standards. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with quality system regulations, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our future product candidates, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third-party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our product candidates. Such approval would require additional non-clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

***We currently have no marketing staff and no sales or distribution organization. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales or distribution capabilities. If our product candidates are approved, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to GlucoTrack DF-F or our future product candidates, if any, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize the GlucoTrack DF-F or our future product candidates, if any. If we are not successful in commercializing the GlucoTrack DF-F or our future product candidates, if any, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.***

We will depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the clinical trials, or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations could adversely affect the clinical development of our product candidates and harm our business.

***If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.***

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize proposed products. For this and other reasons, we may be unable to secure desired patent rights, thereby losing desired exclusivity. Although we do not believe that we need any licenses for the GlucoTrack DF-F, we may need to obtain licenses in the future for other products or in certain circumstances, such as if one of our patents were declared invalid in the future. If such licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we successfully challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. The process of obtaining patent protection is expensive and time-consuming. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or which we may obtain in the future, may be challenged, invalidated, unenforceable or circumvented. Moreover, the United States Patent and Trademark Office may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvention of our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by medical device companies.

Our pending patent applications may not result in issued patents. The patent position of medical device companies, including us, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications or those we may file in the future.

We cannot assure you that any patents that will issue, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own may not adequately protect our product candidates or our future products.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

***Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit potential revenue opportunities.***

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third-party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available on commercially reasonable terms, if at all. If licenses are not available on acceptable terms, we will not be able to market the affected products or conduct the desired activities unless we successfully challenge the validity, enforceability or infringement of the third-party patent or circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

***If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.***

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third-party may claim that we have improperly obtained or used our confidential or proprietary information. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain operations.



***Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.***

We intend to market our product candidates in non-U.S. markets. In order to market product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. In December 2012, we submitted our technical file to the Notified Body in connection with our application to obtain CE Mark approval for the GlucoTrack® DF-F model non-invasive glucose monitoring device. In March 2013 we submitted clinical evaluation data to the Notified body in further support of our CE Mark application. If the Notified Body accepts our technical file and clinical evaluation data as satisfactory, we anticipate receiving CE Mark approval to market and sell the GlucoTrack DF-F glucose monitoring device in certain European Union countries as early as April of 2013. However, there can be no assurance that the Notified Body will find our technical file and/or clinical data acceptable and will approve the issuance of a CE Mark for the GlucoTrack DF-F or at all. Receipt of the CE Mark would allow us to market and sell the GlucoTrack DF-F in EU member countries that have adopted the Medical Devices Directive (93/42/EEC and 2007/47/EC) without being subject to additional national regulations with regard to demonstration of performance and safety. However, certain EU member countries may request or require that we provide additional performance and/or safety data from time to time, on a case-by-case basis, in order to be cleared to market and sale the GlucoTrack DF-F in such countries. Receipt of FDA approval does not ensure approval by regulatory authorities in countries, and approval by one or more non-U.S. regulatory authorities (including receipt of the CE Mark) does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market

***Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.***

We intend to seek approval to market GlucoTrack DF-F and our future product candidates, if any, in both the U.S. and in non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our products. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing may be subject to governmental control under certain circumstances. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations, which could harm our business.***

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws; and
- difficulties associated with staffing and managing foreign operations, including differing labor relations.

***Conditions in Israel may harm our ability to produce and sell our products and may adversely affect our business.***

Our principal executive offices and research and development facilities, as well as some of our suppliers, are located in Israel. Political, economic and military conditions in Israel directly affect our operations. Specifically, we could be materially adversely affected by:

- any major hostilities involving Israel;
- a full or partial mobilization of the reserve forces of the Israeli army;
- the interruption or curtailment of trade between Israel and its present trading partners; and
- a significant downturn in the economic or financial conditions in Israel.

Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighbors. A state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite the progress towards peace between Israel and its neighbors, the future of these peace efforts remains uncertain. Since October 2000, there has been a substantial deterioration in the relationship between Israel and the Palestinian Authority and a significant increase in violence, civil unrest and hostility, including armed clashes between the State of Israel and Palestinian militants, and acts of terror have been committed inside Israel and against Israeli targets in the West Bank and Gaza Strip. Since December 2010, there has been a wave of protests and civil resistance demonstrations in several countries in the Middle East and North Africa, including Egypt and Syria, which share a border with Israel. The demonstrations and acts of civil resistance in Egypt led to the resignation of the former Egyptian president Hosni Mubarak and to extensive revisions in the Egyptian governmental structure. The demonstrations and acts of civil resistance in Syria have led to an extended period of violence and political instability in Syria. It is not clear how this revolutionary wave, also known as the Arab Spring, will develop and how it will affect the political and security situation in the Middle East. It is also not clear how it will affect Israel and its relationship with its Arab neighbors. Presently, there is great international concern in connection with Iran's efforts to develop and enrich uranium which could lead to the development of nuclear weapons. Iran's successful enrichment of uranium could significantly alter the geopolitical landscape in the Middle East, including the threat of international war, which could significantly impact business conditions in Israel. Any on-going or future violence between Israel and the Palestinians, armed conflicts, terrorist activities, tension along the Israeli borders or with other countries in the region, including Iran, or political instability in the region could disrupt international trading activities in Israel and may materially and negatively affect our business and results of operations.

In addition, Israel's economy has been subject to numerous destabilizing factors, including a period of rampant inflation in the early to middle 1980s, low foreign exchange reserves, fluctuations in world commodity prices, military conflicts and civil unrest. Furthermore, several countries restrict business with Israel and Israeli companies, which may limit our ability to make sales in those countries. These restrictions, continuing or escalating hostilities in the region or curtailment of trade between Israel and its present trading partners may have an adverse affect on our operating results and financial condition, including our ability to develop, manufacture and market our products.

***Our operations could be disrupted as a result of the obligations of key personnel to perform Israeli military service.***

Some of our executive officers and employees in Israel are obligated to perform at least 30 days, and up to 40 days, depending on rank and position, of military reserve duty annually and are subject to being called for active duty under emergency circumstances. Moreover, in light of escalating hostilities and threats of armed conflict in the Middle East since October 2000, our executive officers and employees may be called for active military duty for an unlimited period of time. Increased military activity could also result in a reduction of prospective qualified employees available to work for us to increase our business or replace employees on active military duty. Our operations could be disrupted by the absence for a significant period of our executive officers or key employees as a result of military service. Any disruption in our operations could adversely affect our ability to develop and market products.

***It may be difficult to enforce a United States judgment against us or our officers and directors to the extent they are located in Israel based upon asserted United States securities law claims.***

Most of our executive officers and directors are non-residents of the United States and a substantial portion of our assets and the assets of these persons will be located outside of the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a United States court judgment, including a judgment based upon the civil liability provisions of the Securities Act and the Exchange Act, in original actions instituted in an Israeli court against any of these persons. Furthermore, service of process upon these persons may be difficult to obtain within the United States.

***We may not be able to enforce covenants not-to-compete under current Israeli law, which might result in added competition for our products.***

We have non-competition agreements or provisions with all of our employees and executive officers, all of which are governed by Israeli law. These agreements or provisions prohibit our employees from competing with us or working for our competitors, generally during, and for up to 9 months after termination of, their employment with us. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for only relatively brief periods of time or in restricted geographical areas. In addition, Israeli courts typically require the presence of additional circumstances, such as a demonstration of an employer's legitimate interest which was damaged; breach of fiduciary duties, loyalty and acting not in good faith; a payment of a special consideration for employee's non compete obligation; material concern for disclosing employer's trade secrets; or a demonstration that an employee has unique value to the employer specific to that employer's business, before enforcing a non-competition undertaking against such employee.

***The funding that we received through the Office of the Chief Scientist (the "OCS") for research and development activities restricts our ability to manufacture products or to transfer technology outside of Israel.***

On March 4, 2004, the OCS agreed to provide us with a grant of 420,000 New Israeli Shekels, or approximately \$93,462 at an exchange rate of 4.4938 NIS/dollar (the exchange rate in effect on such date), for our plan to develop a non-invasive blood glucose monitor (the "development plan"). This grant constituted 60% of our research and development budget for the development plan. Due to our acceptance of this grant, we are subject to the provisions of the Israeli Law for the Encouragement of Industrial Research and Development, 1984 (the "R&D Law"). Among other things, the R&D Law restricts our ability to sell or transfer rights in technology or know-how developed with OCS funding or transfer any Means of Control (as defined in the R&D Law) of us to non-Israeli entities. The Industrial Research and Development Committee at the OCS (the "research committee") may, under special circumstances, approve the transfer outside of Israel of rights in technology or know-how developed with OCS funding subject to certain conditions, including the condition that certain payments be made to the OCS. Additionally, we may not manufacture products developed with OCS funding outside of Israel without the approval of the research committee. The restrictions regarding the sale or transfer of technology or manufacturing rights out of Israel could have a material adverse effect on our ability to enter into strategic alliances or enter into merger or acquisition transactions in the future that provide for the sale or transfer of our technology or manufacturing rights.

***If we are successful in bringing the GlucoTrack DF-F to market, we will be required to use a portion of our net sales to repay certain loans and to pay royalties to the OCS, which will have a negative impact on our net revenues and profitability.***

Integrity Israel is required to pay royalties to the OCS on the proceeds from the sale of our systems resulting from research and development projects for which the OCS provided a grant. During the first three years of sales, we will be required to pay royalties of 3% of the sales of such products. In the fourth, fifth and sixth years of sales, we will be required to pay royalties of 4% of such sales and from the seventh year on we will be required to pay royalties of 5% of such sales, in all cases, up to 100% of the amount of grants received by us from the OCS plus interest at the London Interbank Offered Rate ("LIBOR"). We do not have any other future performance obligations related to the OCS grants. As of December 31, 2012, the contingent liabilities with respect to OCS grants subject to repayment under these royalty agreements equaled NIS 420,000 (\$93,462 at an exchange rate of 4.4938 NIS/dollar, the exchange rate in effect on such date), not including interest.

Messrs. Avner Gal and Zvi Cohen collectively loaned us \$48,735 in May 2002 pursuant to an oral agreement. Messrs. Nir Tarlovsky, Yitzhak Fisher and Asher Kugler loaned us \$75,000 on March 16, 2004. These loans, in addition to the loan from Dimri mentioned above, are not to be repaid until the first year in which we realize profits in our annual income statement (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 after deduction of VAT in the relevant quarter, beginning the quarter following the first year in which we realize profits in our annual income statement. The total amount to be repaid by the Company to each lender shall be an amount equal to the aggregate principal amount loaned by such lender to the Company, plus an amount equal to the product of the amount of each payment made by the Company 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 abovementioned mechanism, we will not be required to repay the loans during any time when such repayment would cause a deficit in our working capital. The Israeli Consumer Price Index was 177.6386, 178.5793 and 182.3521, respectively, as of the dates of the Gal/Cohen loan, the Tarlovsky/Fisher/Kugler Loan and the Dimri loan. The Israeli Consumer Price Index as of December 31, 2012 was 219.8. 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.

To the extent that we are required to pay royalties to the OCS and repay the loans described above, such payments will reduce our net revenues for the year(s) in which such payment(s) are made, and, as a result, will reduce our profits (or increase our losses, as applicable) for such periods.

***We are subject to certain employee severance obligations, which may result in an increase in our expenditures.***

Under Israeli law, employers are required to make severance payments to dismissed employees and employees leaving employment in certain other circumstances, on the basis of the latest monthly salary for each year of service. This obligation results in an increase in our expenses, including accrued expenses. Integrity Israel currently makes monthly deposits to insurance policies and severance pay funds in order to provide for this liability.

The Company's and its Israeli subsidiary's agreements with certain of their Israeli employees are in accordance with Section 14 of the Israeli Severance Pay Law -1963 ("Section 14"). Payments in accordance with Section 14 release the Company from any other future severance payments in respect of those employees. Deposits under Section 14 are not recorded as an asset in the Company's balance sheet.

***There is currently no public trading market for our common stock and a trading market may not develop, making it difficult for our stockholders to sell their shares.***

There is currently no public trading market for our common stock. In January 2012, our common stock was approved for an unpriced quotation on the OTC Bulletin Board and the OTC Link under the symbol "IGAP." Since being cleared on the OTC Bulletin Board and the OTC Link, there has not been a reported sale of our common stock nor has there been a posted bid or ask price on either such quotation system. In order to obtain a priced quotation for our common stock on the OTC Bulletin Board and the OTC Link, the market maker for our common stock will be required to supplement its application with the Financial Industry Regulatory Authority, Inc. ("FINRA") to provide the basis and factors supporting a priced quotation. There can be no assurance that the market maker for our common stock will supplement its application with FINRA to seek a priced quotation for our common stock, that FINRA will clear our common stock for a priced quotation, or that a market will develop for our common stock.

In the absence of an active public trading market, an investor may be unable to liquidate an investment in our common stock. As a result, investors: (i) may be precluded from transferring their shares of common stock; (ii) may have to hold their shares of common stock for an indefinite period of time; and (iii) must be able to bear the complete economic risk of losing their investment in us. In the event a market should develop for the common stock, there can be no assurance that the market price will equal or exceed the price paid for such share by any of our shareholders.

***The market price of our common stock may fluctuate significantly.***

If a public trading market for our common stock, the market price of the common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;

- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if the common stock is covered by analysts;
- developments in the medical device industry;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, in recent years, the stock market in general, and the market for medical device companies in particular, have experienced extreme price and volume fluctuations. Continued or renewed market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of the common stock. Price volatility of our common stock might be significant if the trading volume of the common stock is low, which often occurs with respect to newly traded securities on the OTC Bulletin Board.

***Future sales of common stock could reduce our stock price.***

We have previously issued and sold 1,295,535 of common stock in the Previous Private Placement, shares of Preferred Stock and Warrants convertible into or exercisable for an aggregate of 2,172,412 shares of our common stock; and placement agent warrants exercisable for an aggregate of 346,794 shares of our common stock. Pursuant to the registration rights agreement entered into with the Unit Purchasers and the placement agent agreement entered into with Andrew Garrett, Inc., we have agreed to file a registration statement registering for resale an aggregate of 2,409,572 shares of common stock underlying the Preferred Stock and Warrants included in the Units and the placement agent warrants issued in respect thereof. In addition, the shares sold by us in the Previous Private Placement may be eligible for resale without registration in accordance with one or more exceptions under the Securities Act. Sales by stockholders of substantial amounts of shares of common stock (pursuant to the registration statement described in the preceding sentence or pursuant to an exemption from registration), the issuance of new shares of common stock (or securities convertible into or exercisable for shares of our common stock) by us or the perception that these sales may occur in the future, could materially and adversely affect the market price of the common stock.

*Because our common stock may be a “penny stock,” it may be more difficult for investors to sell shares of the common stock, and the market price of the common stock may be adversely affected.*

Our common stock may be a penny stock if, among other things, the stock price is below \$5.00 per share, it is not listed on a national securities exchange or approved for quotation on the Nasdaq Stock Market or any other national stock exchange or it has not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser’s written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their shares of common stock. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stocks and the market price of the common stock may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to resell their shares of common stock publicly at times and prices that they feel are appropriate.

*Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.*

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, new regulations promulgated by the SEC and rules promulgated by the national securities exchanges. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our directors, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified directors and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed.



**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

We currently lease approximately 3,100 square feet of office space in Ashkelon, Israel for our principal offices and prototype laboratory on a month-to-month basis at a cost of 11,500 NIS (\$3,080 based on the exchange rate on December 31, 2012) plus VAT per month. We believe that we could easily find similar space at comparable rent if necessary.

