

As filed with the Securities and Exchange Commission on March 22, 2013

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

FORM 20-F  
(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR  
 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

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Date of event requiring this shell company report .....

Commission file number: 001-33042



**ROSETTA GENOMICS LTD.**  
(Exact name of Registrant as specified in its charter)

Not Applicable  
(Translation of Registrant's Name into English)

Israel  
(Jurisdiction of incorporation or organization)

10 Plaut Street, Science Park  
Rehovot 76706, Israel  
(Address of principal executive offices)

Kenneth A. Berlin, CEO and President  
3711 Market St., Suite 740  
Philadelphia, PA, 19104, USA  
Tel: 215-382-9000  
Fax: 215-382-0815

(Name, Telephone, E-mail and or Facsimile number and Address of Company Contact Person)

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

Title of each class	Name of each exchange on which registered
Ordinary shares, par value NIS 0.6 per share	The NASDAQ Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act. None  
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the

Annual Report: As of December 31, 2012, the issuer had 9,096,548 ordinary shares outstanding and no preferred shares outstanding.

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

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or (15)(d) of the Securities Exchange Act of 1934. 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 periods that the registrant was required to file such reports), and (2) has been subject to such reporting requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes

No

---

---

## TABLE OF CONTENTS

	<b>Page</b>
<b>INTRODUCTION</b>	ii
<b>FORWARD-LOOKING STATEMENTS</b>	ii
<b>PART I</b>	1
Item 1. Identity of Directors, Senior Management and Advisers	1
Item 2. Offer Statistics and Expected Timetable	1
Item 3. Key Information	1
Item 4. Information on the Company	16
Item 4A. Unresolved Staff Comments	34
Item 5. Operating and Financial Review and Prospects	34
Item 6. Directors, Senior Management and Employees	42
Item 7. Major Shareholders and Related Party Transactions	54
Item 8. Financial Information	56
Item 9. The Offer and Listing	56
Item 10. Additional Information	57
Item 11. Quantitative and Qualitative Disclosures about Market Risk	71
Item 12. Description of Securities Other than Equity Securities	73
<b>PART II</b>	
Item 13. Defaults, Dividend Arrearages and Delinquencies	73
Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds	73
Item 15. Controls and Procedures	73
Item 16. Reserved	74
Item 16A. Audit Committee Financial Expert	74
Item 16B. Code of Ethics	75
Item 16C. Principal Accountant Fees and Services	75
Item 16D. Exemptions from the Listing Standards for Audit Committees	75
Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers	75
Item 16F. Change in Registrant's Certifying Accountant	75
Item 16G. Corporate Governance	75
Item 16H. Mine Safety Disclosure	76
<b>PART III</b>	
Item 17. Financial Statements	76
Item 18. Financial Statements	76
Item 19. Exhibits	77
<b>SIGNATURE</b>	78
<b>INDEX TO FINANCIAL STATEMENTS</b>	F-1

## INTRODUCTION

As used in this Annual Report on Form 20-F (hereinafter referred to as this “Annual Report”), unless the context requires otherwise, references to “we”, “our”, “us”, “Rosetta” or the “Company” are references to Rosetta Genomics Ltd., a company organized under the laws of the State of Israel, and its subsidiary.

Our consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. Except as otherwise specified, financial information is presented in U.S. dollars. All references in this Annual Report to “U.S. dollars,” “dollars” or “\$” are to United States dollars and all references in this Annual Report to “NIS” or “shekels” are to New Israeli Shekels.

All information in this Annual Report on Form 20-F relating to shares or price per share reflect (i) the 1-for-4 reverse stock split effected by Rosetta on July 6, 2011 and (ii) the 1-for-15 reverse stock split effected by Rosetta on May 14, 2012.

## FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements. These forward-looking statements include, in particular, statements about our plans, strategies and prospects and may be identified by terminology such as “may,” “will,” “should,” “expect,” “scheduled,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “aim,” “potential,” or “continue” or the negative of those terms or other comparable terminology. These forward-looking statements are subject to risks, uncertainties and assumptions about us. Although we believe that our plans, intentions and expectations are reasonable, we may not achieve our plans, intentions or expectations.

Important factors that could cause actual results to differ materially from the forward-looking statements we make in this Annual Report are set forth in “Item 3. Key Information - D. Risk Factors.” All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements in “Risk Factors,” in which we have disclosed the material risks related to our business. These forward-looking statements involve risks and uncertainties, and the cautionary statements identify important factors that could cause actual results to differ materially from those predicted in any forward-looking statements. We undertake no obligation to update any of the forward-looking statements after the date of this Annual Report to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report, that we have filed with the Securities and Exchange Commission (the “SEC”), completely and with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

**PART I****ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not Applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not Applicable.

**ITEM 3. KEY INFORMATION****A. SELECTED CONSOLIDATED FINANCIAL DATA**

We have prepared our historical consolidated financial statements in accordance with generally accepted accounting principles in the United States (U.S. GAAP). The following financial data for the years ended December 31, 2010, 2011 and 2012, and as of December 31, 2011 and 2012 have been derived from our audited financial statements which are included elsewhere in this Annual Report. The following financial data for the years ended December 31, 2008 and 2009 and as of December 31, 2008, 2009 and 2010 have been derived from our audited financial statements which are not included in this Annual Report. In July 2008, through our wholly owned subsidiary Rosetta Genomics Inc., we purchased Parkway Clinical Laboratories, Inc., a privately held Pennsylvania corporation owning a CLIA-certified laboratory. Parkway remained an indirect wholly owned subsidiary until we sold it in May 2009. Operating results for Parkway have been classified as discontinued operations for all presented periods. On February 4, 2010, we established Rosetta Green Ltd. ("Rosetta Green") as a controlled subsidiary. As of December 31, 2010, we owned approximately 76.2% of the outstanding ordinary shares of Rosetta Green, therefore, Rosetta Green results were consolidated in 2010. In December 2011, we sold our complete ownership interest in Rosetta Green, which represented approximately 50.03% of the outstanding ordinary shares of Rosetta Green. Information relating to Rosetta Green is incorporated into the Consolidated Statements of Comprehensive Loss at item net loss from discontinued operations. You should read this information in conjunction with our consolidated financial statements, including the related notes, and "Item 5. Operating and Financial Review and Prospects" included elsewhere in this Annual Report. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
(In thousands, except share and per share data)					
<b>Consolidated Statement of Comprehensive Loss :</b>					
Revenues:	\$ 201	\$ 103	\$ 279	\$ 150	\$ -
Cost of revenues	258	324	628	339	-
Gross loss	57	221	349	189	-
<b>Consolidated Statements of Operations:</b>					
Operating expenses:					
Research and development	1,247	3,386	5,707	6,552	8,705
Marketing and business development	3,938	2,633	4,881	4,451	2,177
General and administrative	3,025	2,537	2,424	3,605	3,189
Other expenses related to the settlement with Prometheus	-	-	554	-	-
Total operating expenses	8,210	8,556	13,566	14,608	14,071
Operating loss	8,267	8,777	13,915	14,797	14,071
Financial expenses (income), net	2,429	(1,391)	(1,031)	(45)	(5,449)
Loss from continuing operations	10,696	7,386	12,884	14,752	8,622
Net loss (income) from discontinued operations	(239)	1,444	1,871	1,753	841
Net loss after discontinued operations	10,457	8,830	14,755	16,505	9,463
Net loss attributable to Rosetta Genomics	\$ 10,457	\$ 8,830	\$ 14,755	\$ 16,505	\$ 9,463
Basic and diluted net loss per ordinary share from continuing operations	\$ 2.40	\$ 14.55	\$ 45.75	\$ 65.4	\$ 43.2
Basic and diluted net loss (income) per ordinary share from discontinued operations attributable to Rosetta Genomics	\$ (0.054)	\$ 2.85	\$ 6.6	\$ 7.8	\$ 4.2
Basic and diluted net loss per ordinary share					