**Item 3. Legal Proceedings.**

We are not presently a party to any material litigation, other than Integrity Israel's matters with Dimri discussed below. We may, however, become involved in other litigation from time to time relating to claims arising in the ordinary course of our business. These claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

Integrity Israel is party to a loan and investment agreement with Dimri, pursuant to which Dimri loaned Integrity Israel a principal amount of NIS 1,440,000, subject to linkage differences in Israel (\$385,748 based on an exchange rate of 3.733 NIS/dollar in effect on December 31, 2012). In connection with such loan, Dimri received shares of common stock representing 25% of Integrity Israel's ordinary shares at such time. Under the Dimri agreement, certain rights in Integrity Israel were granted to Dimri, including an anti-dilution provision that provided that Dimri's holdings in Integrity Israel would not be diluted below 18% of Integrity Israel's issued capital shares as a result of any investment in Integrity Israel, subject to the fulfillment of certain requirements. On the date of the Reorganization, Dimri owned 18% of Integrity Israel's ordinary shares and, therefore, upon the completion of the Reorganization, Dimri was entitled to receive 18% of the shares of common stock of the Company outstanding on such date in exchange for his shares in Integrity Israel, subject to the fulfillment of certain requirements. We believe, based on the advice of Israeli counsel, that, given Dimri no longer owns shares in Integrity Israel as a result of the Reorganization, rights attached to the shares in Integrity Israel no longer exist in Integrity Israel and do not and have never existed in us. However, Dimri has refused to acknowledge or agree to the termination of these rights and has challenged our position. On June 23, 2011, Dimri appealed to the District Court of HaMerkaz District in Petah Tikva, Israel, requesting the court to appoint an arbitrator to decide the dispute between Integrity Israel, the founders of Integrity Israel and Dimri (HPB 40754-06-11). On December 26, 2011, an arbitrator was appointed in this matter. On March 20, 2012, Dimri submitted a statement of claim to the arbitrator and pled for a declaratory judgment against Integrity Israel and the Founders of Integrity Israel. Dimri claimed that its rights under the loan and investment agreement, Integrity Israel's Articles of Association and two other internal agreements entered into among the Founders of Integrity Israel are valid and in effect. Dimri also pled for an injunction requiring the founders of Integrity Israel to transfer shares of our Common Stock held by them to Dimri, from time to time, in such amounts necessary so that Dimri's holdings in us would not be diluted below 18% of our issued share capital at any time. The defendants in the arbitration submitted a statement of defense on May 28, 2012 and Dimri submitted a reply on June 14, 2012. At a preliminary session held on June 19, 2012, the arbitrator suggested that the parties meet with him in order to examine whether a settlement can be reached. A meeting for this purpose had been set for August 27, 2012 but has been postponed by the arbitrator. After several postponements, Dimri submitted its affidavits on October 16, 2012. The defendants submitted their affidavits on February 7, 2013. Testimony and summary hearings have been set for June 2013.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## Part II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Trading Market

There is currently no public trading market for our common stock. In January 2012, our common stock was approved for an unpriced quotation on the OTC Bulletin Board and the OTC Link under the symbol "IGAP." Since being cleared on the OTC Bulletin Board and the OTC Link, there has not been a reported sale of our common stock nor has there been a posted bid or ask price on either such quotation system. In order to obtain a priced quotation for our common stock on the OTC Bulletin Board and the OTC Link, the market maker for our common stock will be required to supplement its application with FINRA to provide the basis and factors supporting a priced quotation. There can be no assurance that the market maker for our common stock will supplement its application with FINRA to seek a priced quotation for our common stock, that FINRA will clear our common stock for a priced quotation, or that a market will develop for our common stock.

#### Holdings

As of March 28, 2013, there were 134 holders of record of our common stock.

#### Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. Any cash that might be available for payment of dividends will be used to expand our business. Payments of any cash dividends in the future will depend on our financial condition, results of operation and capital requirements, as well as other factors deemed relevant to our board of directors. Furthermore, pursuant to the certificate of designations, preferences and rights governing our newly issued Preferred Stock (the "Certificate of Designations"), as long as at least 15% of the originally issued shares of our outstanding Preferred Stock are outstanding, without the written consent of the holders of a majority in stated value of the outstanding Preferred Stock, we will not be permitted to, among other things, pay dividends on or otherwise make distributions in respect of any shares of our common stock or other securities junior to the Preferred Stock.

Pursuant to the Certificate of Designations, the holders of such Preferred Stock will be entitled to receive cumulative dividends at a rate of 5% per annum, based on the stated value per share of Preferred Stock, which was initially \$1,000 per share. Dividends on the Preferred Stock are payable quarterly on March 31, June 30, September 30 and December 31 of each year, beginning on March 31, 2013, and on each conversion date (with respect to the shares of Preferred Stock being converted). See "Recent Sale of Unregistered Securities" on page 54 below for a description of the material terms of the Preferred Stock.

## Recent Sale of Unregistered Securities

In the fiscal year ended December 31, 2012, we issued and sold an aggregate of 165,057 shares of common stock to the First Closing Purchasers without registration under the Securities Act pursuant to an exemption from registration under Section 4(2) of the Securities Act and Regulation D promulgated thereunder. Subsequent to the issuance of such shares, the offering pursuant to which such shares were issued was converted from an offering of common stock to an offering of Units consisting of Preferred Stock and Warrants. On March 13, 2013, we entered into a Securities Purchase Agreement with the Unit Purchasers pursuant to which, on March 13, 2013, we issued and sold to the Unit Purchasers an aggregate of 6,300 Units, each consisting of (a) one share of Preferred Stock and (b) a Warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of common stock issuable upon conversion of such share of Preferred Stock. The shares of Preferred Stock comprising the Units are convertible into an aggregate of 1,086,206 shares of our common stock and the Warrants comprising the Units are exercisable for an aggregate of 1,086,206 shares of our common stock, in each case subject to adjustment as described below.

As previously disclosed, as a result of the conversion of the offering from an offering of Common Stock to an offering of Units, we agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will exchange the shares of common stock acquired by each First Closing Purchaser in the first closing for such number of Units equal to the aggregate purchase price paid by such First Closing Purchaser in the first closing, divided by \$1,000, in each case subject to the execution by the First Closing Purchaser of a consent to such modification.

In addition, as previously disclosed, we also agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will issue to the holders of the 1,295,535 shares of common stock issued by us at a price of \$6.25 per share pursuant to the Previous Private Placement such number of shares of Common Stock as would reduce the per share purchase price paid by such holders for such shares from \$6.25 per share to \$5.80 per share, in each case subject to the execution by the holder of a consent to such modification.

Pursuant to a placement agent agreement between us and Andrew Garrett, Inc., the placement agent for the offering, at the closing of the sale of the Units we paid Andrew Garrett, Inc., as a commission, an amount equal to 7% of the aggregate sales price of the Units, plus 3% of the aggregate sales price as a management fee plus a non-accountable expense allowance equal to 3% of the aggregate sales price of the Units. In addition, pursuant to the placement agent agreement, we issued to Andrew Garrett, Inc., as partial consideration for its services as placement agent for the offering, warrants to purchase up to 217,240 shares of common stock. We will be required to issue to Andrew Garrett, Inc. warrants to purchase up to an additional 19,920 shares of common stock following the exchange of the shares of common stock issued to the First Closing Purchasers for Units. Half of such options are (or, when issued, will be) exercisable at an exercise price of \$5.80 per share, and the remainder of such options are (or, when issued, will be) exercisable at an exercise price of \$6.96 per share.

### Series A 5% Convertible Preferred Stock

Subject to certain ownership limitations described below, the Preferred Stock is convertible at the option of the holder at any time and from time to time into shares of common stock at a conversion price of \$5.80 per share. The conversion price of the Preferred Stock is subject to adjustment for certain issuances of common stock or other securities of the Company at an effective price per share that is lower than the conversion price then in effect, as well as for stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. In addition, the holders of Preferred Stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of common stock to the same extent as if such holders had converted all of their shares of Preferred Stock prior to such distribution. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations of the Company, the holders of Preferred Stock will be entitled to receive, upon conversion of their shares of Preferred Stock, any securities or other consideration received by the holders of the common stock pursuant to the fundamental transaction.

Holders of Preferred Stock are entitled to receive cumulative dividends at a rate of 5% per annum, based on the stated value per share of Preferred Stock, which was initially \$1,000 per share. Dividends on the Preferred Stock are payable quarterly on March 31, June 30, September 30 and December 31 of each year, beginning on March 31, 2013, and on each conversion date (with respect to the shares of Preferred Stock being converted). Until September 13, 2013, dividends are payable only in cash. Thereafter, dividends on the Preferred Stock will be payable, at our option, in cash and/or, if certain conditions are satisfied (including, among others, that the volume weighted average trading price for our common stock on its principal trading market is equal to or greater than 110% of the then current conversion price for the Preferred Stock for five consecutive trading days prior to the dividend payment date), shares of common stock. Shares of common stock issued as payment of dividends will be valued at the then current conversion price of the Preferred Stock. We will incur a late fee of 9% per annum, payable in cash, on dividends that are not paid within three trading days of the applicable dividend payment date.

We may become obligated to redeem the Preferred Stock in cash upon the occurrence of certain triggering events, including, among others, a material breach by us of certain contractual obligations to the holders of the Preferred Stock, the occurrence of a change in control of Integrity, the occurrence of certain insolvency events relating to Integrity, or the failure of the common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or a regulated quotation service. In addition, upon the occurrence of certain triggering events, each holder of Preferred Stock will have the option to require us to redeem such holder's shares of Preferred Stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 9% on all of such holder's outstanding Preferred Stock.

Subject to certain conditions contained in the Certificate of Designations, we will have the option to force the conversion of the Preferred Stock (in whole or in part) if the volume weighted average price for our common stock on its principal trading market exceeds \$11.60 for each of any 20 trading days during any 30 consecutive Trading Day period and the average daily dollar trading value for our common stock during such 30 day period exceeds \$100,000.

If we fail to timely deliver certificates for shares of common stock issuable upon conversion of the Preferred Stock (the "Conversion Shares") and, as a result, the holder is required by its brokerage firm to purchase shares of common stock to deliver in satisfaction of a sale by such holder of the Conversion Shares (a "Buy-In"), we will be required to: (a) pay the converting holder in cash an amount equal to the amount, if any, by which such holder's total purchase price (including any brokerage commissions) for the shares of common stock so purchased exceeds the product of (i) the aggregate number of Conversion Shares due to the holder, *multiplied by* (ii) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions); and (b) at the option of such holder, either reissue (if surrendered) the shares of Preferred Stock equal to the number of shares of Preferred Stock submitted for conversion (in which case, such conversion will be deemed rescinded) or deliver to such holder the number of shares of common stock that would have been issued if we had timely complied with its delivery requirements. In addition, we will be required to pay partial liquidated damages of \$10 for each \$1,000 of stated value of any shares of Preferred Stock which have been converted by a holder and in respect of which we fail to deliver Conversion Shares by the eighth day following the applicable conversion date.

As long as at least 15% of the originally issued shares of Preferred Stock are outstanding, without the written consent of the holders of a majority in stated value of the outstanding Preferred Stock, we will not be permitted to, among other things, incur indebtedness or liens not permitted under the Certificate of Designations; repay, repurchase, pay dividends on or otherwise make distributions in respect of any shares of our common stock or other securities junior to the Preferred Stock; or enter into certain transactions with affiliates of the Company.

Subject to the beneficial ownership limitation described below, holders of Preferred Stock will vote together with the holders of our common stock on an as-converted basis. Holders will not be permitted to convert their Preferred Stock if such conversion would cause such holder to beneficially own more than 4.99% of the outstanding common stock (subject to increase to 9.99%, at the option of the holder, upon no less than 61 days prior written notice to us) (the "Beneficial Ownership Limitation"). In addition, no holder may vote any shares of Preferred Stock (on an as converted to common stock basis) in excess of the Beneficial Ownership Limitation.

Subject to certain limitations, so long as any Unit Purchaser holds any shares of Preferred Stock, if (1) the Company sells any shares of common stock or other securities convertible into, or rights to acquire, common stock and (2) a Unit Purchaser then holding Preferred Stock, Warrants, Conversion Shares or Warrant Shares (defined below) reasonably believes that any of the terms and conditions appurtenant to such issuance or sale are more favorable to the purchaser in such subsequent sale of securities than are the terms and conditions granted to such Unit Purchaser, then the Unit Purchaser will be permitted to require us to amend the terms of this transaction (only with respect to such Unit Purchaser) so as to match the terms of the subsequent issuance (including, for the avoidance of doubt, any terms and provisions that are or may be less favorable to such Unit Purchaser).

## Warrants

The Warrants have a five-year term commencing on March 13, 2013 and ending on March 13, 2018. Until the end of the term, the Warrants will be exercisable at any time and from time to time at an exercise price of \$6.96 per share. The Warrants contain adjustment provisions substantially similar to those to the adjustment provisions of the Preferred Stock as described above. In addition, the Warrants provide for protection for a Buy-In on substantially the same terms as described above with respect to the Preferred Stock. No holder may exercise its Warrants in excess of the Beneficial Ownership Limitation.

## Registration Rights

In connection with the sale of the Units, we entered into a Registration Rights Agreement with the Unit Purchasers (the "Registration Rights Agreement") pursuant to which, subject to certain exceptions, we agreed to file with the Securities and Exchange Commission, no later than 45 days after the issuance of the Units, a registration statement covering the resale of all of (1) the Conversion Shares, (2) the shares of common stock issuable upon exercise of the Warrants in full (the "Warrant Shares"); (3) the shares of common stock issuable as dividends on the Preferred Stock (assuming all dividends are made in shares of common stock); (4) any additional shares of common stock issuable in connection with any anti-dilution provisions in the Preferred Stock or the Warrants; and (5) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing. Subject to certain exceptions and limitations specified in the Registration Rights Agreement, we will be required to pay each holder partial liquidated damages in the amount of 2% of the aggregate purchase price paid by such holder pursuant to the Purchase Agreement if we fail to timely file a registration statement; timely file a request for acceleration of a registration statement; timely respond to SEC comments with respect to a registration statement; obtain the effectiveness of a registration statement within 90 days from the filing thereof; or maintain the effectiveness of a registration statement for the periods required under the Registration Rights Agreement.

## **Item 6. Selected Financial Data**

Not required for smaller reporting companies.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*Prospective investors should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### **Overview**

We are a development stage medical device company focused on the design, development and commercialization of non-invasive glucose monitoring devices for use by persons suffering from diabetes. Our wholly-owned Israeli subsidiary, 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 blood glucose monitor, the GlucoTrack DF-F glucose monitoring device, which is designed to help people with diabetes obtain blood glucose level readings without the pain, inconvenience, cost and difficulty of conventional (invasive) spot finger stick devices. The GlucoTrack DF-F utilizes a patented combination of ultrasound, electromagnetic and thermal technologies to obtain blood 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. Integrity Israel conducted pre-clinical trials involving over 7,000 readings from over 450 patients over the last seven years. Clinical data collected since 2009 at the Soroka University Medical Center in Be'er Sheva, Israel indicate a positive correlation between GlucoTrack DF-F readings and those obtained from conventional invasive devices. More specifically, a safety and performance clinical trial conducted on 135 subjects of various weights, ages, diabetes types and genders involved 6,275 measurements, of which 96.5% were within the clinically acceptable zones (zones A and B) of the CEG. Measurements are clinically acceptable, compared to a referenced invasive device, when the variance between the devices would have no worse than a benign effect on the patients. The results of these pre-clinical trials may not be indicative of future results due to their relatively small sample sizes.

The GlucoTrack DF-F has not yet been approved for commercial sale in the United States, the European Union or any other jurisdiction. There can be no assurance that approval for commercial sale in any jurisdiction will be obtained.

In December 2012, we submitted our technical file to the Notified Body in connection with our application to obtain CE Mark approval for the GlucoTrack® DF-F model non-invasive glucose monitoring device. In March 2013 we submitted clinical evaluation data to the Notified body in further support of our CE Mark application. If the Notified Body accepts our technical file and clinical evaluation data as satisfactory, we anticipate receiving CE Mark approval to market and sell the GlucoTrack DF-F glucose monitoring device in certain European Union countries as early as April of 2013. We expect to begin clinical trials in the United States by late 2013 or early 2014, if our clinical trial protocol is approved by the FDA.

We have not yet generated any revenues from our operations and have incurred losses of \$15,289,826 from inception through December 31, 2012, stockholder's deficit of \$503,069 and cumulative negative operating cash flow of \$11,574,060. We are dependent upon external sources for financing our operations and there can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

## **Recent Corporate Developments**

### *Preferred Stock and Warrant Issuance*

On March 13, 2013, we entered into a Securities Purchase Agreement with the Unit Purchasers pursuant to which, on March 13, 2013, we issued and sold to the Unit Purchasers an aggregate of 6,300 Units, each consisting of (a) one share of Preferred Stock and (b) a Warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of Common Stock issuable upon conversion of such share of Preferred Stock. The shares of Preferred Stock comprising the Units are convertible into an aggregate of 1,086,206 shares of our common stock and the Warrants comprising the Units are exercisable for an aggregate of 1,086,206 shares of our common stock, in each case subject to adjustment as described below. See "Item 5. Market for Registrant's Common Equity, Related Stockholder Matter and Issuer Purchases of Equity Securities - Recent Sale of Unregistered Securities" on page 54 above for a description of the material terms of the Preferred Stock and the Warrants.

The issuance and sale of the Units constituted the second and final closing of an offering of our securities in a private placement transaction. On November 19, 2012, we completed the first closing of the offering, pursuant to which we issued and sold an aggregate of 165,057 shares of common stock at a price of \$7.00 per share to the First Closing Purchasers. As previously disclosed, as a result of the conversion of the offering from an offering of Common Stock to an offering of Units, we agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will exchange the shares of common stock acquired by each First Closing Purchaser in the first closing for such number of Units equal to the aggregate purchase price paid by such First Closing Purchaser in the first closing, divided by \$1,000, in each case subject to the execution by the First Closing Purchaser of a consent to such modification.

In addition, as previously disclosed, we also agreed with the placement agent for the offering that, following the closing of the sale of the Units, we will issue to the holders of the 1,295,535 shares of common stock issued by us at a price of \$6.25 per share pursuant to the Previous Private Placement such number of shares of Common Stock as would reduce the per share purchase price paid by such holders for such shares from \$6.25 per share to \$5.80 per share, in each case subject to the execution by the holder of a consent to such modification.



Pursuant to a placement agent agreement between us and Andrew Garrett, Inc., the placement agent for the offering, at the closing of the sale of the Units we paid Andrew Garrett, Inc., as a commission, an amount equal to 7% of the aggregate sales price of the Units, plus 3% of the aggregate sales price as a management fee plus a non-accountable expense allowance equal to 3% of the aggregate sales price of the Units. In addition, pursuant to the placement agent agreement, we issued to Andrew Garrett, Inc., as partial consideration for its services as placement agent for the offering, warrants to purchase up to 217,240 shares of common stock. We will be required to issue to Andrew Garrett, Inc. warrants to purchase up to an additional 19,920 shares of common stock following the exchange of the shares of common stock issued to the First Closing Purchasers for Units. Half of such options are (or, when issued, will be) exercisable at an exercise price of \$5.80 per share, and the remainder of such options are (or, when issued, will be) exercisable at an exercise price of \$6.96 per share.

### **Critical Accounting Policies**

This Management's Discussion and Analysis of Financial Condition and Results of Operations discuss our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("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. As applicable to the consolidated financial statements included elsewhere in this report, the most significant estimates and assumptions relate to stock-based compensation and to the going concern assumption.

Our significant accounting policies are discussed in Note 2, Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included elsewhere in this report. Our management believes that, as for the financial statements for the periods included in this report, the going concern assessment is a critical accounting policy. 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 revenues and have incurred substantial accumulated losses and cumulative negative operating cash flows since inception. 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. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. Management's plans concerning these matters are described in Note 1B to the financial statements appearing elsewhere in this report; however management cannot assure that its plans will be successful in addressing these issues. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## Recently Issued Accounting Pronouncements

### 1. *ASC Topic 220, "Comprehensive Income"*

a. Effective January 1, 2012, the Company adopted retrospectively the provisions of Accounting Standard Update No. 2011-05, "Comprehensive Income (Topic 220) - Presentation of Comprehensive Income" ("ASU 2011-05"). ASU 2011-05 eliminated the option to present the components of other comprehensive income as part of the statement of equity and requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income (as applied by the Company) or in two separate but consecutive statements.

The adoption of ASU 2011-05 did not have a material impact on the consolidated financial statements.

b. In February 2013, the FASB issued Accounting Standard Update No. 2013-02 "Comprehensive Income (Topic 220) "Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income" (ASU 2013-02). ASU 2013-02 requires an entity to provide information about amounts reclassified out of accumulated other comprehensive income.

According to ASU 2013-02, significant items that are required under U.S. GAAP to be reclassified to net income in their entirety shall be presented by the respective line items of net income either on the face of the financial statements or in the footnotes. Items that are not required under U.S. GAAP to be reclassified to net income in their entirety, will be required to be cross-referenced to other disclosures required under U.S. GAAP that provide additional detail about those amounts.

ASU 2013-02 is effective for public entities prospectively for annual and interim reporting periods beginning after December 15, 2012 (fiscal year 2013 for the Company).

The adoption of ASU 2013-02 is not expected to have a material impact on the financial position or results of operations of the Company.

### 2. *ASC Topic 210, "Balance Sheet"*

In December 2011, the FASB issued Accounting Standard Update (ASU) 2011-11, "Balance Sheet (Topic 210) - Disclosures about Offsetting Assets and Liabilities" (ASU 2011-11). ASU 2011-11 enhances disclosures about financial instruments and derivative instruments that are either offset in accordance with the Accounting Standards Codification or are subject to an enforceable master netting arrangement or similar agreement.

The amended guidance will be effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods (fiscal year 2013 for the Company) and should be applied retrospectively to all comparative periods presented.

We are currently evaluating the impact that the adoption of ASU 2011-11 would have on our consolidated financial statements, if any.

## Results of Operations

The following discussion of the our operating results explains material changes in our results of operations for the years ended, December 31, 2012, December 31, 2011 and December 31, 2010. The discussion should be read in conjunction with the financial statements and related notes included elsewhere in this report.

*Year Ended December 31, 2012 Compared to Year Ended December 31, 2011*

Revenues

We had no revenue during the years ended December 31, 2012 and 2011 as we have not yet commercialized the GlucoTrack product candidate.

Research and Development Expenses

Research and development expenses were \$1,920,690 for year ended December 31, 2012, as compared to \$1,789,301 for the prior-year period. The increase is primarily attributable to an increase in employee salaries as a result of the hiring of additional employees, including a quality assurance manager. Research and development expenses consist primarily of salaries and other personnel-related expenses, including stock-based compensation expenses, materials, travel expenses, clinical trials and other expenses. We expect research and development expenses to increase in 2013 and beyond in connection with our efforts to seek regulatory approval to market and sell the GlucoTrack DF-F (including Post Market Clinical Follow-up (PMCF) trials); subject to the receipt of regulatory approval, commence the marketing, sale and manufacture of the GlucoTrack DF-F; and develop a new model of the GlucoTrack (including clinical trials for that purpose).

General and Administrative Expenses

General and administrative expenses were \$852,908 for the year ended December 31, 2012, as compared to \$544,145 for the prior-year period. The increase is primarily attributable to an increase in stock-based compensation expenses and salaries (including costs and expenses for employing our Chief Financial Officer and book-keeper). General and administrative expenses consist primarily of professional services, salaries and other related expenses for executive, finance and administrative personnel, including stock-based compensation expense. 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. We expect general and administrative expenses to increase in 2013 and beyond as we incur increased costs to comply with the reporting and other obligations applicable to public reporting companies and, subject to regulatory approval, market, sell and manufacture the GlucoTrack DF-F (including post-market clinical follow-up studies).

Financing Expenses, net

Financing (income) expenses, net was (\$1,291) for the year ended December 31, 2012, as compared to expenses of \$30,893 for the prior-year period. The change is primarily attributable to a decrease in the fair value of warrants with down-round protection offset by an increase in foreign exchange rates for balances denominated in New Israeli Shekels and an increase in linkage difference on principal of loans from shareholders.

### Net Loss

Net loss was \$2,772,307 for the year ended December 31, 2012, as compared to \$2,364,339 for the prior-year period.

### ***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

#### Revenues

We had no revenue during the years ended December 31, 2011 and 2010 as we have not yet commercialized the GlucoTrack product candidate.

#### Research and Development Expenses

Research and development expenses were \$1,789,301 for year ended December 31, 2011, as compared to \$934,056 for the prior-year period. The increase is primarily attributable to an increase in stock-based compensation expenses, employee salaries, development of a new model of the main unit for GlucoTrack DF-F and costs involved in expediting product readiness for clinical trials. Research and development expenses consist primarily of salaries and other personnel-related expenses, including stock-based compensation expenses, materials, travel expenses, clinical trials and other expenses.

#### General and Administrative Expenses

General and administrative expenses were \$544,145 for the year ended December 31, 2011, as compared to \$457,495 for the prior-year period. The increase is primarily attributable to an increase in stock-based compensation expenses and salaries (including costs and expenses for employing our Chief Financial Officer). General and administrative expenses consist primarily of professional services, salaries and other related expenses for executive, finance and administrative personnel, including stock-based compensation expense. 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.

#### Financing Expenses, net

Financing expenses, net was \$30,893 for the year ended December 31, 2011, as compared to expenses of \$1,397,807 for the prior-year period. The decrease is primarily attributable to decrease in stock-based interest compensation to holders of convertible notes, the changes in exchange rates, which impact the principal of loans from stockholders that are denominated in NIS, and the decrease in other interest expenses.

## Net Loss

Net loss was \$2,364,339 for the year ended December 31, 2011, as compared to \$2,788,446 for the prior-year period.

## **Liquidity and Capital Resources**

We currently have limited liquidity. As of December 31, 2012, cash on hand was approximately \$0.5 million. As described above under "Item 1. Business - Overview - Recent Developments - Preferred Stock and Warrant Issuance," on March 13, 2013, we issued and sold to the Unit Purchasers an aggregate of 6,300 Units, each consisting of (a) one share of Preferred Stock and (b) a Warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of Common Stock issuable upon conversion of such share of Preferred Stock. We received gross proceeds of \$6.3 million from the sale of the Units. After giving effect to the payment of commissions to the placement agent for the offering and the payment of certain offering expenses, our cash on hand was approximately \$5.3 million as of March 13, 2013. 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 approximately 23 months from the date of this report. In order to fund our anticipated liquidity needs beyond such 23 month 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.

As of December 31, 2012, we had NIS 300,000 (approximately \$80,000 at the rate of that date) available for borrowing under our line of credit with Bank HaPoalim. Borrowings under the line of credit are secured by our funds on deposit with the bank at the time of borrowing, which generally must be sufficient to cover the principal amount of the borrowings in full. As of March 29, 2013, we did not have any borrowings outstanding under the line of credit.

Integrity Israel is party to a loan and investment agreement dated February 18, 2003 with Dimri pursuant to which Dimri loaned Integrity Israel a principal amount of NIS 1,440,000 (\$385,748, based on an exchange rate of \$3.733 NIS/dollar as of December 31, 2012), subject to linkage differences in Israel. In addition, Messrs. Avner Gal and Zvi Cohen collectively loaned Integrity Israel NIS 176,000 (\$47,147 based on the same exchange rate) in May 15, 2002 pursuant to a board approval. Messrs. Nir Tarlovsky, Yitzhak Fisher and Asher Kugler loaned Integrity Israel \$75,000 on March 16, 2004. These loans, in addition to the loan from Dimri mentioned above, are not to be repaid until the first year in which we realize profits in our annual income statement (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 after deduction of VAT in the relevant quarter, beginning on the quarter following the first year in which we realize profits in our annual income statement. 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. The Israeli Consumer Price Index was 177.6386, 178.5793 and 182.3521 as of the dates of the Gal/Cohen loan, Dimri loan and the Tarlovsky/Fisher/Kugler Loan, respectively. The Israeli Consumer Price Index as for December 31, 2012 was 219.8. 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 committed to pay royalties to the OCS on the proceeds from the sale of our systems resulting from research and development projects for which the OCS provided a grant. During the first three years of sales, we are required to pay royalties of 3% of the sales of such products. In the fourth, fifth and sixth years of sales, we are required to pay royalties of 4% of such sales and from the seventh year on we are required to pay royalties of 5% of such sales, in all cases, up to 100% of the amount of grants received by us from the OCS plus interest at LIBOR. We do not have any other future performance obligations related to the OCS grants. As of March 31, 2010 and December 31, 2009, the contingent liabilities with respect to OCS grants subject to repayment under these royalty agreements equaled \$93,462 (NIS 420,000), not including interest.

***Net Cash Used in Operating Activities for the Years Ended December 31, 2012 and December 31, 2011***

Net cash used in operating activities was \$2,296,989 and \$1,916,113 for years ended December 31, 2012 and 2011, respectively. Net cash used in operating activities primarily reflects the net loss for those periods of \$2,772,307 and \$2,364,339, respectively, which was reduced in part by stock-based compensation of \$349,522 and \$378,072, respectively, and cash provided due to the adjustment to the net loss and changes in operating assets and liabilities in the amounts of \$143,530 and \$21,048, respectively.

***Net Cash Used in Investing Activities for the Years Ended December 31, 2012 and December 31, 2011***

Net cash used in investing activities was \$17,334 and \$40,183 for the years ended December 31, 2012, and 2011, respectively, and was used primarily to purchase equipment (such as computers, R&D and office equipment), and fund deposits in respect of employees' rights upon retirement.

***Net Cash Provided by Financing Activities for the Years Ended December 31, 2012 and December 31, 2011***

Net cash provided by financing activities was \$953,527 and \$2,382,545 for the years ended December 31, 2012 and 2011, respectively. Cash provided by financing activities reflects net capital raised in the amounts of \$917,179 and \$2,401,214 for the years ended December 31, 2012 and 2011, respectively

***Net Cash Used in Operating Activities for the Years Ended December 31, 2011 and December 31, 2010***

Net cash used in operating activities was \$1,916,113 and \$1,367,837 for years ended December 31, 2011 and 2010, respectively. Net cash used in operating activities primarily reflects the net loss for those periods of \$2,364,339 and \$2,788,446, respectively, which was reduced in part by stock-based compensation of \$378,072 and \$14,575, respectively, interest compensation expenses to convertible notes of \$0 and \$1,214,943 respectively, and cash provided due to the adjustment to the net loss and changes in operating assets and liabilities in the amounts of \$21,048 and \$62,465, respectively.

***Net Cash Used in Investing Activities for the Years Ended December 31, 2011 and December 31, 2010***

Net cash used in investing activities was \$40,183 and \$29,321 for the years ended December 31, 2011, and 2010, respectively, and was used primarily to purchase equipment (such as computers, R&D and office equipment), and fund deposits in respect of employees' rights upon retirement.

***Net Cash Provided by Financing Activities for the Years Ended December 31, 2011 and December 31, 2010***

Net cash provided by financing activities was \$2,382,545 and \$2,897,791 for the years ended December 31, 2011 and 2010, respectively. Cash provided by financing activities reflects capital raised in the amounts of \$2,401,214 and \$2,357,032 for the years ended December 31, 2011 and 2010, respectively, and in net cash received from convertible note holders, of \$0 and \$616,604, respectively.

**Off-Balance Sheet Arrangements**

As of December 31, 2011, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not required for smaller reporting companies.

**Item 8. Financial Statements and Supplementary**

**INTEGRITY APPLICATIONS, INC.**  
**(A Development Stage Company)**

**Consolidated Financial Statements**  
**as of December 31, 2012**



INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

Consolidated Financial Statements  
as of December 31, 2012

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**Report of Independent Registered Public Accounting Firm**

**To the Stockholders of**

**INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)**

**Fahn Kanne & Co.**  
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Levinstein Tower  
23 Menachem Begin  
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Tel-Aviv 66184, ISRAEL  
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We have audited the accompanying consolidated balance sheets of **Integrity Applications, Inc.** (a development stage company) and subsidiary (hereinafter: the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2012 and for the cumulative period from September 30, 2001 (date of inception) through December 31, 2012. These consolidated financial statements are the responsibility of the Board of Directors and management of the Company. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Integrity Applications, Inc. and subsidiary as of December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 and for the cumulative period from September 30, 2001 (date of inception) through December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1, the Company is in the development stage as defined in FASB Accounting Standards Codification (ASC) Topic 915, "*Development Stage Entities*". It has not yet generated any revenues from its operations to fund its activities and is therefore dependent upon external sources for financing its operations. As of December 31, 2012, the Company has incurred accumulated losses of US\$ 15,289,826, stockholder's deficit of US\$ 503,069 and cumulative negative operating cash flow of US\$ 11,574,060. These factors among others, as discussed in Note 1 to the consolidated financial statements raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**/s/ FAHN KANNE & CO. GRANT THORNTON ISRAEL**  
Certified Public Accountants (Isr.)