attributable to Rosetta Genomics	\$	2.35	\$	17.4	\$	52.35	\$	73.2	\$	7.4
Weighted average number of ordinary shares used to compute basic and diluted net loss per ordinary share attributable to Rosetta Genomics		4,448,449		507,622		281,801		225,722		270,638

**As of December 31,**

	<b>2012</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>(In thousands)</b>					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 30,798	\$ 735	\$ 2,635	\$ 3,329	\$ 13,727
Restricted cash	34	37	-	1,076	643
Short-term bank deposits	130	112	190	3,143	840
Marketable securities	-	-	148	2,756	426
Trade receivable	88	11	21	72	-
Working capital (deficiency)	30,487	(638)	501	8,628	14,004
Total assets	32,530	2,044	5,293	12,743	20,268
Convertible loan	-	-	-	1,500	750
Long-term liabilities	364	552	2,592	3,596	1,615
Total shareholders' equity (deficiency)	30,900	(356)	(630)	6,842	16,100
Capital stock	126,402	84,689	74,778	68,206	61,052

**B. CAPITALIZATION AND INDEBTEDNESS**

Not applicable.

**C. REASONS FOR THE OFFER AND USE OF PROCEEDS**

Not applicable.

**D. RISK FACTORS**

*If any of the following risks occur, our business, business prospects, financial condition, results of operations, or cash flows could be materially harmed.*

**Risks Related to Our Business, Our Financial Results and Need for Financing**

*We will require substantial additional funds to continue our operations and, if additional funds are not available, we may need to significantly scale back or cease our operations.*

We have used substantial funds to discover, develop and protect our microRNA tests and technologies and will require substantial additional funds to continue our operations. As of December 31, 2012, we had cash, cash equivalents, short-term bank deposits and restricted cash of \$31.0 million, compared to \$884,000 as of December 31, 2011. Based on our current operations, we believe our existing funds will be sufficient to fund operations for approximately the next 24 months. We may seek additional funding through collaborative arrangements and public or private equity offerings and debt financings, and we may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. Additional funds may not be available to us when needed on acceptable terms, or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our existing shareholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing shareholders may result. Debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, tests or products in development or approved tests or products that we would otherwise pursue on our own. Our failure to raise capital when needed will materially harm our business, financial condition and results of operations.

***The approach we are taking to discover and develop novel diagnostics and therapeutics is new and may never lead to commercially accepted products.***

We have concentrated our research and development efforts on diagnostics and therapeutics in the new field of microRNAs. To date, we have commercialized six diagnostic tests: miRview® mets, miRview® meso and miRview® squamous, which were launched in late 2008, miRview® mets<sup>2</sup>, which was launched in December 2010, miRview® lung, which was launched in July 2011, and miRview® kidney, which was launched in May 2012. To date, these tests have achieved very limited commercial success. The scientific discoveries that form the basis for our efforts to develop diagnostics and therapeutics are relatively new, and the scientific evidence to support the feasibility of developing products based on these discoveries is limited. Further, our focus solely on developing microRNA-based diagnostics and therapeutics as opposed to multiple or more proven technologies for the development of diagnostics and therapeutics increases the risks associated with the ownership of our ordinary shares. If we or a collaborative partner are not successful in commercializing our existing diagnostic tests or developing and commercializing additional microRNA-based tests or products, our business may fail.

***Because we have a short operating history, there is a limited amount of information about us upon which our business and prospects can be evaluated.***

Our operations began in 2000, and we have only a limited operating history upon which our business and prospects can be evaluated. In addition, as a company providing relatively new diagnostic services, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology area. For example, to execute our business plan, we will need to successfully:

- maintain and further build our strong intellectual property portfolio;
- execute development activities using an unproven technology;
- execute marketing and distribution activities;
- continue to develop and maintain successful strategic relationships;
- manage our spending while costs and expenses increase as we expand our efforts to discover, develop and commercialize diagnostics and therapeutics based on microRNAs; and
- gain commercial and, if applicable, regulatory acceptance of our tests and products.

If we are unsuccessful in accomplishing these objectives, we may not be able to raise capital, develop tests or products, expand our business or continue our operations.

***We have a history of losses and may never be profitable.***

We have experienced significant operating losses since our inception in 2000, and as of December 31, 2012, we had an accumulated deficit of \$95.5 million. We had net loss after discontinued operations of \$10.5 million for the year ended December 31, 2012. Our net loss before discontinued operations for the year ended December 31, 2012 was \$10.7 million. We anticipate that the majority of any revenues we generate over the next several years will be from sales of our currently marketed products in the United States and from existing and future collaborations and licensing arrangements and the sale of future diagnostic tests using our microRNA technology. We cannot be certain, however, that our sales efforts in the United States or our existing collaborations will be successful or that we will be able to secure any collaborations or achieve any milestones that may be required to receive payments or that diagnostic tests based on our technologies, including that our currently marketed tests, will be successfully commercialized. If we are unable to secure significant revenues from our current selling efforts or through collaborations and the sale of tests or products, we may be unable to continue our efforts to discover, develop and commercialize microRNA-based diagnostics and therapeutics without raising additional funds from other sources.

***Fluctuations in currency exchange rates of the New Israeli Shekel vs. the U.S. dollar may have a significant impact on our reported results of operations.***

Fluctuations in currency exchange rates may have a significant impact on our reported results of operations. Although our reporting currency is the U.S. dollar, significant portions of our expenses are denominated in New Israeli Shekels, or NIS. In periods when the U.S. dollar is devalued against the NIS, our reported results of operations may be adversely affected. In addition, fluctuations in currencies may result in valuation adjustments in our assets and liabilities which could affect our reported results of operations.

***Fluctuations in our share price may have a significant impact on our reported liabilities and reported results of financial income or expenses.***

Fluctuations in our share price may have a significant impact on our reported liabilities because certain outstanding warrants are classified as liabilities measured at fair value each reporting period until they are exercised or expire, with changes in the fair values being recognized in our statement of operations as financial income or expense. In periods when share price is ascending, the reported liability and the reported results of financial expense are adversely affected.

### **Risks Related to Our Intellectual Property**

***If we are not able to obtain and enforce patent protection for our discoveries, our ability to develop and commercialize microRNA-based diagnostics and therapeutics will be harmed.***

Our success depends, in large 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, Israel and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. As of March 21, 2013, our patent portfolio included a total of 25 issued U.S. patents, one issued Australian patent, one issued European patent, two issued Israeli patents, 41 pending patent applications worldwide, consisting of 21 U.S. patent applications, three of which received notice of allowance, five PCT applications, three applications that were nationalized in Europe, three applications nationalized in Israel, two applications nationalized in Japan, two applications nationalized in Australia, two applications nationalized in Canada, two applications nationalized in China and one application that was nationalized in Korea. There can be no assurance, however, that any of these pending patent applications will result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented.

Furthermore, the standards that the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and may change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Furthermore, the field of microRNAs is new and developing. Accordingly, there is significant uncertainty about what patents will be issued, and what their claims may cover. It is likely that there will be significant litigation and other proceedings, such as interference proceedings and opposition proceedings, in certain patent offices, relating to patent rights in the microRNA field. Others may attempt to invalidate our intellectual property rights. Currently, there are two oppositions filed against one of our issued patents in the European Union. These oppositions relate to a patent allowed by the European Patent Office that claims the use of a certain microRNA for the preparation of a pharmaceutical composition for treating cancer, wherein the cancer is p53 negative. The oppositions both cite, as grounds, added subject matter, priority entitlement, sufficiency, prior art and that the patent is not novel for various reasons. Even if these oppositions are successful, we do not anticipate that they will have an adverse effect on our business. Even if our other rights are not directly challenged, disputes among third parties could lead to the weakening or invalidation of our intellectual property rights. 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. Additionally, the mere issuance of a patent does not guarantee that it is valid or enforceable, so even issued patents may not be valid or enforceable against third parties.

In addition, we cannot be certain that we hold the rights to the technology covered by our pending patent applications or to other proprietary technology required for us to commercialize our proposed tests and products. Because certain U.S. patent applications are confidential until patents issue, and because certain applications will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we may be unable to secure desired patent rights, thereby losing desired exclusivity. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we will not be able to market our tests and products.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. There have been several cases involving “gene patents” and diagnostic claims that have been considered by the U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO, could impact biotechnology and diagnostic patents. That case involves certain of Myriad’s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the decision of the U.S. District Court for the Southern District of New York that Myriad’s composition claims to “isolated” DNA molecules cover unpatentable subject matter. The Federal Circuit court instead held that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or *Prometheus*, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus’ claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted *certiorari* in the Myriad case, vacated the judgment, and remanded the

case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a *writ of certiorari* asking the Supreme Court to review the Federal Circuit's decision. On November 30, 2012, the Supreme Court granted the petition and agreed to review the case. Many companies have submitted amicus briefs, or friend of the court briefs, in the case. The Supreme Court is scheduled to hear oral argument on April 15, 2013. A decision by the Supreme Court is expected by the end of June 2013. There can be no assurance that the Supreme Court's decision in the Myriad case will not have a negative impact on gene or diagnostic patents generally or the ability of biotechnology and diagnostic companies to obtain or enforce their patents in the future. Any such negative decision by the Supreme Court could have a material adverse effect on the Company's existing patent portfolio and the Company's ability to protect and enforce its intellectual property in the future.

On July 3, 2012, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in *Prometheus*. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

In addition, Congress has directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: "Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress." The USPTO issued a Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing on January 25, 2012, and held additional public hearings in February and March 2013. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our patent portfolio or our future research and development efforts.

***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 development and commercialization efforts.***

A third party may sue us for infringing its 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 third-party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its 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 our 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, and we may not have sufficient resources to adequately enforce our intellectual property rights. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we are found to infringe upon intellectual property rights of third parties, we could 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. 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, tests and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in our revenues from tests or products developed through collaborations.

***We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.***

We are a party to license agreements that give us rights to third-party intellectual property that we believe may be necessary or useful for our business, such as our agreements with The Rockefeller University, Max Planck Innovation GmbH, or Max Planck, and Johns Hopkins University. We intend to enter into additional licenses of intellectual property with third parties in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive or co-exclusive rights. Our licensors may not successfully prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical tests or products for sale, which could adversely affect our competitive business position and harm our business prospects. Our current material license agreements contain the following patent enforcement provisions:

- under our license agreements with The Rockefeller University, if Rockefeller University fails to enforce the patents we licensed, we have the right to enforce the patents and pursue litigation against any infringement of such patents;



- under our license agreement with Max Planck for diagnostic purposes, we have the responsibility to assist in the prosecution of any patent infringement actions undertaken by Max Planck;
- under our license agreement with Max Planck for research purposes, Max Planck controls the filing, prosecution, maintenance and abandonment of all patents; and
- under our agreement with Johns Hopkins University, Johns Hopkins is responsible for prosecution and maintenance of patents, and we have the right but not the obligation to enforce the patents against any infringement by third parties.

***If we fail to comply with our obligations under any licenses or related agreements, we could lose license rights that may be necessary for developing microRNA-based diagnostics and therapeutics.***

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, royalty, diligence, sublicensing, insurance and other obligations on us. Such obligations may include:

- royalty payments;
- annual maintenance fees;
- payment of fees relating to patent prosecution, maintenance and enforcement;
- maintaining insurance coverage; and
- using commercially reasonable efforts to develop tests and products using the licensed technology.

If we breach any of our obligations under our licenses, the licensor may have the right to terminate the license, which could result in our being unable to develop, manufacture and sell tests or products that are covered by the licensed technology or a competitor gaining access to the licensed technology.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.***

We rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

## **Risks Related to Development, Clinical Testing and Regulatory Approval of Diagnostics and Therapeutics**

***We and others who may develop diagnostic tests applying our microRNA technology are subject to a variety of regulatory frameworks.***

We and others who may develop diagnostic tests based on our microRNA technology are subject to a variety of laws enforced by the U.S. federal government and the states in which they, and we conduct, or will conduct, business, including CLIA, state clinical laboratory licensure laws and regulations, and the Federal Food, Drug, and Cosmetic Act and related regulations. The growth of our business may subject us to increasing regulation. Any action brought against us, or any business partners, for alleged violations of these laws or regulations, even if we or they successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If their or our operations are found to be in violation of any of these laws and regulations, they or we may be subject to a range of penalties associated with the violation, including injunctions, fines, civil or criminal penalties, and exclusion from government programs and they or we could be required to curtail or cease operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our operations.***

The operations of our laboratory in Philadelphia, Pennsylvania are subject to regulation by numerous federal, state and local governmental authorities in the United States. The laboratory holds a CLIA certificate of compliance and is licensed by the Commonwealth of Pennsylvania, which enables us to provide testing services to residents of most states. We have also obtained licenses from California, Maryland, Rhode Island, Florida and New York, and plan to obtain licenses from other states as required. In addition, we are accredited by the College of American Pathologists, or CAP. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can also be used to meet CLIA and state certification requirements.