Tel-Aviv, Israel  
March 31, 2013

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

		US dollars (except share data)	
		December 31,	
		2012	2011
<b>ASSETS</b>			
<b>Current Assets</b>			
Cash and cash equivalents		543,411	1,896,504
Other current assets (Note 3)		81,472	92,817
<b>Total current assets</b>		624,883	1,989,321
<b>Property and Equipment, Net (Note 4)</b>		70,200	82,868
<b>Funds in Respect of Employee Rights Upon Retirement</b>		119,488	110,310
<b>Total assets</b>		814,571	2,182,499
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>			
<b>Current Liabilities</b>			
Credit from banking institutions		37,427	-
Accounts payable (Note 5)		122,537	71,763
Other current liabilities (Note 6)		297,989	211,278
<b>Total current liabilities</b>		457,953	283,041
<b>Long-Term Loans from Stockholders (Note 8)</b>		630,575	606,144
<b>Liability for Employee Rights Upon Retirement</b>		229,112	241,176
<b>Warrants with Down-Round Protection (Note 9C)</b>		-	83,899
<b>Total liabilities</b>		1,317,640	1,214,260
<b>Commitments and Contingent Liabilities (Note 9)</b>			
<b>Stockholders' Equity (Deficit) (Note 10)</b>			
<b>Common Stock of US\$ 0.001 par value ("Common Stock"):</b>			
40,000,000 shares authorized as of December 31, 2012 and 2011; issued and outstanding 5,460,600 shares and 5,295,543 shares as of December 31, 2012 and 2011, respectively		5,461	5,296
<b>Preferred Stock of US\$ 0.001 par value ("Preferred Stock"):</b>			
10,000,000 shares and 0 shares authorized as of December 31, 2012 and 2011, respectively; issued and outstanding 0 shares as of December 31, 2012 and 2011			
Additional paid in capital		14,772,371	13,457,828
Accumulated other comprehensive income		8,925	22,634
Deficit accumulated during the development stage		(15,289,826)	(12,517,519)
<b>Total stockholders' equity (deficit)</b>		(503,069)	968,239
<b>Total liabilities and stockholders' equity (deficit)</b>		814,571	2,182,499

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

US dollars

	Year ended December 31,			Cumulative period from September 30, 2001 (date of inception) through December 31, 2012(*)
	2012	2011	2010(*)	
Research and development expenses, net (Note 11)	1,920,690	1,789,301	934,056	10,476,404
General and administrative expenses (Note 12)	852,908	544,145	457,495	3,014,642
Other income	-	-	(912)	(912)
Operating loss	2,773,598	2,333,446	1,390,639	13,490,134
Financing expenses (income), net (Note 13)	(1,291)	30,893	1,397,807	1,799,692
Loss for the period	2,772,307	2,364,339	2,788,446	15,289,826
<b>Other comprehensive (income) loss:</b>				
Foreign currency translation adjustment	(13,709)	39,052	(119,019)	8,925
Comprehensive loss for the period	2,758,598	2,403,391	2,669,427	15,298,751
<b>Loss per share (Basic and Diluted) (Note 15)</b>	0.52	0.46	0.70	

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (\*)

	US Dollars (except share data)					Total stockholders equity (deficit)
	Common Stock		Additional paid in capital	Accumulated	Deficit	
	Number of shares	Amount			other comprehensive income (loss)	accumulated during development stage
<b>September 30, 2001 (date of inception)</b>						
2,136,307 Common Stock of US\$ 0.001 per share issued for cash	2,136,307	2,136	38,306	-	-	40,442
Loss for the period	-	-	-	-	(63,293)	(63,293)
Other comprehensive loss	-	-	-	(5)	-	(5)
<b>Balance as of December 31, 2002</b>	<b>2,136,307</b>	<b>2,136</b>	<b>38,306</b>	<b>(5)</b>	<b>(63,293)</b>	<b>(22,856)</b>
Loss for the year	-	-	-	-	(350,290)	(350,290)
Other comprehensive loss	-	-	-	(15,035)	-	(15,035)
<b>Balance as of December 31, 2003</b>	<b>2,136,307</b>	<b>2,136</b>	<b>38,306</b>	<b>(15,040)</b>	<b>(413,583)</b>	<b>(388,181)</b>
Loss for the year	-	-	-	-	(288,233)	(288,233)
Other comprehensive loss	-	-	-	(15,069)	-	(15,069)
Issuance of 42,727 Common Stock for cash at US\$ 1.76 per share on March 16, 2004	42,727	43	74,957	-	-	75,000
Issuance of 72,773 Common Stock for cash of US\$ 1.72 per share on November 25, 2004	72,773	73	128,783	-	-	128,856
<b>Balance as of December 31, 2004</b>	<b>2,251,807</b>	<b>2,252</b>	<b>242,046</b>	<b>(30,109)</b>	<b>(701,816)</b>	<b>(487,627)</b>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (\*) (cont.)

	US Dollars (except share data)					
	Common Stock		Additional paid in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during development stage	Total stockholders equity (deficit)
	Number of shares	Amount				
<b>Balance as of January 1, 2005</b>	2,251,807	2,252	242,046	(30,109)	(701,816)	(487,627)
Loss for the year	-	-	-	-	(1,055,594)	(1,055,594)
Other comprehensive income	-	-	-	8,542	-	8,542
Issuance of 218,281 shares of Common Stock for cash of US\$ 1.72 per share on January 14, 2005	218,281	218	374,782	-	-	375,000
Issuance of 291,051 shares of Common Stock for cash of US\$ 1.72 per share on April 5, 2005	291,051	291	499,709	-	-	500,000
Issuance of 59,389 shares of Common Stock for cash of US\$ 3.37 per share on May 31, 2005	59,389	60	199,940	-	-	200,000
Stock-based compensation	52,147	52	189,564	-	-	189,616
<b>Balance as of December 31, 2005</b>	<u>2,872,675</u>	<u>2,873</u>	<u>1,506,041</u>	<u>(21,567)</u>	<u>(1,757,410)</u>	<u>(270,063)</u>
Loss for the year	-	-	-	-	(1,282,842)	(1,282,842)
Other comprehensive loss	-	-	-	(57,127)	-	(57,127)
Issuance of 87,315 shares of Common Stock for cash of US\$ 1.47 per share on January 26, 2006	87,315	87	128,118	-	-	128,205
Issuance of 1,899 shares of Common Stock for cash of US\$ 3.63 per share on March 31, 2006	1,899	2	6,888	-	-	6,890
Issuance of 13,786 shares of Common Stock for cash of US\$ 3.63 per share on June 16, 2006	13,786	14	49,986	-	-	50,000
Issuance of 14,113 shares of Common Stock for cash of US\$ 3.63 per share on June 30, 2006	14,113	14	51,166	-	-	51,180
Issuance of 51,207 shares of Common Stock for cash of US\$ 3.91 per share on August 15, 2006	51,207	51	199,949	-	-	200,000
Issuance of 301,948 shares of Common Stock for cash of US\$ 4.31 per share on October 5, 2006	301,948	302	1,299,698	-	-	1,300,000
Issuance of 348,402 shares of Common Stock for cash of US\$ 4.31 per share on December 14, 2006	348,402	349	1,372,146	-	-	1,372,495
Stock-based compensation	63,395	63	277,434	-	-	277,497
<b>Balance as of December 31, 2006</b>	<u>3,754,740</u>	<u>3,755</u>	<u>4,891,426</u>	<u>(78,694)</u>	<u>(3,040,252)</u>	<u>1,776,235</u>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (\*) (cont.)

US Dollars (except share data)

	Common Stock		Additional paid in capital	Accumulated other comprehensive income (loss)	Receivable in respect of stock issuance	Deficit accumulated during development stage	Total stockholders equity (deficit)
	Number of shares	Amount					
<b>Balance as of January 1, 2007</b>	3,754,740	3,755	4,891,426	(78,694)	-	(3,040,252)	1,776,235
Loss for the year	-	-	-	-	-	(1,593,205)	(1,593,205)
Other comprehensive income	-	-	-	84,528	-	-	84,528
Stock-based compensation	28,707	29	274,630	-	-	-	274,659
<b>Balance as of December 31, 2007</b>	<u>3,783,447</u>	<u>3,784</u>	<u>5,166,056</u>	<u>5,834</u>	<u>-</u>	<u>(4,633,457)</u>	<u>542,217</u>
Loss for the year	-	-	-	-	-	(1,528,981)	(1,528,981)
Other comprehensive income	-	-	-	110,134	-	-	110,134
Issuance of 61,989 shares of Common Stock for cash of US\$ 5.52 per share on September 27, 2008	61,989	62	341,938	-	-	-	342,000
Issuance of 104,220 shares of Common Stock for cash of US\$ 5.52 per share on October 7, 2008	104,220	104	574,896	-	(75,000)	-	500,000
Stock-based compensation	-	-	84,380	-	-	-	84,380
<b>Balance as of December 31, 2008</b>	<u>3,949,656</u>	<u>3,950</u>	<u>6,167,270</u>	<u>115,968</u>	<u>(75,000)</u>	<u>(6,162,438)</u>	<u>49,750</u>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (\*) (cont.)

US Dollars (except share data)

	Common Stock		Additional paid in capital	Accumulated other comprehensive income (loss)	Receivable in respect of stock issuance	Deficit accumulated during development stage	Total stockholders equity (deficit)
	Number of shares	Amount					
<b>Balance as of January 1, 2009</b>	3,949,656	3,950	6,167,270	115,968	(75,000)	(6,162,438)	49,750
Loss for the year	-	-	-	-	-	(1,202,296)	(1,202,296)
Other comprehensive loss	-	-	-	(13,367)	-	-	(13,367)
Issuance of 50,342 shares of Common Stock for cash of US\$ 6.02 per share in January 2009	50,342	50	302,950	-	-	-	303,000
Repayment of receivable in respect of stock issuance	-	-	-	-	75,000	-	75,000
Stock-based compensation	-	-	12,171	-	-	-	12,171
<b>Balance as of December 31, 2009</b>	<u>3,999,998</u>	<u>4,000</u>	<u>6,482,391</u>	<u>102,601</u>	<u>-</u>	<u>(7,364,734)</u>	<u>(775,742)</u>
Loss for the year	-	-	-	-	-	(2,788,446)	(2,788,446)
Other comprehensive loss	-	-	-	(119,019)	-	-	(119,019)
Issuance of 530,600 shares of Common Stock for cash of US\$ 6.25 per share in December 2010, net of related expenses	530,600	531	2,356,501	-	-	-	2,357,032
Stock-based interest compensation to convertible notes holders	194,391	194	1,214,749	-	-	-	1,214,943
Conversion of convertible notes	119,586	120	694,676	-	-	-	694,796
Stock-based compensation	-	-	14,575	-	-	-	14,575
<b>Balance as of December 31, 2010</b>	<u>4,844,575</u>	<u>4,845</u>	<u>10,762,892</u>	<u>(16,418)</u>	<u>-</u>	<u>(10,153,180)</u>	<u>598,139</u>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (\*) (cont.)

	US Dollars (except share data)					Total stockholders equity (deficit)
	Common Stock		Additional paid in capital	Accumulated other comprehensive loss	Deficit accumulated during development stage	
	Number of shares	Amount				
<b>Balance as of January 1, 2011</b>	4,844,575	4,845	10,762,892	(16,418)	(10,153,180)	598,139
Loss for the year	-	-	-	39,052	(2,364,339)	39,052
Other comprehensive income	-	-	-	-	-	-
Issuance of 16,320 shares of Common Stock for cash of US\$ 6.25 per share in January 31, 2011,						
net of related expenses	16,320	16	83,164	-	-	83,180
Issuance of 90,768 shares of Common Stock for cash of US\$ 6.25 per share in March 31, 2011,						
net of related expenses	90,768	91	479,810	-	-	479,901
Issuance of 40,000 shares of Common Stock for cash of US\$ 6.25 per share in April 29, 2011,						
net of related expenses	40,000	40	191,682	-	-	191,722
Issuance of 34,200 shares of Common Stock for cash of US\$ 6.25 per share in May 31, 2011,						
net of related expenses	34,200	34	179,992	-	-	180,026
Issuance of 269,680 shares of Common Stock for cash of US\$ 6.25 per share on July 29, 2011,						
net of related expenses	269,680	270	1,466,115	-	-	1,466,385
Fair value of warrants with down-round protection issued in connection with Common Stock issuances	-	-	(83,899)	-	-	(83,899)
Stock-based compensation	-	-	378,072	-	-	378,072
<b>Balance as of December 31, 2011</b>	<u>5,295,543</u>	<u>5,296</u>	<u>13,457,828</u>	<u>22,634</u>	<u>(12,517,519)</u>	<u>968,239</u>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (\*) (cont.)

	US Dollars (except share data)					Total stockholders equity (deficit)
	Common Stock		Additional paid in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during development stage	
	Number of shares	Amount				
<b>Balance as of January 1, 2012</b>	5,295,543	5,296	13,457,828	22,634	(12,517,519)	968,239
Loss for the year	-	-	-	-	(2,772,307)	(2,772,307)
Other comprehensive income	-	-	-	(13,709)	-	(13,709)
Issuance of 165,057 shares of Common Stock for cash of US\$ 7.00 per share in November 19, 2012, net of related expenses (**)	165,057	165	917,014	-	-	917,179
Warrants classified to equity due to the laps of the down-round protection period	-	-	48,007	-	-	48,007
Stock-based compensation	-	-	349,522	-	-	349,522
<b>Balance as of December 31, 2012</b>	<u>5,460,600</u>	<u>5,461</u>	<u>14,772,371</u>	<u>8,925</u>	<u>(15,289,826)</u>	<u>(503,069)</u>

(\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.

(\*\*) See also Note 10L.

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

INTEGRITY APPLICATIONS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	US dollars			Cumulative period from September 30, 2001 (date of inception) through December 31, 2012(*)
	Year ended December 31,			
	2012	2011	2010(*)	
<b>Cash flows from operating activities:</b>				
Loss for the period	(2,772,307)	(2,364,339)	(2,788,446)	(15,289,826)
Adjustments to reconcile loss for the period to net cash used in operating activities:				
Depreciation	25,546	23,045	19,153	158,033
Increase (decrease) in liability for employee rights upon retirement	(17,237)	1,127	16,284	206,465
Stock-based compensation	349,522	378,072	14,575	1,580,425
Stock-based interest compensation to convertible notes holders	-	-	1,214,943	1,214,943
Changes in the fair value of warrants with round down protection	(35,892)	-	-	(35,892)
Linkage difference on principal of loans from stockholders (**)	9,849	24,934	15,909	186,898
Interest on convertible notes	-	-	78,192	78,192
Gain on sale of property and equipment	-	-	(912)	(912)
Gain from trading marketable securities	-	-	-	(12,920)
<b>Changes in assets and liabilities:</b>				
Decrease (increase) in other current assets	14,106	(23,968)	(46,562)	(69,418)
Increase (decrease) in accounts payable	48,850	64,697	(14,120)	121,992
Increase (decrease) in other current liabilities	80,574	(19,681)	123,147	287,960
<b>Net cash used in operating activities</b>	<u>(2,296,989)</u>	<u>(1,916,113)</u>	<u>(1,367,837)</u>	<u>(11,574,060)</u>
<b>Cash flows from investment activities:</b>				
Decrease (increase) in funds in respect of employee rights upon retirement	(6,387)	14,436	(25,387)	(109,192)
Purchase of property and equipment	(11,347)	(54,619)	(8,725)	(220,120)
Proceeds from sale of property and equipment	-	-	4,791	4,791
Investment in marketable securities	-	-	-	(388,732)
Proceeds from sale of marketable securities	-	-	-	406,995
Short-term loan granted to related party, net of repayments	-	-	-	(14,252)
<b>Net cash used in investment activities</b>	<u>(17,734)</u>	<u>(40,183)</u>	<u>(29,321)</u>	<u>(320,510)</u>
<b>Cash flows from financing activities</b>				
Credit from banking institutions (repayment)	36,348	(18,669)	(75,845)	30,130
Proceeds from issuance of convertible notes	-	-	1,144,000	1,144,000
Repayment of convertible notes	-	-	(527,396)	(527,396)
Proceeds from issuance of Common Stock, net of issuance expenses	917,179	2,401,214	2,357,032	11,323,559
Proceeds from stockholders loans	-	-	-	347,742
<b>Net cash provided by financing activities</b>	<u>953,527</u>	<u>2,382,545</u>	<u>2,897,791</u>	<u>12,318,035</u>
Effect of exchange rate changes on cash and cash equivalents	8,103	(23,993)	(68,417)	119,946
Increase (decrease) in cash and cash equivalents	(1,353,093)	402,256	1,432,216	543,411
Cash and cash equivalents at beginning of the period	1,896,504	1,494,248	62,032	-
Cash and cash equivalents at end of the period	<u>543,411</u>	<u>1,896,504</u>	<u>1,494,248</u>	<u>543,411</u>
<b>Supplementary information on financing activities not involving cash flows:</b>				
Conversion of convertible notes to Common Stock (see Note 10C)	-	-	694,796	694,796
Fair value of warrants with down-round protection issued in connection with Common Stock issuances (See Note 9C)	-	83,899	-	83,899
Warrants classified to equity due to the laps of the down-round protection period	48,007	-	-	48,007

- (\*) As described in Note 1A, the financial statements were retroactively restated to reflect the historical financial statements of the subsidiary A.D. Integrity Applications Ltd., which merged with a subsidiary of the Company on July 15, 2010, as part of a structural reorganization of the Group.
- (\*\*) Represents charges taken to reflect changes in the Israeli Consumer Price index with respect to loans from stockholders that are denominated in New Israeli Shekels and linked to the Israeli Consumer Price Index.

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

**INTEGRITY APPLICATIONS, INC.**  
**(A Development Stage Company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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 which was previously held by the stockholders of the Company. Pursuant to the merger, all stockholders, option holders and warrant holders of Integrity Israel received an equal number of shares, options and warrants of the Company, as applicable, in exchange for their shares, options and/or warrants in Integrity Israel. Following the merger, Integrity Israel remained 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. On this basis, stockholders' equity has been retroactively restated such that each ordinary share of Integrity Israel is reflected in stockholders' equity as a share of Common Stock of the Company as of the date of the issuance thereof by Integrity Israel. In addition, the historical financial statements of the Company for all dates prior to May 18, 2010 have been retroactively restated to reflect the activities of Integrity Israel.