CLIA is a federal law that regulates clinical laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA imposes quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of reporting patient test results. CLIA-certified laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of these laboratories. If we were to lose our CLIA certification or our state licenses, or if they were limited in scope, we would no longer be able to continue our testing operations which would have a material adverse effect on our business.

***Any diagnostic tests that may be developed by us or others using our microRNA technology may be subject to regulatory approval, which can be lengthy, costly and burdensome.***

Although the U.S. Food and Drug Administration, or FDA, has consistently stated that it has the authority to regulate clinical laboratory tests as medical devices, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and validated at the high complexity CLIA-certified laboratory at which the test is performed. These tests are known as laboratory-developed tests, or LDTs. Our currently marketed tests were launched as LDTs by our CLIA-certified clinical laboratory operating in Philadelphia, Pennsylvania. In 2012, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs, and held a public meeting to obtain input from stakeholders on how it should apply its authority to implement a reasonable risk-based and effective regulatory framework for LDTs. The FDA has not indicated when or how those changes will be implemented, but it left little doubt that changes are forthcoming. We are monitoring this development carefully, and although we intend to continue to launch new clinical tests as LDTs in our CLIA-certified laboratory, we cannot provide any assurance that FDA regulation, including pre-market clearance or approval, will not be required in the future for LDTs applying our microRNA technology. If pre-market clearance or approval is required, our business could be negatively impacted because we would have to obtain the data required to support required submissions to the FDA and because our CLIA-certified laboratory may be required to stop offering our tests until they are cleared or approved by the FDA.

***Diagnostic tests based on our microRNA technology may require the performance of clinical trials, which can be lengthy, costly and burdensome.***

If the FDA decides to require pre-market clearance or approval of tests based on our microRNA technology, it may require us to perform clinical trials prior to submitting a marketing application. If we are required to conduct clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase development costs and delay commercialization. The commencement of clinical trials may be delayed due to our inability to obtain a sufficient number of patient samples, which is a function of many factors, including the size of the relevant patient population and the nature of the disease or condition being studied. It also may be necessary to engage contract research organizations, or CROs, to perform data collection and analysis and other aspects of these clinical trials, which might increase the cost and increase the time to completion.

***We may be unable to obtain regulatory approval of any therapeutic product that we or a collaborator may develop.***

Any therapeutic product that we or our collaborators may develop will be subject to extensive governmental regulations including those relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing, the performance of clinical trials and an extensive regulatory review process are required to be successfully completed in the United States and in many foreign jurisdictions before a new therapeutic product can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA and other approvals for therapeutic products is unpredictable but typically exceeds several years. It is possible that none of the therapeutic products we or our collaborators may develop will obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them.

Furthermore, the FDA has not yet established any definitive policies, practices or guidelines in relation to the newly discovered class of therapeutic products we seek to develop. The lack of such policies, practices or guidelines may hinder or slow review by the FDA of any regulatory filings that we or our collaborators may submit. Moreover, the FDA may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the approval of therapeutic products. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from a particular therapeutic product.

Furthermore, any regulatory approval to market a therapeutic product may be subject to limitations on the indicated uses. These limitations may limit the size of the market for the therapeutic product. Any therapeutic product that we or our collaborators may develop will also be subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement among other things. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Therefore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa.

***We have no experience in conducting, managing or sponsoring clinical trials for potential therapeutic products.***

We have no experience in conducting and managing the clinical trials necessary to obtain regulatory approvals for any therapeutic product, and we intend to rely on third parties such as CROs, medical institutions and clinical investigators to perform these functions. Our reliance on third parties for clinical development activities reduces our control over these activities. Third-party contractors may not complete activities on schedule, or may not conduct clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet required performance standards or expected deadlines, we might be required to replace them or the data that they provide could be rejected, all of which may result in a delay of the affected trial.

***If we are found to have violated laws protecting the privacy or security of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.***

There are a number of U.S. federal and state laws and foreign laws protecting the privacy and security of individually identifiable patient health information, or “protected health information” including patient records, and restricting the use and disclosure of that protected health information that we are subject to. In the United States, the U.S. Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and then significantly strengthened and broadened the applicability of HIPAA under the Health Information Technology for Economic and Clinical Health Act (HITECH). HIPAA and HITECH and their implementing regulations and guidance will be collectively referred to herein as “HIPAA”. HIPAA’s privacy rules protect medical records and protected health information in all forms by limiting its use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting, in some circumstances, the use and disclosure of protected health information to the minimum amount reasonably necessary to accomplish the intended purpose of the use or disclosure. HIPAA’s security standards require regulated entities or “covered entities” to implement administrative, physical and technical security measures to maintain the security of protected health information in electronic form. Covered entities must conduct initial and ongoing risk assessments to ensure the ongoing effectiveness of security measures and maintain a written information security plan. HITECH amended HIPAA to require the reporting of breaches of protected health information to affected individuals, the federal government and in some cases, to the media. We are also subject to random audit by federal authorities, or audit and investigation in response to complaints. If we are found to be in violation of the privacy rules or security standards under HIPAA, we could be subject to civil or criminal penalties as well as fines, which could increase our liabilities and harm our reputation or our business. Any publicly reported breach could cause significant reputational harm to our business and significant expense for reporting, mitigation of harm and implementation of corrective actions mandated by regulators. HITECH expanded HIPAA enforcement authority to state attorneys general, so we are subject to additional enforcement and penalties from each state where individuals affected by a HIPAA violation may reside. Allegations that we have violated individuals’ privacy or security rights, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Beyond HIPAA, most states have adopted data security laws protecting the personal data of state residents. Personal data subject to protection typically includes name coupled with social security number, state-issued identification number, or financial account number. Most states require specific, technical security measures for the protection of all personal data, including employee data, and impose their own breach notification requirements in the event of a loss of personal data. State data security laws generally overlap and apply simultaneously with HIPAA. In the event of a data breach affecting individuals from more than one state, we must comply with all relevant state notification requirements as well as HIPAA and are subject to enforcement by all relevant state and federal authorities as well as fines and penalties imposed by each state. Non-U.S. privacy protection requirements such as the European Union’s Data Protection Directive governing the processing of personal data, may be stricter than the U.S. law and violation would impose similar penalties.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development activities involve the use of hazardous and chemicals materials, and we maintain quantities of various flammable and toxic chemicals in our facilities in Israel and the United States. We believe our procedures for storing, handling and disposing these materials in our Israel and U.S. facilities comply with the relevant guidelines of the State of Israel and the United States. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***If we do not comply with laws regulating the use of human tissues, our business could be adversely affected.***

We use human tissue samples for the purpose of development and validation of our tests. Our access and use of these samples is subjected to government regulation, in the United States, Israel and elsewhere and may become subject to further regulation. For example, the Israeli Ministry of Health requires compliance with the principles of the Helsinki Declaration, the Public Health Regulations (Clinical Trials in Human Subjects) 1980, the provisions of the Guidelines for Clinical Trials in Human Subjects and the provisions of the current Harmonized Tripartite Guideline for Good Clinical Practice. Our failure to comply with these or similar regulations could impact our business and results of operations.

## **Risks Related to Competition and Commercialization**

***If we are unable to expand sales of our diagnostic tests in the United States, it would have a material adverse effect on our business and financial condition.***

In November 2010, we reacquired the U.S. commercial rights to our current diagnostic tests, and in May 2011, we established our own internal oncology sales team consisting of four oncology sales specialists, which has been since been increased and currently stands at seven oncology sales specialists and one national sales director. To date, this team has had very limited success in commercializing our diagnostic tests. In addition, in July 2012 (as amended in October 2012), we entered into a co-marketing agreement with Precision Therapeutics, pursuant to which we have granted Precision Therapeutics the co-exclusive right, along with us, to market miRview<sup>®</sup> mets<sup>2</sup> in the United States. Precision Therapeutics launched its marketing effort in October 2012. We cannot assure you, however, that Precision Therapeutics will be successful in commercializing miRview<sup>®</sup> mets<sup>2</sup> in the United States. If we are unable to establish adequate sales, marketing and distribution capabilities in the United States, whether independently or with third parties, such as Precision Therapeutics, it would have a material adverse effect on our business and financial condition.

***The intensely competitive biotechnology market could diminish demand for our tests and products.***

The biopharmaceutical market is intensely competitive and rapidly changing. Many diagnostic, pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the research of technologies and development of novel diagnostic tests and therapeutic products for the same diseases that we and others who may develop products based on our microRNA technology are targeting or may target. We and they will face intense competition from tests and products that have already been approved and accepted by the medical community for the diseases for which we or they may develop tests or products. We and others who may develop products based on our microRNA technology may also face competition from new tests or products that enter the market. We believe a significant number of tests and products are currently under development, and may become commercially available in the future, for the diseases for which we, our collaborators, or third-party licensees may try to develop tests and products. In addition to the competition we face from existing tests and products in development, we and others who may develop products based on our microRNA technology will also face competition from other companies working to develop novel tests and products using technology that competes more directly with our microRNA technologies. We are aware of several other companies that are working to develop microRNA-based diagnostics and therapeutics, including Combimatrix Corporation, Alnylam Pharmaceuticals, Inc., Asuragen Inc., Exiqon A/S, Life Technologies Corporation, Isis Pharmaceuticals, Merck & Co., Inc., Santaris Pharma A/S, Regulus Therapeutics and others. In addition, we face competition from companies that have developed or are developing diagnostic tests based on other non-microRNA technologies such as Pathwork Diagnostics, Inc. and Biotheranostics, Inc. Any of these companies may develop microRNA-based or other tests or products more rapidly and more effectively than we or our collaborators will. If we are unable to compete effectively with existing tests and products, new treatment methods and new technologies, we and others who may develop products based on our microRNA technology may be unable to commercialize any diagnostic tests or therapeutic products that we or they develop.

Many of our competitors have:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization process;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing and marketing diagnostics and therapeutics;
- tests or products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Our competitors may develop or commercialize tests or products with significant advantages over any diagnostic tests or therapeutic products we, our collaborators or third-party licensees may develop. Our competitors may therefore be more successful in commercializing their tests and products than we, our collaborators, or third party licensees are, which could adversely affect our competitive position and business.

***Health insurers and other third-party payors may decide not to cover our diagnostic products or may provide inadequate reimbursement, which could jeopardize our commercial prospects.***

In the United States, private and government payors decide whether to cover a new diagnostic test, the amount that they will pay for a covered test and the specific conditions for reimbursement. In May 2012, we announced that the designated Medicare Administrative Contractor, or MAC, for the miRview<sup>®</sup> mets<sup>2</sup> test had informed us that it plans to cover this test for Medicare beneficiaries, and in June 2012, we announced that the MAC had established a reimbursement rate for the test. Each third-party payor, however, makes its own decision about which tests it will cover and how much it will pay. While many third-party payors will follow the lead of Medicare, we cannot provide any assurance that other payors will cover this

test or any of our other tests. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of each of our tests to each payor separately, with no assurance that approval will be obtained. If third-party payors decide not to cover our diagnostic tests or if Medicare or other payors offer inadequate payment amounts, our ability to generate revenue from our diagnostic tests could be limited. Third-party payors that decide to reimburse for our tests may stop or lower payment at any time, which would reduce revenue. We cannot predict whether third-party payors will cover our tests or offer adequate payments. We also cannot predict the timing of such decisions. In addition, physicians or patients may decide not to order our tests if third-party payments are inadequate, especially if ordering the test could result in financial liability for the patient.

In the United States, the American Medical Association, or AMA, assigns specific Current Procedural Terminology, or CPT, codes, which are a medical nomenclature used to report medical procedures and services under public and private health insurance plans. Once the CPT code is established, the Centers for Medicare and Medicaid Services, or CMS, establishes reimbursement payment levels and coverage rules for Medicare, and private payors establish rates and coverage rules independently. While we have received a CPT code for miRview<sup>®</sup> mets<sup>2</sup>, we cannot guarantee that any of our other tests will receive a CPT code and will be approved for reimbursement by Medicare or other third-party payors. Additionally, any or all of our diagnostic tests developed in the future may not be approved for reimbursement or may be approved at a level that limits our commercial success.

In addition, payment for diagnostic tests furnished to Medicare beneficiaries in most instances is made based on a fee schedule set by CMS. In recent years, payments under these fee schedules have decreased and may decrease more, which could jeopardize our commercial prospects. Reimbursement decisions in the European Union and in other jurisdictions outside of the United States vary by country and regions and there can be no assurance that we will be successful obtaining adequate reimbursement.

***Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our tests.***

In March 2010, the President of the United States signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA. This law substantially changes the way health care will be financed by both governmental and private insurers, and significantly impacts our industry. The ACA contains a number of provisions that are expected to impact our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs.