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 home use by persons suffering with diabetes.

Since its inception, Integrity Israel has devoted substantially all of its efforts to business planning, research and development and raising capital, and has not yet generated any revenues. Accordingly, Integrity Israel (and therefore the Company) is considered to be in the development stage as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification (ASC) Topic 915, "*Development Stage Entities*".

**B. Going concern uncertainty**

Since its incorporation (May 18, 2010), the Company has not had any 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 have not yet generated any revenues from its operations to fund its activities, and therefore they are dependent upon external sources for financing their operations. There can be no assurance that Integrity Israel and the Company will succeed in obtaining the necessary financing to continue their operations. Since inception, Integrity Israel and the Company have incurred accumulated losses of US\$ 15,289,826, stockholder's deficit of US\$ 503,069 and cumulative negative operating cash flow of US\$ 11,574,060. These factors raise substantial doubt about Integrity Israel's and the Company'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 2010, the Company raised funds via the issuance of Common Stock (including via the conversion of convertible notes), in a total amount of approximately US\$ 4 million (before related expense). During 2011, the Company raised funds via the issuance of Common Stock in a total amount of approximately US\$ 2.4 million (net of related expenses). During 2012, the Company raised a total amount of approximately US\$ 1 million (net of related expenses).

As described in Note 17A, in March 2013 the Company completed a private offering of convertible preferred stock for an approximate amount of US\$ 5.5 million (net of related expenses).

**INTEGRITY APPLICATIONS, INC.**  
**(A Development Stage Company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 1 – GENERAL (cont.)**

**C. Stock split**

The Board of Directors and stockholders of the Company approved in July 2010 a stock split of the outstanding shares of common stock and options to purchase shares of common stock of the Company, pursuant to which each share of common stock and each stock option was split into 2.1363 shares of common stock or options, as applicable (the "split"). The split became effective as of July 23, 2010. Unless otherwise noted, all share and option amounts for all periods presented have been retroactively restated to give effect to the split.

**D. Risk factors**

The Company and Integrity Israel (collectively, the "Group") have a limited operating history and face a number of risks, including uncertainties regarding finalization 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.

In addition, the Group expects to continue incurring significant operating costs and losses in connection with the development of its products and marketing efforts.

As mentioned above, the Group has not yet generated any revenues from its operations to fund its activities and therefore the Group is dependent on the receipt of additional funding from its stockholders and investors in order to continue as a going concern.

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP).

**A. Functional currency**

The functional currency of the Company is the US dollar ("US\$"), which is the currency of the primary economic environment in which the operations of the Company are conducted and is also the reporting currency of the Group. The functional currency of Integrity Israel is the New Israeli Shekel ("NIS").

The financial statements of the subsidiary were translated into US dollars in accordance with the relevant standards of the FASB. Accordingly, assets and liabilities were translated from NIS to US dollars using year-end exchange rates, and income and expense items were translated at average exchange rates during the year.

Gains or losses resulting from translation adjustments are reflected in stockholders' equity (deficit), under "accumulated other comprehensive income (loss)".

Balances denominated in or linked to foreign currency are stated on the basis of the exchange rates prevailing at the applicable balance sheet date. For foreign currency transactions included in the statement of operations, the exchange rates applicable on the relevant transaction dates are used. Gains or losses arising from changes in the exchange rates used in the translation of such transactions are carried as financing income or expenses.

	<u>Year ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Official exchange rate of NIS 1 to US dollar	0.268	0.262	0.282

**INTEGRITY APPLICATIONS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

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

**B. Principles of consolidation**

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

As described in Note 1A above, the merger of Integrity Israel has been accounted for in a manner similar to a pooling of interests at historical cost.

**C. Use of estimates in the preparation of financial statements**

The preparation of consolidated financial statements in conformity with US 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 stock based compensation and to the going concern assumption.

**D. Cash and cash equivalents**

The Group considers all short-term investments, which are highly liquid investments with original maturities of three months or less at the date of purchase, to be cash equivalents.

**E. Property and equipment, net**

1. Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. When an asset is retired or otherwise disposed of, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition is reflected in the statements of operations.

2. Rates of depreciation:

	%
Computers	33
Furniture and office equipment	7-15
Leasehold improvements	Shorter of lease term and 10 years

**F. Impairment of long-lived assets**

The Group's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. The Group has not recorded any impairment losses in the reported periods.



**INTEGRITY APPLICATIONS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

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

**G. Deferred income taxes**

Deferred income taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and the tax bases of assets and liabilities under the applicable tax law. Deferred tax balances are computed using the tax rates expected to be in effect when these differences reverse. Valuation allowances in respect of deferred tax assets are provided for if, based upon the weight of available evidence, it is more likely than not that all or a portion of the deferred income tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with ASC Topic 740-10, which prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements. According to ASC Topic 740-10, tax positions must meet a more-likely-than-not recognition threshold. The Company's accounting policy is to classify interest and penalties relating to uncertain tax positions under income taxes, however the Company did not recognize such items in its fiscal 2012, 2011 and 2010 financial statements and did not recognize any liability with respect to unrecognized tax position in its balance sheet.

**H. Liability for employee rights upon retirement**

Integrity Israel's liability for employee rights upon retirement with respect to its Israeli employees is calculated, pursuant to Israeli severance pay law, based on the most recent salary of each employee multiplied by the number of years of employment, as of the balance sheet date. Employees are entitled to one month's salary for each year of employment, or a portion thereof. Integrity Israel makes monthly deposits to insurance policies and severance pay funds. The liability of the Company is fully provided for.

The deposited funds include profits accumulated up to the balance sheet date. The deposited funds may be withdrawn upon the fulfillment of Integrity Israel's severance obligations pursuant to Israeli severance pay laws or labor agreements with its employees. The value of the deposited funds is based on the cash surrender value of these policies, and includes immaterial profits/losses.

Commencing in 2011, the Company's and its Israeli subsidiary's agreements with certain of their Israeli employees are in accordance with Section 14 of the Severance Pay Law -1963. Payments in accordance with Section 14 release the Company from any future severance payments in respect of those employees. Related obligations and liabilities under Section 14 are not recorded as an asset or as a liability in the Company's balance sheet.

Severance expenses for the year ended December 31, 2012, 2011 and 2010 amounted to US\$ 78,556, US\$ 42,358 and US\$ 28,873, respectively.

**I. Research and development expenses**

Research and development expenses are charged to operations as incurred. Grants received from the Government of Israel for development of approved projects were recognized as a reduction of expenses when the related costs were incurred (see also J. below).

**J. Royalty-bearing grants**

Royalty-bearing grants from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor (the "OCS") for funding approved research and development projects are recognized at the time Integrity Israel is entitled to such grants, on the basis of the costs incurred and reduce research and development costs. The cumulative research and development grants received by Integrity Israel from inception through December 2004 amount to US\$ 93,462. Integrity Israel has not received any research and development grants since December 2004.

As of December 31, 2012, 2011 and 2010, the Company has not accrued any royalties, since no revenues have been recognized in respect of the funded project.

**INTEGRITY APPLICATIONS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

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

**K. Loss per share**

Basic loss per share is computed by dividing loss for the period by the weighted average number of common shares outstanding during the period.

In computing diluted earnings per share, basic earnings per share are adjusted to reflect the potential dilution that could occur upon the exercise of options or warrants issued or granted using the "treasury stock method" and upon the conversion of convertible notes using the "if-converted method", if their effect is dilutive.

**L. Stock-based compensation**

Share-based payments including grants of stock options and shares are recognized in the statement of operations as an operating expense, based on the fair value of the award on the date of grant. The fair value of options is estimated using the Black-Scholes option-pricing model and the fair value of share grants is estimated using recent transaction prices. The Group has expensed compensation costs, net of estimated forfeitures, applying the accelerated vesting method, over the requisite service period or over the implicit service period when a performance condition affects the vesting, and it is considered probable that the performance condition will be achieved.

Share-based payments awarded to consultants (non-employees) are accounted for in accordance with ASC Topic 505-50, "Equity-Based Payments to Non-Employees".

**M. Fair value of financial instruments**

ASC Topic 825-10, "Financial Instruments" defines financial instruments and requires disclosure of the fair value of financial instruments held by the Company. The Company considers the carrying amount of cash and cash equivalents, other current assets, credit from banking institutions, accounts payable and other current liabilities balances, to approximate their fair values because of the short period of time between the origination of such instruments and their expected realization. The Company did not estimate the fair value of the long-term loans from stockholders which do not bear any interest, since the repayment schedule has not been determined.

**N. Convertible notes**

The Company has considered the provisions of ASC Topic 815, "Derivatives and Hedging", and determined that the conversion feature should not be separated from the host instrument. Furthermore, the Company applied ASC Topic 470-20, "Debt - Debt with Conversion and Other Options" which clarifies the accounting for instruments with beneficial conversion features or contingency adjustable conversion ratios. As described in Note 10C, the Company has determined that the convertible notes did not provide beneficial conversion feature.

The entire balance of the convertible notes (which were issued during fiscal year 2010) was either repaid in cash or converted into Common Stock during fiscal year 2010 (see also Note 10C).

**O. Concentrations of credit risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. Cash and cash equivalents are deposited with major banks in Israel and the United States of America. Management believes that such financial institutions are financially sound and, accordingly, minimal credit risk exists with respect to these financial instruments.

The Company has no significant off-balance-sheet concentration of credit risk, such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

INTEGRITY APPLICATIONS, INC.  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

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

**P. Contingencies**

The Company records accruals for loss contingencies arising from claims, litigation and other sources when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. As of December 31, 2012, the Company has not recorded an expense related to the its outstanding arbitration discussed in Note 9D because it has not yet been determined if a liability has been incurred and if so, if the liability can be reasonably estimated (see Note 9D). Legal costs incurred in connection with loss contingencies are expensed as incurred.

**Q. Warrants with down-round protection**

Warrants that were issued to a certain non employee, which include down-round protection that would adjust the strike price of the warrants to a price per share at which the Company will subsequently issue stock, if such price per share is less than the original strike price of the warrants, were classified as liability and measured at fair value through earnings until such date that the down-round protection has lapsed. See also Note 9C.

**R. Recently issued accounting pronouncements**

**1. ASC Topic 220, "Comprehensive Income"**

- a. Effective January 1, 2012, the Company adopted retrospectively the provisions of Accounting Standard Update No. 2011-05, "*Comprehensive Income (Topic 220) - Presentation of Comprehensive Income*" ("ASU 2011-05"). ASU 2011-05 eliminated the option to present the components of other comprehensive income as part of the statement of equity and requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income (as applied by the Company) or in two separate but consecutive statements.

The adoption of ASU 2011-05 did not have a material impact on the consolidated financial statements.

- b. In February 2013, the FASB issued Accounting Standard Update No. 2013-02 "Comprehensive Income (Topic 220) "Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income" (ASU 2013-02). ASU 2013-02 requires an entity to provide information about amounts reclassified out of accumulated other comprehensive income.

According to ASU 2013-02, significant items that are required under U.S. GAAP to be reclassified to net income in their entirety shall be presented by the respective line items of net income either on the face of the financial statements or in the footnotes. Items that are not required under U.S. GAAP to be reclassified to net income in their entirety, will be required to be cross-referenced to other disclosures required under U.S. GAAP that provide additional detail about those amounts.

ASU 2013-02 is effective for public entities prospectively for annual and interim reporting periods beginning after December 15, 2012 (fiscal year 2013 for the Company).

The adoption of ASU 2013-02 is not expected to have a material impact on the financial position or results of operations of the Company.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

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

R. Recently issued accounting pronouncements (cont.)

2. ASC Topic 210, “Balance Sheet”

In December 2011, the FASB issued Accounting Standard Update (ASU) 2011-11, “Balance Sheet (Topic 210) - Disclosures about Offsetting Assets and Liabilities” (ASU 2011-11). ASU 2011-11 enhances disclosures about financial instruments and derivative instruments that are either offset in accordance with the Accounting Standards Codification or are subject to an enforceable master netting arrangement or similar agreement.

The amended guidance will be effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods (fiscal year 2013 for the Company) and should be applied retrospectively to all comparative periods presented.

We are currently evaluating the impact that the adoption of ASU 2011-11 would have on our consolidated financial statements, if any.

NOTE 3 – OTHER CURRENT ASSETS

	US dollars	
	December 31,	
	2012	2011
Prepaid expenses	29,460	21,282
Government Institution (*)	52,012	70,346
Other	-	1,189
	81,472	92,817

(\*) Represents amounts prepaid by Integrity Israel to the Israeli tax authorities or amounts owed to Integrity Israel by the Israeli Value Added Tax authorities.

NOTE 4 – PROPERTY AND EQUIPMENT, NET

	US dollars	
	December 31,	
	2012	2011
Computers	85,517	75,982
Furniture and office equipment	114,982	108,485
Leasehold improvements	23,953	23,401
	224,452	207,868
Less – accumulated depreciation	(154,252)	(125,000)
	70,200	82,868

In years ended December 31, 2012, 2011 and 2010, depreciation was US\$ 25,546, US\$ 23,045 and US\$ 19,153, respectively, and additional equipment was purchased in an amount of US\$ 11,347, US\$ 54,619 and US\$ 8,725, respectively.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 5 – ACCOUNTS PAYABLE**

	US dollars	
	December 31,	
	2012	2011
Open accounts	96,870	57,662
Checks payable	25,667	14,101
	122,537	71,763

**NOTE 6 – OTHER CURRENT LIABILITIES**

	US dollars	
	December 31,	
	2012	2011
Employees and related institutions	184,394	130,918
Accrued expenses and other	113,595	80,360
	297,989	211,278

**NOTE 7 – LINE OF CREDIT**

As of December 31, 2012, the Company used US\$ 37,427 of its credit facilities with its Israeli banks. As of December 31, 2012, the Company has an unutilized credit line of approximately US\$ 42,937 (NIS 160,286).

**NOTE 8 – LONG-TERM LOANS FROM STOCKHOLDERS**

During the years 2003-2004, Integrity Israel received loans from stockholders (three separate lenders). The loans are indexed to the Israeli Consumer Price Index from their origination date and bear no interest.

These loans are not required to be repaid until the first year in which the Company reports profits in its annual statements of operations (accounting profit). The Company has not reported any profits since inception and does not expect to report profit in the near future, at least not before the issuance date of the financial statements for the 2013 (March 2014) fiscal year. Accordingly, the loans have been presented as long-term liabilities. At such time as the Company reports profits, repayment of the stockholder loans is to be made from cash flows that will be received from sales, such that 10% of the total sales of the Company after deduction of VAT in every quarter, starting with the quarter following the first year in which the Company reports profits in its annual statement of operations, will be transferred to the lenders, until full repayment of the loans. However, notwithstanding the abovementioned mechanism, the Company will not be required to repay the loans during any time when such repayment would cause a deficit in the Company's working capital.

As of December 31, 2012, no repayments of the stockholders loans have been made.

**INTEGRITY APPLICATIONS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 9 – COMMITMENTS AND CONTINGENT LIABILITIES**

- A. On March 4, 2004, the OCS agreed to provide Integrity Israel with a grant of NIS 420,000, or approximately US\$ 93,462, for its development plan. This grant constituted 60% of Integrity Israel's research and development budget for the development plan as of that date. Due to Integrity Israel's acceptance of this grant, it is subject to the provisions of the R&D Law. Integrity Israel is required to pay royalties to the OCS on the proceeds from the sale of the Company's systems resulting from research and development projects for which the OCS provided a grant. The maximum royalties payable by Integrity Israeli will be an amount equal to US\$ 93,462, plus interest from the date of grant at LIBOR. In the first 3 years of sales, Integrity Israel will be required to pay a 3% royalty on the sale of any product developed under the research and development projects. In the fourth, fifth and sixth years of sales, Integrity Israel will be required to pay a 4% royalty on sales of such products and from the seventh year onward Integrity Israel will be required to pay a 5% royalty. Integrity Israel was entitled to the grant only upon incurring research and development expenditures. There were no future performance obligations related to the grant received from the OCS. As of December 31, 2012, the contingent liabilities with respect to the grants received from the OCS subject to repayment under this royalty agreement on future sales equal an amount of US\$ 93,462, not including interest. There is no expiration date with respect to Integrity Israel's obligations to pay royalties to the OCS in respect of the above.
- B. Integrity Israel currently leases approximately 3,100 sq. ft. of office space in the city of Ashkelon, Israel for its principal offices and prototype laboratory. The lease term began on February 1, 2006 and was extended until January 31, 2009. Pursuant to a verbal agreement with the landlord, Integrity Israel currently leases these facilities on a monthly basis at a cost of NIS 11,500 plus VAT per month (US\$ 3,080).
- C. In 2010, the Company engaged Andrew Garrett, Inc. as its exclusive placement agent (the "Placement Agent") in connection with an offering on a "best efforts" basis of a minimum 560,000 shares (US\$ 3,500,000) of the Company's Common Stock and a maximum of 2,000,000 shares of the Company's Common Stock (US\$ 12,500,000). Pursuant to a placement agent agreement with the Placement Agent, the Placement Agent (or its sub-agents) was entitled to receive, as a commission, an amount equal to 7% of the funds raised in the offerings, such amounts to be paid in cash, plus 3% of the funds as a management fee plus a 3% non-accountable expense allowance (13% in the aggregate). In addition, the placement agent agreement required the Company to issue to the Placement Agent (or its sub-agents) warrants to purchase up to 10% of the shares of Common Stock issued to investors (or underlying convertible securities issued to investors) in connection with the offerings at a price per share that will be equal to the offering price and subject to certain price adjustments as described below. In 2012, the Company engaged the Placement Agent, on substantially the same financial terms as those described above, in connection with an offering of up to \$5,000,000 of its Common Stock, which offering was subsequently converted to an offering of up to \$7,500,000 of Units consisting of Preferred Stock and Warrants.