Additional provisions of the ACA, some of which became effective in 2011, may negatively affect our revenues. For example, the ACA mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. It also imposes an excise tax of 2.3% on the sales of medical devices in the United States beginning in 2013.

In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep these costs down while expanding individual healthcare benefits. Some of these changes could impose additional limitations on the prices we will be able to charge for our tests or the amounts of payment available for our tests from governmental agencies or third-party payors. While in general it is too early to predict specifically what effect the ACA and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

***The market may not be receptive to any diagnostic tests or therapeutic products using our microRNA technology upon their commercial introduction.***

Any diagnostic tests or therapeutic products using our microRNA technology that we, our collaborators or third-party licensees have developed or are developing are based upon new technologies or diagnostic or therapeutic approaches. Key participants in pharmaceutical marketplaces, such as physicians, third-party payors and consumers, may not accept a microRNA-based approach. As a result, it may be more difficult for us, our collaborators or third-party licensees to convince the medical community and third-party payors to accept and use such tests and products. Other factors that we believe will materially affect market acceptance of diagnostic tests or therapeutic products using our microRNA technology include:

- the timing of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained;
- the success of physician education programs;
- the availability of alternative diagnostics and therapeutics; and
- the pricing of such tests or products, particularly as compared to alternatives.

## **Risks Related to Our Dependence on Third Parties**

***We are largely dependent upon our distributors for the success of commercialization of our current diagnostic tests.***

We currently have the following distribution agreements relating to our diagnostic tests:

- with Teva Pharmaceutical Industries Ltd., pursuant to which Teva has the right to distribute these tests in Turkey and Israel;
- with Warnex Medical Laboratories, a division of Warnex, Inc., pursuant to which Warnex has the right to distribute some of these tests in Canada;
- with Genekor S.A., pursuant to which Genekor has the exclusive right to distribute these tests in Greece;
- with Super Religare Laboratories Limited (SRL), pursuant to which SRL has the non-exclusive right to distribute these tests in India, Saudi Arabia, Qatar and the United Arab Emirates; and
- with Genetic Technologies Limited (GTL), pursuant to which GTL has the exclusive right to distribute these tests in Australia, New Zealand and Singapore.

We are largely dependent upon these distributors for the commercial success of our tests outside of the United States. The potential revenues from these agreements are based on the sale of our products by these distributors and will depend upon our distributors' ability to devote the necessary resources to successfully commercialize these tests. In addition, if any of our current or potential future distributors were to breach or terminate its agreement with us, the commercialization of these tests could be adversely affected because we may not have sufficient financial resources or capabilities to successfully commercialize these tests on our own or find other partners.

In addition, in July 2012, we entered into a co-marketing agreement with Precision Therapeutics, which was revised in October 2012, pursuant to which we have granted Precision Therapeutics the co-exclusive right, along with us, to market miRview<sup>®</sup> mets<sup>2</sup> in the United States. Accordingly, the successful marketing of miRview<sup>®</sup> mets<sup>2</sup> in the United States will depend to a significant degree on the ability of Precision Therapeutics to devote the necessary resources to successfully market this test.

If any of our distributors or co-marketers does not devote sufficient time and resources to the collaboration or if a collaboration is breached or terminated, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected.

***We contract with a single manufacturer for the purchase of microarray chips for miRview<sup>®</sup> mets<sup>2</sup> and miRview<sup>®</sup> kidney. The failure of this manufacturer to supply sufficient quantities on a timely basis could have a material adverse effect on our business.***

We use a single manufacturer for the supply of microarray chips for our miRview<sup>®</sup> mets<sup>2</sup> and miRview<sup>®</sup> kidney tests. While we believe that there are a number of manufacturers from whom we could obtain such chips, we have not screened or approved any such manufacturers as potential back-up manufacturers for these chips, and it could take a significant amount of time and would be costly to do so. Accordingly, if this manufacturer is unable or unwilling to supply sufficient quantities of chips on a timely basis, it could have a material adverse effect on our business.

***We may not be able to execute our business strategy if we are unable to enter into additional collaborations with other companies that can provide capabilities and funds for the development and commercialization of our microRNA-based diagnostics and therapeutics.***

We have limited capabilities for sales, marketing, distribution and product development, including obtaining regulatory approval of therapeutic products. Accordingly, we may enter into additional collaborations with pharmaceutical, biotechnology or diagnostic companies to jointly develop specific tests or products and to jointly commercialize them. In such collaborations, we would expect our collaborators to provide substantial capabilities in clinical development, regulatory affairs, marketing and sales. While such agreements could provide us with an opportunity to develop and commercialize tests and products, they may necessitate a reliance on our collaboration partner in numerous aspects of the research and development, regulation, manufacturing, marketing and sales of these tests and products. We may not be successful in entering into any additional collaborations on favorable terms or maintaining any such collaborations into which we enter. In addition, while such agreements would provide us with opportunities, they would also require us to share the down-stream profits with our collaborators, thereby reducing our ability to fully capitalize on sales.

***If any collaborator terminates or fails to perform its obligations under agreements with us, the development and commercialization of our tests and products could be delayed or terminated.***

Our expected dependence on collaborators for certain capabilities and funding means that our business would be adversely affected if any collaborator terminates its collaboration agreement with us or fails to perform its obligations under that agreement. Our current or future

collaborations, if any, may not be scientifically or commercially successful. Disputes may arise in the future with respect to the ownership of rights to tests or products developed with collaborators, which could have an adverse effect on our ability to develop and commercialize any affected test or product. If a collaborator terminates its collaboration with us, for breach or otherwise, it could be difficult for us to attract new collaborators and it could adversely affect how we are perceived in the business and financial communities. In addition, a collaborator could determine that it is in its financial interest to:

- pursue alternative technologies or develop alternative tests or products, either on its own or jointly with others, that may be competitive with the tests or products on which it is collaborating with us or which could affect its commitment to the collaboration with us;
- pursue higher priority programs or change the focus of their development programs, which could affect the collaborator's commitment to us; or
- if it has marketing rights and obligations, choose to devote fewer resources to the marketing of our tests or products, than they do for tests or products of their own development, or of their co-development with third parties.

If any of these occur, we may not have sufficient financial resources or capabilities to continue the development and commercialization of such test or product on our own.

***We rely on third parties for tissue samples and other materials required for our research and development activities and if we are unable to reach agreements with these third parties our research and development activities would be delayed.***

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. We may not be able to reach agreements with a sufficient number of suppliers or do so on terms acceptable to us. If we are unable to reach acceptable agreements with a sufficient number of suppliers of research materials, our research and development activities will be delayed and our ability to implement our business plan will be compromised.

***We currently have limited sales, marketing or distribution experience and may depend significantly on third parties to commercialize microRNA-based diagnostic tests or therapeutic products we may develop.***

We currently have a small U.S. sales and marketing team. We will need to significantly expand our sales team or rely on collaborators or other third parties (such as Precision Therapeutics) to commercialize our current tests and any future tests we may develop in the United States. We have limited control over the sales, marketing and distribution activities of our collaborators, and our future revenues will depend on the success of the efforts of our collaborators. To significantly expand our internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, and we will face a number of additional risks, including:

- we may not be able to attract and build a significant marketing or sales force;
- the cost of establishing a marketing or sales force may not be justifiable in light of the revenues generated by any particular test or product; and
- our direct sales and marketing efforts may not be successful.

## **Risks Related to Our Operations**

***If we are unable to attract and retain qualified key management and scientists, staff consultants and advisors, our ability to implement our business plan may be adversely affected.***

We are highly dependent upon certain of our senior management and scientific staff. The loss of the service of these persons may significantly delay or prevent our achievement of product development and other business objectives. Our employment agreements with our key personnel are terminable by the employee at any time with notice. Additionally, although we have generally been successful in our recruiting efforts, we face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain suitably qualified individuals, and our failure to do so could have an adverse effect on our ability to implement our business plan.

***There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of diagnostics and therapeutics. Product liability claims could delay or prevent completion of our clinical development programs. We currently have product liability insurance covering our current commercial tests, and clinical trial insurance for certain trials and cancer programs requiring insurance in an amount up to \$5 million in the aggregate. We plan to obtain insurance for all research programs at appropriate levels prior to initiating any required clinical trials and at higher levels prior to marketing approved therapeutic products. Any insurance we obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business.



***If we are unable to manage the challenges associated with our international operations, the growth of our business could be limited.***

In addition to our operations in Rehovot, Israel, our wholly owned subsidiary, Rosetta Genomics Inc., operates our CLIA- and CAP-certified laboratory in Philadelphia, Pennsylvania. We are subject to a number of risks and challenges that specifically relate to these international operations. Our international operations may not be successful if we are unable to meet and overcome these challenges, which could limit the growth of our business and may have an adverse effect on our business and operating results. These risks include:

- fluctuations in foreign currency exchange rates that may increase the U.S. dollar cost of our international operations;
- difficulty managing operations in multiple locations, which could adversely affect the progress of our development programs and business prospects;
- local regulations that may restrict or impair our ability to conduct pharmaceutical and biotechnology-based research and development;
- foreign protectionist laws and business practices that favor local competition;
- failure of local laws to provide the same degree of protection against infringement of our intellectual property, which could adversely affect our ability to develop tests or products or reduce future product or royalty revenues, if any, from tests or products we may develop;
- laws and regulations governing U.S. immigration and entry into the United States that may restrict free movement of our employees between Israel and the United States; and
- laws and regulations governing U.S. immigration and entry into the United States that may restrict employment of Israeli citizens in our U.S. facilities.

***We are exposed to risks relating to evaluations of controls required by Section 404 of the Sarbanes-Oxley Act of 2002.***

Under the rules of the SEC, we are required to comply with the management assessment of internal control over financial reporting requirement of Section 404 of the Sarbanes-Oxley Act of 2002. We have evaluated our internal control systems to allow management to report on our internal control over financial reporting as of December 31, 2012. We have not identified any internal control deficiencies that constitute a “material weakness” under applicable SEC and Public Company Accounting Oversight Board rules and regulations or that otherwise would materially affect internal controls over financial reporting. A “material weakness” is a control deficiency, or combination of control deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We cannot guarantee that we will not identify material weaknesses or significant control deficiencies in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in significant deficiencies or material weaknesses and cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements, which in turn could lead to a decline in our stock price. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting.

### **Risks Related to Israeli Law and Our Operations in Israel**

***For certain calendar years, we were a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. There may be negative tax consequences for holders of our ordinary shares who are U.S. residents and do not make certain timely tax elections.***

We believe that we were a PFIC for the years ended December 31, 2003, 2006, 2007, 2010, 2011. In addition, we may be a PFIC for the year ended December 31, 2012, (collectively, the “PFIC Years”). We nevertheless recognize that there are significant areas of uncertainty in the PFIC rules and the Internal Revenue Service, or IRS, may not agree with our belief. We are deemed to be a PFIC if 75% or more of our gross income in a taxable year, including our pro rata share of the gross income of any company, U.S. or foreign, in which we are considered to own, directly or indirectly, 25% or more of the shares by value, is passive income. We are also deemed to be a PFIC if at least 50% of our assets in a taxable year, averaged over the year and ordinarily determined based on fair market value, including our pro rata share of the assets of any company in which we are considered to own, directly or indirectly, 25% or more of the shares by value, are held for the production of, or produce, passive income.

Accordingly, for any U.S. shareholders who either: (i) held our ordinary shares during the PFIC Years, or (ii) holds shares in any subsequent year that we are deemed a PFIC, and who does not make an election to treat us as a “qualified electing fund,” or QEF, or make a “mark-to-market” election, then “excess distributions” to such U.S. shareholder, and any gain recognized by such U.S. shareholder on a disposition of our ordinary shares, would be taxed in an unfavorable way. Among other consequences, “excess distributions” and gains on a disposition of our ordinary shares would be taxed at the highest rates applicable to ordinary income, rather than potentially lower rates for qualified dividends and long-term capital gains to non-corporate taxpayers. PFIC status is determined annually and cannot be definitively determined until the close of the year in question. In addition, if the IRS determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it might be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who held or hold ordinary shares during the PFIC Years will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election.



***We are headquartered in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel.***

Our principal executive offices and research and development facilities and many of our suppliers are located in Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, as well as incidents of civil unrest. During the winter of 2008, Israel was engaged in an armed conflict with Hamas in the Gaza Strip. This conflict involved missile strikes against civilian targets in central Israel that resulted in economic losses. Although Israel has entered into various agreements with the Palestinian Authority, Israel has been and is subject to related civil unrest and Palestinian terrorist activity, with varying levels of severity, since September 2000. Furthermore, during the winter of 2012, missile strikes against civilian targets in central Israel, originating from the Gaza strip, led to a conflict which resulted in various economic losses. In addition, tension among the different Palestinian factions may create additional unrest and uncertainty.

In addition, during 2011, riots and uprisings in several countries in the Middle East have led to severe political instability and to a decline in the regional security situation. Such instability may affect the global economy and marketplace, could negatively affect business conditions and therefore could adversely affect our operations and make it more difficult for us to raise capital.

We can give no assurance that security and political conditions will have no impact on our business in the future. Hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations and could make it more difficult for us to raise capital. Ongoing and revived hostilities or other adverse political or economic developments in Israel or the region could harm our operations and product development and cause sales of any approved products to decrease. In addition, Israel and companies doing business with Israel have, in the past, been subject to economic boycotts. Several countries, principally those in the Middle East, still restrict business with Israel and Israeli companies. These restrictive laws and policies may seriously limit our ability to sell any approved products in these countries.