In connection with the offerings described in Note 10, the Company paid to the Placement Agent US\$ 150,202, US\$ 366,412 and US\$ 753,850, respectively, in cash during 2012, 2011 and 2010, respectively. In addition, the Company issued to the Placement Agent warrants to purchase 0, 45,097 and 83,281 shares, respectively, of the Company's Common Stock with an exercise price of US\$ 0, US\$ 6.25 and US\$ 6.25 respectively. The warrants expire on the fifth anniversary of the date on which the shares of common stock underlying such warrants are fully registered with the SEC. The warrants include customary adjustment provisions for stock splits, reorganizations and other similar transactions and in addition, the warrants that were issued to the placement agent, included a limited Period (until September 1, 2012) Down-Round Protection under which the strike price of the warrants would be adjusted to a price per share at which the Company will subsequently issue stock, if such price per share is less than the original strike price of the warrants. See also Note 2Q, Note 10M, 10N and 17A.

INTEGRITY APPLICATIONS, INC.  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 9 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

- D. Y.H. Dimri Holdings, which was a shareholder of Integrity Israel prior to the reorganization and merger described in Note 1 ("Dimri"), has alleged (post the reorganization) that, in connection with such reorganization, certain of Dimri's rights in Integrity Israel were violated. Under Dimri's investment agreement, certain rights in Integrity Israel were granted to Dimri, including an anti-dilution provision that provided that Dimri's holdings in Integrity Israel would not be diluted below 18% of Integrity Israel's issued capital shares as a result of any investment in Integrity Israel. On the date of the reorganization, Dimri owned 18% of Integrity Israel's ordinary shares and, therefore, upon the completion of the reorganization, Dimri was entitled to receive 18% of the shares of common stock of the Company outstanding on such date in exchange for his shares in Integrity Israel, subject to the fulfillment of certain requirements. The Company's management, considering the legal advice of Israeli legal counsel, believe that, given Dimri no longer owns shares in Integrity Israel as a result of the reorganization, rights attached to the shares in Integrity Israel no longer exist in Integrity Israel and do not and have never existed in the Company. However, Dimri has refused to acknowledge or agree to the termination of these rights and has challenged the Company's position.

On June 23, 2011, Dimri appealed to the District Court of HaMerkaz District in Petah Tikva, Israel, requesting the court to appoint an arbitrator to decide the dispute between Integrity Israel, the founders of Integrity Israel and Mr. Dimri (HPB 40754-06-11). On September 25, 2011, Integrity Israel's legal counsel filed an answer with the Court, disputing the facts and allegation raised in Dimri's motion and suggesting choosing an arbitrator with certain capacities, experience and skills. On December 26, 2011, an arbitrator was appointed in this matter.

On March 20, 2012, Dimri submitted a statement of claim to the arbitrator and pled for a declaratory judgment against Integrity Israel and the founders of Integrity Israel. Dimri claimed that its rights under the loan and investment agreement, Integrity Israel's Articles of Association and two other internal agreements entered into among the founders of Integrity Israel are valid and in effect. Dimri also pled for an injunction requiring the founders of Integrity Israel to transfer shares of the Company's Common Stock held by them to Dimri, from time to time, in such amounts necessary so that Dimri's holdings in the Company would not be diluted below 18% of the Company's issued share capital at any time. The defendants in the arbitration submitted a statement of defense on May 28, 2012 and Dimri submitted a reply on June 14, 2012. At a preliminary session held on June 19, 2012, the arbitrator suggested that the parties meet with him in order to examine whether a settlement can be reached. A meeting for this purpose had been set for August 27, 2012 but has been postponed by the arbitrator. After several postponements, Dimri submitted its affidavits on October 16, 2012. The defendants submitted their affidavits on February 7, 2013. Testimony and summary hearings have been set for June 2013.

The Company does not know what other actions Mr. Dimri will ultimately bring, if any, and against whom they will be brought. Nevertheless, the Company, its legal counsel and Integrity Israel's legal counsel believe that the Company and Integrity Israel have substantial defenses to any such claims and appropriate claims and counterclaims of their own and they intend to strongly defend against any such action by Mr. Dimri and to assert their own claims and counterclaims as they deem necessary.

Notwithstanding the aforesaid, the Company, considering the advice of its Israeli legal counsel, is unable to assess or make any estimate of the amount of the reasonably possible range of loss, if any. Accordingly, no provision has been made for this claim.

**INTEGRITY APPLICATIONS, INC.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL**

**A. Description of the rights attached to the Shares in the Company**

Each share of Common Stock entitles the holder to one vote, either in person or by proxy, at meetings of stockholders. The holders are not permitted to vote their shares cumulatively. Accordingly, the stockholders of the Company's Common Stock who hold, in the aggregate, more than fifty percent of the total voting rights can elect all of the directors and, in such event, the holders of the remaining minority shares will not be able to elect any of such directors. The vote of the holders of a majority of the issued and outstanding shares of Common Stock entitled to vote thereon is sufficient to authorize, affirm, ratify or consent to such act or action, except as otherwise provided by law.

**B. Stock-based compensation**

1. Grants to non-employees

- a. During 2005, Integrity Israel granted to three consultants an aggregate sum of 144,250 of its ordinary shares of NIS 0.01 par value as consideration for consulting services. The compensation expense was recorded as an expense over the consulting service period (varying from 2 months to 2 years).

The non-cash compensation recorded with respect to such grants was US\$ 123,625, US\$ 229,564 and US\$ 175,516 for the years 2007, 2006 and 2005, respectively. The fair value of the shares was based on the recent share price applicable.

Following the merger with Integrity Israel, the shares were replaced with shares of common stock of the Company.

- b. In October 2006, the Company granted 45,531 options with an exercise price of US\$ 4.305 per share in consideration of investor finders. In November 2008, the Company granted 8,989 options with an exercise price of US\$ 5.517 per share in consideration of investor finders. The fair value of the grant was based on the most recent share price with respect to the relevant grant date.

Following the merger with Integrity Israel, the options were replaced with options of the Company.

- c. See Note 9C.

2. Grants to employees

- a. During 2005-2006, Integrity Israel granted to two individuals (an officer and a director), options exercisable into 24,394 options of NIS 0.01 par value of Integrity Israel. The exercise price of each option was US\$ 3.49 (with respect to 4,486 options) and US\$ 3.84 (with respect to 19,908 options). The vesting period was three years with respect to the 4,486 options and two months with respect to the 19,908 options.

The total non-cash compensation recorded with respect to such grants was US\$ 45,291, US\$ 2,435 and US\$ 203 for the years 2007, 2006 and 2005, respectively. The fair value of the grants, which was estimated using Black-Scholes option pricing model, was based, among other factors, on the most recent share price with respect to the relevant grant date.

Following the merger with Integrity Israel, the options were replaced with options of the Company.



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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 10 – SHARE CAPITAL (cont.)

**B. Stock-based compensation (cont.)**

2. Grants to employees (cont.)

- b. In August 2007, Integrity Israel's Board of Directors ("Integrity Israel's Board") approved a stock option plan ("Integrity Israel's plan") for the grant, without consideration of options exercisable into ordinary shares of NIS 0.01 par value of Integrity Israel to employees, officers and directors of Integrity Israel. The exercise price and vesting period for each grantee of options was determined by Integrity Israel's Board and specified in such grantee's option agreement. The options were to vest over a period of 1-12 quarters based on each grantee's option agreements. Any option not exercised within 10 years after the date of grant thereof will expire.

In July 2010, following the merger with Integrity Israel, the Company adopted the 2010 Share Incentive Plan (the "2010 Share Incentive Plan"), pursuant to which the Company's Board of Directors is authorized to grant options exercisable into Common Stock of the Company. The Company has reserved 529,555 shares of Common Stock for issuance under the plan. The purpose of the 2010 Share Incentive Plan is to offer an incentive to employees, directors, officers, consultants, advisors, suppliers and any other person or entity whose services are considered valuable to the Company, as well as to replace the Integrity Israel Plan and to replace all options granted in the past by Integrity Israel.

Upon the adoption of the 2010 Share Incentive Plan, all options granted under the Integrity Israel's Plan were replaced by options subject to the 2010 Share Incentive Plan on a 1 for 1 basis.

- c. On March 12, 2012, the Company granted to certain employees options to purchase 17,500 shares of Company's Common Stock at an exercise price of US\$6.25 per share. All options were granted in accordance with and subject to the terms of the Company's 2010 incentive Compensation Plan. The total non-cash compensation of this grant was approximately US\$ 50 thousand.
- d. As of December 31, 2012, 109,329 options have been granted to employees and 21,641 options to non-employees (excluding the options granted to related parties – see Notes 16A and 16B). All options granted in the Integrity Israel Plan until the date of the merger, were replaced with options of the Company and are subject to the 2010 Share Incentive Plan. The non-cash compensation relating to options granted to employees and directors was US\$ 21,859, US\$ 320 and US\$ 14,575 during the years ended December 31, 2012, 2011 and 2010, respectively.

As of December 31, 2012, there are 167,843 shares available for future grants under the 2010 Share Incentive Plan.

As of December 31, 2012, there were approximately \$29,326 of total unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the grants. This amount, which relate to the grants described beforehand, is expected to be recognized in 2013.

- e. As described in Note 16A and 16B, during the year ended December 31, 2011 and 2010, the Company granted to related parties 29,315 and 314,897 options, respectively.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL (cont.)**

**B. Stock-based compensation (cont.)**

2. Grants to employees (cont.)

The following tables present a summary of the status of the grants to employees, officers and directors as of December 31, 2012 and 2011:

	<u>Number</u>	<u>Weighted average exercise price (US\$)</u>
<b>Year ended December 31, 2012</b>		
Balance outstanding at beginning of year	454,354	5.44
Granted	17,500	6.25
Exercised	-	-
Forfeited	-	-
Balance outstanding at end of the year	<u>471,854</u>	<u>5.47</u>
Balance exercisable at the end of the year	<u>321,039</u>	<u>3.12</u>
	<u>Number</u>	<u>Weighted average exercise price (US\$)</u>
<b>Year ended December 31, 2011</b>		
Balance outstanding at beginning of year	428,367	5.37
Granted (*)	29,315	6.25
Exercised	-	-
Forfeited	<u>(3,328)</u>	<u>3.84</u>
Balance outstanding at end of the year	<u>454,354</u>	<u>5.44</u>
Balance exercisable at the end of the year	<u>110,142</u>	<u>2.81</u>

(\*) Represent the aggregate number of options required to be issued to Messrs. Gal and Malka with respect to the periods indicated pursuant to their employment agreements with the Company. The total number of options issuable to Messrs. Gal and Malka under their employment agreements was finalized in August 2011 and such options were issued in March 2012. See Note 16.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL (cont.)**

**B. Stock-based compensation (cont.)**

2. Grants to employees (cont.)

The aggregate intrinsic value of the awards exercisable as of December 31, 2012 and 2011 is US\$ 609,706 and US\$ 368,926, respectively. The aggregate intrinsic value of the awards outstanding as of December 31, 2012 and 2011 is US\$ 722,817 and US\$368,926, respectively. These amounts represent the total intrinsic value, based on management's estimate of the Company's stock price of US\$ 7 (based on the issuance described in Note 10L, below) as of December 31, 2012 and December 31, 2011, respectively, less the weighted exercise price.

The following tables summarize information about options outstanding at December 31, 2012:

Exercise prices US\$	Outstanding at December 31, 2012	Weighted average remaining contractual life years	Weighted average exercise price	Exercisable at December 31, 2012	Weighted average exercise price
1.72	46,004	4.6	1.72	46,004	1.72
3.27	30,966	2.9	3.27	30,966	3.27
3.48	4,486	2.9	3.48	4,486	3.48
3.63	4,849	4.6	3.63	4,849	3.63
3.84	16,580	4.0	3.84	16,580	3.84
5.52	2,984	6.6	5.52	2,984	5.52
6.02	4,273	4.1	6.02	4,273	6.02
6.25	344,212	8.0	6.25	202,997	6.25
6.25	17,500	9.8	6.25	7,900	6.25
	<u>471,854</u>			<u>321,039</u>	

The fair value of options granted was estimated at the dates of grant using the Black-Scholes option pricing model. The following are the data and assumptions used:

	2012	2011	2010
Dividend yield (%)	0	0	0
Expected volatility (%) (*)	50	50	50
Risk free interest rate (%)	2	2	2
Expected term of options (years) (**)	6	5-6	5-6
Exercise price (US dollars)	6.25	6.25	6.02/6.25
Share price (US dollars) (***)	6.25	6.25	6.02/6.25
Fair value (US dollars)	3.08	3.08	2.81/3.08

(\*) Due to the fact that the Company shares are not traded in a sufficient volume, the expected volatility was based on the historic volatility of public companies which operate in the same industry sector.

(\*\*) Due to the fact that the Company does not have sufficient historical exercise data, the expected term was determined based on the "simplified method" in accordance with Staff Accounting Bulletin No. 110.

(\*\*\*) The fair value of the share was based on the most recent share prices, as applicable to each grant.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL (cont.)**

**C. Convertible notes**

1. In April 2010, the Company issued Secured Notes (“Senior Notes”) in the aggregate initial principal amount of US\$ 999,000 together with rights to acquire Common Stock following the reorganization and merger described in Note 1. The principal amount of the notes, together with any interest accrued but unpaid thereon, and any fees and charges, are referred to collectively as the “Outstanding Amount” of such Senior Notes.

The Senior Notes provided for an interest rate of 9% per annum and were due and payable on the first to occur of (a) the date of the closing of the Company’s next Qualified Financing (as defined therein); or (b) August 9, 2010, provided that the holders of Senior Notes were permitted to extend the date in clause (b) by up to 60 days with respect to all of the Senior Notes (the “Maturity Date”). Interest on the Senior Notes was to be paid on the Maturity Date if such interest was not exchanged for Common Stock in the manner described above.

Immediately after the initial closing of the Offering, each purchaser of a Senior Note (a “Senior Note Purchaser”) was entitled to receive Common Stock issued and sold at the closing of the Offering in accordance with the following:

- (i) If the Senior Note Purchaser elected, to be repaid under its Senior Note in shares of Common Stock in lieu of any cash, such Senior Note Purchaser received the number of shares of Common Stock equal to the quotient obtained by dividing (i) 200% of the unpaid portion of the Outstanding Amount of such Senior Note Purchaser’s Senior Note by (ii) the offering price per share of the Common Stock, rounded to the nearest whole share; or
- (ii) If the Senior Note Purchaser did not make the election in clause (i) above, such Senior Note Purchaser instead received the number of shares of Common Stock equal to the quotient obtained by dividing (i) 100% of the unpaid portion of the Outstanding Amount of such Senior Note Purchaser’s Senior Note by (ii) the offering price per share of the Common Stock, rounded to the nearest whole share, in addition to a cash payment equal to the Outstanding Amount of such Senior Note Purchaser’s Senior Note pursuant to the terms thereof.

The original amount of the Senior Notes (US\$ 999,000), which entitled the holders of the Senior Notes to an either cash or stock settlement at a price per share equal to the fair value of the share that would be determined at the offering, represented stock-settled debt under the provisions of ASC Topic 47-20, “*Debt-Debt with Conversion and Other Options*”. Due to the conversion price, the Company has determined that this component did not provide an active beneficial conversion feature. However, the entitlement of the Senior Note holders to receive a fixed value of Common Stock in an amount equal to 100% of the original amount of the Senior Notes (in addition to the stock settled debt described above), which represented an obligation to issue a variable number of shares under the provisions of ASC Topic 480, “*Distinguishing Liabilities for Equity*” (totaling US\$ 999,000), was recognized as a stock-based interest compensation (which was included among financing expenses, net), over the term of the Senior Notes (April 2010 - August 2010).

On December 16, 2010, the Company completed an initial closing of the Offering, at which the Company issued 87,977 shares of Common Stock to certain holders of Senior Notes, who held an amount of US\$ 549,797 (including unpaid interest) and which elected to be repaid in shares. The remaining amount of the Senior Notes, US\$ 527,396 (including unpaid interest), was settled in cash.

In addition, the Company issued 171,208 shares of Common Stock to the holders of Senior Notes as a repayment of the obligation to issue a variable number of shares. The fair value of the shares (US\$ 1,069,244) represents 100% of the original amount of the Senior Notes and interest accumulated up to the Offering date.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL (cont.)**

**C. Convertible notes (cont.)**

1. (cont.)

The Company issued to the Placement Agent warrants to purchase an aggregate of 25,919 shares of Common Stock with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 129,870 in cash (see Note 9C).

2. In November 2010, Integrity Israel issued Unsecured Junior Promissory Notes ("Junior Notes") in the aggregate initial principal amount of US\$ 170,000 (of which US\$ 25,000 was received in 2011). The Junior Promissory Notes were substantially similar to the Senior Notes, except that immediately after the initial closing of the Offering, each holder of Junior Promissory Notes was entitled to receive the number of shares of Common Stock equal to the quotient obtained by dividing (i) 200% of the Outstanding Amount of such holder's Junior Promissory Note by (ii) the price per share of the Common Stock in the Offering, rounded to the nearest whole share. The entitlement to receive a fixed value of Common Stock sold at the closing of the Offering in an amount equal to 200% of the original amount of the Junior Notes was recognized as an obligation to issue a variable number of shares under the provisions of ASC Topic 480, "*Distinguishing Liabilities for Equity*", accordingly an amount equal to 100% of the original amount of the Junior Notes was recognized as stock-based interest compensation (which was included among financing expenses, net) over the term of the Junior Notes (November 2010 – December 2010).

On December 16, 2010, the Company completed an initial closing of the Offering, at which, 54,792 shares of Common Stock were issued to the purchasers of the Junior Promissory Notes pursuant to the terms and in full repayment of such Junior Promissory Notes. The fair value of the shares (US\$ 345,100) represents 200% of the original amount of the Senior Notes and interest accumulated up to the Offering date.

The Company issued to the Placement Agent, warrants to purchase an aggregate of 5,480 shares of Common Stock with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 77,292 in cash (see Note 9C).

- D.** On December 16, 2010, the Company completed an initial closing of the Offering at which the Company received an amount of US\$ 3,016,250 for 482,600 shares of Common Stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 48,260 shares of Common Stock at the third closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 392,112 in cash (see Note 9C).
- E.** On December 30, 2010, the Company completed a second closing of the Offering at which the Company received an amount of US\$ 300,000 for 48,000 shares of Common Stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 4,800 shares of Common Stock at the third closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 39,000 in cash (see Note 9C).
- F.** On January 31, 2011, the Company completed a third closing of the Offering at which the Company received an amount of US\$ 102,000 for 16,320 shares of Common Stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 1,632 shares of Common Stock at the third closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 13,260 in cash (see Note 9C).

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 10 – SHARE CAPITAL (cont.)**

- G.** On March 31, 2011, the Company completed a fourth closing of the Offering at which the Company received an amount of US\$ 567,300 for 90,768 shares of Common Stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 9,077 shares of Common Stock at the fourth closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 73,749 in cash (see Note 9C).
- H.** On April 29, 2011, the Company completed a fifth closing of the Offering at which the Company received an amount of US\$ 250,000 for 40,000 shares of common stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 4,000 shares of common-stock at the fifth closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 32,500 in cash (see Note 9C).
- I.** On May 31, 2011, the Company completed a sixth closing of the Offering at which the Company received an amount of US\$ 213,750 for 34,200 shares of common stock issued to investors in the Offering representing a price per share of US\$ 6.25. The Company issued to the Placement Agent, warrants to purchase an aggregate of 3,420 shares of common-stock at the sixth closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 27,788 in cash (see Note 9C).
- J.** On July 29, 2011, the Company completed a seventh closing of the Offering at which the Company received an amount of US\$ 1,685,500 for 269,680 shares of Common Stock. The Company issued to the Placement Agent, warrants to purchase an aggregate of 26,968 shares of common-stock at the seventh closing with an exercise price of US\$ 6.25 and in addition was required to pay US\$ 219,115 in cash (see Note 9C).
- K.** Purchasers of the common stock in the Offering are entitled to anti-dilution protection until September 1, 2012 for certain issuances of common stock by the Company for less than US\$ 6.25 per share.
- L.** On November 19, 2012, the Company issued 165,057 shares of its Common Stock at a price of \$7.00 per share. The issuance and sale of such shares constitutes the initial closing (the “Initial Closing”) of an offering by the Company of up to 785,714 shares of its Common Stock to accredited investors (the “First Closing Purchasers”) at a price of \$7.00 per share in a private placement transaction.

The Company received gross proceeds of \$1.15 million from the sale of the shares described above. The Company intends to use the remainder of the proceeds from the initial closing, and additional proceeds from the offering, for general corporate purposes. See also M. above.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 10 – SHARE CAPITAL (cont.)

- M. Subsequent to the Initial Closing (during 2013), the offering was converted from an offering of Common Stock to an offering of Units, each consisting of (a) one share of our newly designated Series A 5% Convertible Preferred Stock, par value \$0.001 per share (the “Preferred Stock”), convertible into shares of Common Stock at an initial conversion price of \$5.80 per share, and (b) a warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of Common Stock issuable upon conversion of such share of Preferred Stock. As a result of the conversion of the offering from an offering of Common Stock to an offering of Units, the Company agreed with the placement agent for the offering that, following the closing of the sale of the Units, the Company will exchange the shares of Common Stock acquired by each First Closing Purchaser in the first closing for such number of Units equal to the aggregate purchase price paid by such First Closing Purchaser in the first closing, divided by \$1,000, in each case subject to the execution by the First Closing Purchaser of a consent to such modification. In addition, the Company also agreed with the placement agent for the offering that, following the closing of the sale of the Units, the Company will issue to the holders of the 1,295,535 shares of common stock issued by it at a price of \$6.25 per share pursuant to seven closings of a private placement (the “Previous Private Placement”) described in paragraphs D-J above, respectively, such number of shares of Common Stock as would reduce the per share purchase price paid by such holders for such shares from \$6.25 per share to \$5.80 per share, in each case subject to the execution by the holder of a consent to such modification.

In connection with the conversion of the offering from an offering of Common Stock to an Offering of Units, the Company agreed with the placement agent for the offering that any warrants issuable to the placement agent in connection with its services as placement agent for the offering would be issuable after the exchange of the shares of Common Stock issued to the First Closing Purchasers for Units as described above.

The Company also agreed to amend the warrants issued to the placement agent in connection with previous issuers in order to lower the exercise price from US\$ 6.25 to US\$ 5.8 per share.

On March 13, 2013, the Company issued and sold 6,300 Units at a price of \$1,000 per Unit. See Note 17A, subsequent events.

- N. During the reported period, the down-round protection period of the warrants that were issued to the placement agent in connection with the Company’s prior private placement completed in July 2011 (the “Previous Private Placement”) lapsed. Such warrants included a limited period (until September 1, 2012) down-round protection under which, if the Company issued additional shares of its common stock during such period for a price of less than \$6.25 per share, the strike price of the warrants would be adjusted down from \$6.25 per share to the price per share at which such additional shares of Company common stock (if any) were issued. The warrants were classified as a liability and measured at fair value through earnings until the down-round protection period ended and their exercise price became fixed, at which date such warrants were reclassified to equity.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 11 – RESEARCH AND DEVELOPMENT EXPENSES, NET

	US dollars			Cumulative period from September 30, 2001 (date of inception) through December 31, 2012
	Year ended December 31,			
	2012	2011	2010	
Salaries and related expenses	1,289,890	1,194,170	557,042	6,136,912
Professional fees	262,752	210,674	94,711	1,705,505
Materials	166,480	60,360	19,114	646,195
Depreciation	25,546	22,835	53,219	251,221
Travel expenses	4,116	119,498	58,215	348,183
Vehicle maintenance	33,035	33,856	33,697	274,455
Other	138,871	147,908	118,058	1,207,395
	1,920,690	1,789,301	934,056	10,569,866
Less: Grants from the OCS (*)	-	-	-	(93,462)
	1,920,690	1,789,301	934,056	10,476,404

(\*) See Note 9A.

NOTE 12 – GENERAL AND ADMINISTRATIVE EXPENSES

	US dollars			Cumulative period from September 30, 2001 (date of inception) through December 31, 2012
	Year ended December 31,			
	2012	2011	2010	
Salaries and related expenses	255,839	162,221	55,995	686,595
Professional fees	392,832	336,308	365,398	1,883,855
Travel & expenses	119,757	-	-	119,757
Vehicle maintenance	14,506	5,534	5,947	53,962
Other	69,974	40,082	30,155	270,473
	852,908	544,145	457,495	3,014,642



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 13 – FINANCING EXPENSES, NET**

	US dollars			Cumulative period from September 30, 2001 (date of inception) through December 31 2012
	Year ended December 31,			
	2012	2011	2010	
Linkage difference on principal of loans from stockholders	9,849	24,934	15,909	186,898
Exchange rate differences	18,147	(4,638)	(51,844)	252,044
Warrants with down-round protection	(35,892)	-	-	(35,892)
Stock-based interest compensation to holders of convertible notes (see Note 10C)	-	-	1,214,943	1,214,943
Interest expenses on credit from banks and other	6,605	10,597	17,987	(19,113)
Interest expenses and other, related to convertible notes	-	-	200,812	200,812
	(1,291)	30,893	1,397,807	1,799,692

**NOTE 14 – INCOME TAX**

**A. Measurement of results for tax purposes under the Israeli Income Tax (Inflationary Adjustments) Law, 1985 (the “Inflationary Adjustment Law”)**

Until December 31, 2007, Integrity Israel reported for tax purposes in accordance with the provisions of the Inflationary Adjustments Law, whereby taxable income was measured in NIS, adjusted for changes in the Israeli Consumer Price Index.

Results of operations for tax purposes were measured in terms of earnings in NIS after adjustments for changes in the Israeli Consumer Price Index (“CPI”). Commencing January 1, 2008, the Inflationary Adjustment Law became void and in its place there are transition provisions, whereby the results of operations for tax purposes are to be measured on a nominal basis.

**B. Reduction in Israeli corporate tax rates**

On July 23, 2009, as part of the Economic Efficiency Law (Legislative Amendments for the Implementation of the Economic Plan for the years 2009 and 2010) – 2009 (the “Arrangements Law”), article 126 of the Income Tax Ordinance (New Version) – 1961 was amended, whereby the Israeli corporate tax rate would be gradually reduced commencing in the 2011 tax year and thereafter, as follows: 2011 – 24%, 2012 – 23%, 2013 – 22%, 2014 – 21%, 2015 – 20% and 2016 and thereafter – 18%.

On December 6, 2011, the Law for the Change in the Tax Burden (Legislative Amendments) – 2011 was publicized. As part of the law, among other, the Economic Efficiency Law (Legislative Amendments for the Implementation of the Economic Plan for 2009 and 2010) – 2009 and the Income Tax Ordinance (New Version) – 1961 were amended whereby, commencing in 2012, the blueprint for the reduction in the corporate tax rates will be cancelled and the corporate tax rate will be 25%. Publication of the Law did not have a material impact on the financial statements of the Company.

**C. Tax assessments**

The Company and Integrity Israel have not received final tax assessments since their inception.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 14 – INCOME TAX (cont.)**

**D. Carryforward tax losses**

As of December 31, 2012, the Company and Integrity Israel has loss carry forward balances for income tax purposes of nearly US\$ 0.9 million and US\$ 12 million, respectively, that are available to offset future taxable income, if any.

**E.** The following is a reconciliation between the theoretical tax on pre-tax income, at the tax rate applicable to the Company (federal tax rate) and the tax expense reported in the financial statements:

	US dollars		
	Year ended December 31,		
	2012	2011	2010
Pretax loss	(2,772,307)	(2,364,339)	(2,788,446)
Federal tax rate	35%	35%	35%
Income tax benefit computed at the ordinary tax rate	(970,307)	(827,519)	(975,956)
Non-deductible expenses	4,553	4,885	4,688
Stock-based compensation	122,333	132,325	5,101
Stock-based interest compensation to holders of convertible notes	-	-	425,229
Tax in respect of differences in corporate tax rates	277,231	236,434	278,844
Losses and timing differences in respect of which no deferred taxes were generated	566,190	453,875	262,094
	-	-	-

**F.** Deferred taxes result principally from temporary differences in the recognition of certain revenue and expense items for financial and income tax reporting purposes. Significant components of the Group's future tax assets are as follows:

	US dollars		
	2012	December 31, 2011	2010
Composition of deferred tax assets:			
Provision for employee-related obligation	47,440	42,137	36,568
Non-capital loss carry forwards	3,496,123	2,890,426	2,393,919
Valuation allowance	(3,543,563)	(2,932,563)	(2,430,487)
	-	-	-

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 15 – LOSS PER SHARE**

The loss and the weighted average number of shares used in computing basic and diluted loss per share for the years ended December 31, 2012, 2011 and 2010, are as follows:

	US dollars		
	Year ended December 31,		
	2012	2011	2010
Loss for the year	2,772,307	2,364,339	2,788,446
	Number of shares		
	Year ended December 31,		
	2012	2011	2010
Weighted average number of shares used in the computation of basic and diluted earnings per share	5,314,800	5,091,330	4,034,706
Total weighted average number of ordinary shares related to outstanding options and warrants excluded from the calculations of diluted loss per share (*)	600,232	582,732	511,648

(\*) All outstanding stock options and warrants have been excluded from the calculation of the diluted net loss per share for all the reported periods, since the effect of the shares issuable with respect of these instruments was anti-dilutive.

**NOTE 16 – RELATED PARTIES**

- A. Avner Gal, the owner of approximately 9.7% of the Company's outstanding Common Stock as of March 31, 2013, entered into an employment agreement with Integrity Israel in July 2010 pursuant to which Mr. Gal agreed to continue to serve as the chief executive officer and managing director of Integrity Israel. The agreement was approved by the board of directors and stockholders of Integrity Israel. Mr. Gal's employment agreement provides for an annual salary of NIS 480,000 (US\$ 125,622) and an annual bonus to be determined by the Board of Directors and an additional sum provided that Mr. Gal reaches certain milestones approved by the Board, as well as the payment of certain social and insurance benefits and the use of a group four car. The agreement also provides for a renegotiation of Mr. Gal's annual salary on the one-year anniversary thereof and the renegotiation of Mr. Gal's bonus formula once Integrity Israel has begun commercialization of its products. The agreement is terminable by either party on 180 days notice, immediately by Integrity Israel with the payment of an amount equal to 180 days of annual salary, or immediately by Integrity Israel for cause (as defined in the agreement) without the payment of severance. Mr. Gal is subject to a non-compete and a confidentiality agreement during the term of the agreement and for one year thereafter.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 16 – RELATED PARTIES (cont.)**

**A. (cont.)**

Pursuant to his employment agreement with Integrity Israel, Mr. Gal was entitled to receive options to purchase 5% of all issued and outstanding Common Stock of the Company after the offering for sale of a minimum 560,000 shares (\$3,500,000) of the Company's Common Stock and a maximum of 2,000,000 shares of the Company's Common Stock (\$12,500,000). The offering (which commenced in December 2010) was completed in July 2011 and in March 2012, Mr. Gal was granted options to purchase up to 264,778 shares of Common Stock. The options shall be deemed vested, in 3 equal parts, in accordance with the achievement of the following milestones: (i) submission of clinical trials' results to the Notified Body; (ii) CE mark approval; (iii) FDA approval. The options will be exercisable at \$6.25 per share. In the event of a merger and/or acquisition in which one or more of the abovementioned milestones have not yet been met, the options shall be deemed vested on the date of the merger and/or acquisition. All options granted as described above are subject to the terms of the 2010 share incentive plan.

The total non-cash compensation recorded with respect to such grants was US\$ 252,048 for the year ended December 31, 2012. The fair value of the shares was based on the recent share price applicable.

- B.** David Malka, the owner of 4.5% of the Company's outstanding Common Stock as of March 31, 2013, entered into an employment agreement with Integrity Israel in July 2010 pursuant to which Mr. Malka agreed to continue to serve as the vice president of operations of Integrity Israel. The agreement was approved by the board of directors and stockholders of Integrity Israel. Mr. Malka's employment agreement provides for an annual salary of NIS 240,000 (US\$ 62,811) and an annual bonus to be determined by the Board of Directors in its sole discretion and an additional sum provided that Mr. Malka reaches certain milestones approved by the Board, as well as the payment of certain social and insurance benefits and the use of a group three car. The agreement also provided for a renegotiation of Mr. Malka's annual salary on the one-year anniversary thereof and the renegotiation of Mr. Malka's bonus formula once Integrity Israel has begun commercialization of its products. The agreement is terminable by either party on 90 days notice, immediately by Integrity Israel with the payment of an amount equal to 90 days of annual salary, or immediately by Integrity Israel for cause (as defined in the agreement) without the payment of severance. Mr. Malka is subject to a non-compete and confidentiality agreement during the term of the agreement and for one year thereafter.

Pursuant to his employment agreement with Integrity Israel, Mr. Malka was entitled to receive options to purchase 1.5% of all issued and outstanding Common Stock of the Company after the offering for sale of a minimum 560,000 shares (\$3,500,000) of the Company's Common Stock and a maximum of 2,000,000 shares of the Company's common stock (\$12,500,000). The offering (which commenced in December 2010) was completed in July 2011 and in March 2012 Mr. Malka was granted options to purchase up to 79,434 shares of Common Stock. The options shall be deemed vested, in equal parts, in accordance with the achievement of the following milestones: (i) Submission of clinical trials' results to the Notified Body; (ii) CE mark approval; (iii) FDA approval. The options will be exercisable at \$6.25 per share. In the event of a merger and/or acquisition in which one or more of the abovementioned milestones have not yet been met, the options shall be deemed vested on the date of the merger and/or acquisition. All options granted as described above are subject to the terms of the 2010 share incentive plan.

The total non-cash compensation recorded with respect to such grants was US\$ 75,615 for the year ended December 31, 2012. The fair value of the shares was based on the recent share price applicable.

- C.** Zicon Ltd., a company of which Zvi Cohen, a director of the Company and an owner of 6.83% of the Company's outstanding Common Stock, was a principal stockholder, officer and director, has manufactured certain PC boards for Integrity Israel during the years 2006-2010. In the years 2008-2010, total compensation paid by the Company to Zicon has been less than US\$ 20,000, each year.

- D.** See Notes 3, 6 and 8.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)

NOTE 17 – SUBSEQUENT EVENTS

- A. On March 13, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors (the “Unit Purchasers”) pursuant to which, on March 13, 2013, the Company issued to the Unit Purchasers an aggregate of 6,300 Units, each consisting of (a) one share of the Company’s newly designated Preferred Stock, convertible into shares of Common Stock at an initial conversion price of \$5.80 per share, and (b) a Warrant to purchase, at an exercise price of \$6.96 per share, up to 100% of the shares of Common Stock issuable upon conversion of such share of Preferred Stock. The shares of Preferred Stock comprising the Units are convertible into an aggregate of 1,086,206 shares of Common Stock and the Warrants comprising the Units are exercisable for an aggregate of 1,086,206 shares of common stock, in each case subject to adjustment as described below. The Company received \$5.5 million from the sale of the Units (net of related expenses).

The conversion price of the Preferred Stock is subject to adjustment for certain issuances of Common Stock or other securities of the Company at an effective price per share that is lower than the conversion price then in effect, as well as for stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders.

Holders of Preferred Stock are entitled to receive cumulative dividends at a rate of 5% per annum, based on the stated value per share of Preferred Stock, which was initially \$1,000 per share. Dividends on the Preferred Stock are payable quarterly on March 31, June 30, September 30 and December 31 of each year, beginning on March 31, 2013, and on each conversion date (with respect to the shares of Preferred Stock being converted). Until September 13, 2013, dividends are payable only in cash. Thereafter, dividends on the Preferred Stock will be payable, at the option of the Company, in cash and/or, if certain conditions are satisfied (including, among others, that the volume weighted average trading price for the Common Stock on its principal trading market is equal to or greater than 110% of the then current conversion price for the Preferred Stock for five consecutive trading days prior to the dividend payment date), in shares of Common Stock. Shares of Common Stock issued as payment of dividends, if any, will be valued at the then current conversion price of the Preferred Stock. The Company will incur a late fee of 9% per annum, payable in cash, on dividends that are not paid within three trading days of the applicable dividend payment date.

The Company may become obligated to redeem the Preferred Stock in cash upon the occurrence of certain triggering events, including, among others, a material breach by the Company of certain contractual obligations to the holders of the Preferred Stock, the occurrence of a change in control of the Company, the occurrence of certain insolvency events relating to the Company, or the failure of the Common Stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or a regulated quotation service. In addition, upon the occurrence of certain triggering events, each holder of Preferred Stock will have the option to require the Company to redeem such holder’s shares of Preferred Stock for a redemption price payable in shares of Common Stock or receive an increased dividend rate of 9% on all of such holder’s outstanding Preferred Stock.

Subject to certain conditions contained in the Certificate of Designations, Preferences and Rights relating to the Preferred Stock (the “Certificate of Designations”), the Company will have the option to force the conversion of the Preferred Stock (in whole or in part) if the volume weighted average price for the Common Stock on its principal trading market exceeds \$11.60 for each of any 20 trading days during any 30 consecutive Trading Day period and the average daily dollar trading value for the Common Stock during such 30 day period exceeds \$100,000.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 17 – SUBSEQUENT EVENTS (cont.)**

**A.** (cont.)

If the Company fails to timely deliver certificates for shares of Common Stock issuable upon conversion of the Preferred Stock (the “Conversion Shares”) and, as a result, the holder is required by its brokerage firm to purchase shares of Common Stock to deliver in satisfaction of a sale by such holder of the Conversion Shares (a “Buy-In”), the Company will be required to: (a) pay the converting holder in cash an amount equal to the amount, if any, by which such holder’s total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds the product of (i) the aggregate number of Conversion Shares due to the holder, multiplied by (ii) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions); and (b) at the option of such holder, either reissue (if surrendered) the shares of Preferred Stock equal to the number of shares of Preferred Stock submitted for conversion (in which case, such conversion will be deemed rescinded) or deliver to such holder the number of shares of Common Stock that would have been issued if the Company had timely complied with its delivery requirements. In addition, the Company will be required to pay partial liquidated damages of \$10 for each \$1,000 of stated value of any shares of Preferred Stock which have been converted by a holder and in respect of which the Company fails to deliver Conversion Shares by the eighth day following the applicable conversion date.

As long as at least 15% of the originally issued shares of Preferred Stock are outstanding, without the written consent of the holders of a majority in stated value of the outstanding Preferred Stock, the Company will not be permitted to, among other things, incur indebtedness or liens not permitted under the Certificate of Designations; repay, repurchase, pay dividends on or otherwise make distributions in respect of any shares of Common Stock or other securities junior to the Preferred Stock; or enter into certain transactions with affiliates of the Company.

Subject to the beneficial ownership limitation described below, holders of Preferred Stock will vote together with the holders of Common Stock on an as-converted basis. Holders will not be permitted to convert their Preferred Stock if such conversion would cause such holder to beneficially own more than 4.99% of the outstanding Common Stock (subject to increase to 9.99%, at the option of the holder, upon no less than 61 days prior written notice to the Company) (the “Beneficial Ownership Limitation”). In addition, no holder may vote any shares of Preferred Stock (on an as converted to Common Stock basis) in excess of the Beneficial Ownership Limitation.

Subject to certain limitations, so long as any Purchaser holds any shares of Preferred Stock, if (1) the Company sells any shares of Common Stock or other securities convertible into, or rights to acquire, Common Stock and (2) a Purchaser then holding Preferred Stock, Warrants, Conversion Shares or Warrant Shares (defined below) reasonably believes that any of the terms and conditions appurtenant to such issuance or sale are more favorable to the purchaser in such subsequent sale of securities than are the terms and conditions granted to such Purchaser, then the Purchaser will be permitted to require the Company to amend the terms of this transaction (only with respect to such Purchaser) so as to match the terms of the subsequent issuance (including, for the avoidance of doubt, any terms and provisions that are or may be less favorable to such Purchaser).

The Warrants have a five-year term commencing on March 13, 2013 and ending on March 31, 2018. Until the end of the term, the Warrants will be exercisable at any time and from time to time at an exercise price of \$6.96 per share. The Warrants contain adjustment provisions substantially similar to those to the adjustment provisions of the Preferred Stock as described above. In addition, the Warrants provide for protection for a Buy-In on substantially the same terms as described above with respect to the Preferred Stock. No holder may exercise its Warrants in excess of the Beneficial Ownership Limitation.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (cont.)**

**NOTE 17 – SUBSEQUENT EVENTS (cont.)**

**A.** (cont.)

In addition, pursuant to the Placement Agent Agreement, the Company is required to issue to the Placement Agent, as partial consideration for its services as such, warrants to purchase up to 108,620 Shares of Common Stock at an exercise price of \$5.8 per share and up to an additional 108,620 Shares of Common Stock at an exercise price of \$6.96 per share (plus warrants to purchase up to an additional 19,920 shares of Common Stock following the exchange of the shares of Common Stock issued to the First Closing Purchasers for Units, as described in Note 10M above).

In connection with the closing of the issuance and sale of the Units, the Company agreed to exchange the shares of Common Stock sold to the First Closing Purchasers and to issue additional shares to certain investors in the Company. See Note 10M.

**B.** See Note 9D.

**Item 9. Change in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. 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 December 31, 2012. 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 SEC’s rules and forms. 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, 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 December 31, 2012, 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.



### ***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control --- Integrated Framework. Management has concluded that, as of December 31, 2012, its internal control over financial reporting is effective based on these criteria.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the fiscal year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### ***Attestation Report of the Registered Public Accounting Firm***

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm because we are a smaller reporting company.

### **Item 9B. Other Information.**

None.

### PART III

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information required for this item is incorporated by reference from our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Shareholders.

**Item 11. Executive Compensation.**

The information required for this item is incorporated by reference from our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Shareholders.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required for this item is incorporated by reference from our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Shareholders.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required for this item is incorporated by reference from our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Shareholders.

**Item 14. Principal Accounting Fees and Services.**

The information required for this item is incorporated by reference from our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Shareholders.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules.

#### (a) Document List

##### (1) *Financial Statements:*

The financial statements of the Company filed herewith are set forth in Part II, Item 8 of this Report.

##### (2) *Financial Statement Schedules:*

None.

##### (3) *Exhibits Required by Item 601 of Regulation S-K:*

<b>Exhibit Number</b>	<b>Description</b>
2.1	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)
3.1	Certificate of Incorporation of Integrity Applications, Inc. (1)
3.2	Certificate of Amendment to Certificate of Incorporation of Integrity Applications, Inc. (1)
3.3	Certificate of Designation of Preferences and Rights of Series A 5% Convertible Preferred Stock (2)
3.4	Bylaws of Integrity Applications, Inc. (1)
4.1	Specimen Certificate Evidencing Shares of Common Stock (1)
4.2	Form of Common Stock Purchase Warrant (1)
4.3	Form of Securities Purchase Agreement (2)
4.4	Form of Common Stock Purchase Warrant (2)
4.5	Form of Registration Rights Agreement (2)
10.1*	Integrity Applications, Inc. 2010 Incentive Compensation Plan (1)
10.2	Form of Subscription Agreement between Integrity Applications, Inc. and the investor signatory thereto (1)
10.3	Registration Rights Agreement, dated December 16, 2010, by and among Integrity Applications, Inc., Andrew Garrett, Inc. and each investor signatory thereto (1)
10.4*	Form of Director and Officer Indemnification Agreement (1)
10.5	Exclusive Placement Agent Agreement, dated as of September 1, 2009, by and between Andrew Garrett, Inc. and A.D. Integrity Applications Ltd. (1)
10.6	Amendment No. 1 to Exclusive Placement Agent Agreement, effective as of December 16th, 2010, by and between Andrew Garrett, Inc., Integrity Applications, Inc. and A.D. Integrity Applications Ltd. (1)
10.7*	Personal Employment Agreement, dated as of July 22, 2009, between A.D. Integrity Applications Ltd. and Avner Gal (1)

10.8*	Personal Employment Agreement, dated as of July 22, 2010, between A.D. Integrity Applications Ltd. and David Malka (1)
10.9*	Letter Agreement, dated November 10, 2010, by and among Integrity Applications Inc., Integrity Applications Ltd. and Xplanit Ltd. (1)
10.10	Irrevocable Undertaking of Indemnification, dated as of July 26, 2010, by and among Integrity Applications, Inc., Avner Gal, Zvi Cohen, Ilana Freger, David Malka and Alexander Raykhman (1)
10.11	Investment Agreement, dated February 18, 2003, between A.D. Integrity Applications Ltd., Avner Gal, Zvi Cohen, David Freger and David Malka and Yigal Dimri (1)
10.12	Agreement, dated as of November 1, 2005 by and between A.D. Integrity Applications Ltd. and Diabeasy Diabeasy cc. (4)
10.13	Agreement, dated as of October 2, 2005, by and between Technology Transfer Group and Integrity Applications Ltd. (1)
10.14*	Form of Stock Option Agreement (1)
10.15*	Form of Stock Option Agreement (ESOP) (1)
10.16	Letter of Approval, addressed to Integrity Applications Ltd. from the Ministry of Industry, Trade and Employment of the State of Israel (5)
10.17	Letter of Undertaking, addressed to the Ministry of Industry, Trade and Employment of the State of Israel - Office of the Chief Scientist from Integrity Applications Ltd. (3)
10.18	Investment Agreement, dated March 16, 2004, by and among A.D. Integrity Applications Ltd., Yitzhak Fisher, Asher Kugler and Nir Tarlovsky. (4)
10.19*	Personal Employment Agreement, dated as of December 6, 2011, between A.D. Integrity Applications Ltd. and Jacob Bar-Shalom. (6)
21.1	Subsidiaries of Integrity Applications, Inc. (1)
31.1	Certification of Chief Executive Officer Pursuant to Exchange Act Rule 13a-14(a) or 15(d)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15(d)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS	XBRL Instance Document (7)
101.SCH	XBRL Schema Document (7)
101.CAL	XBRL Calculation Linkbase Document (7)
101.LAB	XBRL Label Linkbase Document (7)
101.PRE	XBRL Presentation Linkbase Document (7)
101.DEF	XBRL Definition Linkbase Document (7)

- (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.
- (2) Previously filed as an exhibit to the Company's Current Report on Form 8-K, as filed with the SEC on March 18, 2013.
- (3) Previously filed as an exhibit to Amendment No. 1 to the Company's Registration Statement on Form S-1, as filed with the SEC on October 7, 2011.
- (4) Previously filed as an exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-1, as filed with the SEC on October 27, 2011.
- (5) Previously filed as an exhibit to Amendment No. 3 to the Company's Registration Statement on Form S-1, as filed with the SEC on November 10, 2011.
- (6) Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC on March 14, 2012.
- (7) Filed herewith pursuant to Rule 405(a)(2)(ii) of Regulation S-T. Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 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, and otherwise are not subject to liability under those sections.



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 as of this 1<sup>st</sup> day of April, 2013.

### INTEGRITY APPLICATIONS, INC.

By: /s/ Avner Gal

Name: Avner Gal

Title: Chairman of the Board  
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Avner Gal</u> Avner Gal	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	April 1, 2013
<u>/s/ Jacob Bar-Shalom</u> Jacob Bar-Shalom	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 1, 2013
<u>/s/ Zvi Cohen</u> Zvi Cohen	Director	April 1, 2013
<u>/s/ Israel Ehrlich</u> Israel Ehrlich	Director	April 1, 2013
<u>/s/ Dr. Robert Fischell</u> Dr. Robert Fischell	Director	April 1, 2013
<u>/s/ Joel L. Gold</u> Joel L. Gold	Director	April 1, 2013
<u>/s/ David Malka</u> David Malka	Director and Vice President of Operations	April 1, 2013

**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, Avner Gal, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2012 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: April 1, 2013

By: /s/ Avner Gal  
Avner Gal  
*Chairman of the Board and Chief Executive Officer*

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**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, Jacob Bar-Shalom, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2012 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: April 1, 2013

By: /s/ Jacob Bar-Shalom  
Jacob Bar-Shalom  
Chief Financial Officer

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**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 Annual Report on Form 10-K of Integrity Applications, Inc. (the "Company") for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Avner Gal, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: April 1, 2013

By: /s/ Avner Gal  
Avner Gal  
Chairman of the Board and Chief Executive Officer

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**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 Annual Report on Form 10-k of Integrity Applications, Inc. (the "Company") for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jacob Bar-Shalom, 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:

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

Date: April 1, 2013

By: /s/ Jacob Bar-Shalom  
Jacob Bar-Shalom  
Chief Financial Officer

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