Our business insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

***Our operations could be disrupted as a result of the obligation of management or key personnel to perform military service in Israel.***

Many of our male employees in Israel are obligated to perform military reserve duty annually for extended periods of time through the age of 45 (or older for citizens with certain occupations) and, in the event of a military conflict, could be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of military service of one or more of our key employees.

***The government tax benefits that we are currently eligible to receive require us to meet several conditions and may be terminated or reduced in the future, which would increase our costs.***

Some of our operations in Israel have been granted “approved enterprise” status by the Investment Center in the Israeli Ministry of Industry, Trade and Labor that resulted in our currently being eligible for tax benefits under the Israeli Law for Encouragement of Capital Investments, 1959, as amended. These benefits will commence in the first year in which we produce taxable income. Pursuant to these benefits, undistributed income that we generate from our “approved enterprise” will be tax exempt for two years and, thereafter, will be subject to a corporate tax at a rate of 10% – 25% for an additional five to eight years, depending on the extent of foreign investment in us. The availability of these tax benefits, however, is subject to certain requirements, including, among other things, making specified investments in fixed assets and equipment, financing a percentage of those investments with our capital contributions, compliance with our marketing program which was submitted to the Investment Center, filing of certain reports with the Investment Center and compliance with Israeli intellectual property laws. If we do not meet these requirements in the future, these tax benefits may be cancelled and we may be required to refund the amount of the benefits already received, in whole or in part, with the addition of linkage differentials to the Israeli consumer price index and interest, or other monetary penalty. The tax benefits that we anticipate receiving under our current “approved enterprise” program may not be continued in the future at their current levels or at all.

***We participate in a “consortium” that may restrict the transfer of know-how that we develop.***

We are currently participating in the consortium “Rimonim,” which is supported by the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor of the State of Israel, or the OCS. The aim of this consortium is to develop technologies for the use of siRNA and microRNA mimetics for therapeutics. The consortium includes five companies and five academic groups. The transfer of know-how developed in the

framework of the consortium or rights to manufacture based on and/or incorporating such know-how to third parties which are not members of the consortium requires the consent of the OCS.

***Provisions of Israeli law may delay, prevent or impede an acquisition of us, which could prevent a change of control.***

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be completed unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the approval of a majority of each class of securities of the target company is required to approve a merger.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when the time expires, tax then becomes payable even if no actual disposition of the shares has occurred.

These provisions could delay, prevent or impede an acquisition of us, even if such an acquisition would be considered beneficial by some of our shareholders.

***It may be difficult to enforce a U.S. judgment against us, our officers and directors or to assert U.S. securities law claims in Israel.***

We are incorporated in Israel. Most of our executive officers and directors are not residents of the United States, and a majority of our assets and the assets of these persons are located outside of the United States. Therefore, it may be difficult to enforce a judgment obtained in the United States, against us or any of these persons, in U.S. or Israeli courts based on the civil liability provisions of the U.S. federal securities laws. Additionally, it may be difficult to enforce civil liabilities under U.S. federal securities laws in original actions instituted in Israel.

***Being a foreign private issuer exempts us from certain SEC and NASDAQ requirements***

We are a “foreign private issuer” within the meaning of rules promulgated by the SEC. As such, we are exempt from certain provisions applicable to U.S. public companies including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q and current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information; and
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and establishing insider liability for profits realized from any “short-swing” trading transaction (a purchase and sale, or sale and purchase, of the issuer’s equity securities within less than six months).

In addition, under the rules and regulations of The NASDAQ Stock Market, a foreign private issuer may follow its home country practice in lieu of certain NASDAQ listing requirements. For example, under NASDAQ’s rules, each of (1) the private placement completed in December 2010, (2) the concurrent private placement and registered direct offering completed in February 2011, (3) the private placement completed in October 2011, (4) the Debenture transaction completed in January 2012, (5) the registered direct offering completed in April 2012, and (6) the registered direct offerings completed in May 2012, would have required shareholder approval because these offerings represented the issuance (or potential issuance) of more than 20% of our outstanding ordinary shares at a price per share below the greater of book value per share or market value per share. However, we chose to follow our home country practice, which did not require shareholder approval of these offerings. Because of these SEC and NASDAQ exemptions, investors are not afforded the same protections or information generally available to investors holding shares in public companies organized in the United States.

## **Risks Related to this Offering and our Ordinary Shares**

*Our stock price has been and is likely to continue to be volatile and the market price of our ordinary shares may drop.*

Prior to our February 2007 initial public offering, there was not a public market for our ordinary shares. There is a limited history on which to gauge the volatility of our stock price; however, since our ordinary shares began trading on NASDAQ on February 27, 2007 through March 15, 2013, our stock price has fluctuated from a low of \$1.40 to a high of \$619.77 (after giving effect to the reverse stock splits effected in July 2011 and May 2012). Furthermore, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology, and other life sciences company stocks. The volatility of pharmaceutical, biotechnology, and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our ordinary shares to fluctuate include:

- failure of any of our diagnostic tests to achieve commercial success;
- introduction of technological innovations or new commercial products by us or our competitors;
- our entry into new, or termination or other developments relating to our existing, collaboration, distribution and licensing agreements;
- developments relating to our efforts to commercialize our tests in the United States;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- failure to secure adequate capital to fund our operations, or the issuance of equity securities at prices below fair market price;
- changes in estimates or recommendations by securities analysts, if any cover our securities;
- litigation;
- future sales of our ordinary shares;
- general market conditions;
- changes in the structure of healthcare payment systems;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial results; and
- overall fluctuations in U.S. equity markets.

These and other external factors may cause the market price and demand for our ordinary shares to fluctuate substantially, which may limit or prevent investors from readily selling their shares and may otherwise negatively affect the liquidity of our ordinary shares. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

*We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on an investment in our ordinary shares must come from increases in the fair market value and trading price of our ordinary shares.*

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on an investment in our ordinary shares must come from increases in the fair market value and trading price of our ordinary shares.

## **ITEM 4. INFORMATION ON THE COMPANY**

### **A. HISTORY AND DEVELOPMENT OF THE COMPANY**

#### **History**

We were incorporated under the laws of the State of Israel on March 9, 2000 as Rosetta Genomics Ltd., an Israeli company. The principal legislation under which we operate is the Israeli Companies Law, 5759-1999, as amended (referred to herein as the “Companies Law”). Our principal executive office is located at 10 Plaut Street, Science Park, Rehovot 76706 Israel, and our telephone number is + 972-73-222-0700. Our wholly owned subsidiary, Rosetta Genomics Inc., which was incorporated in Delaware on April 21, 2005, is located at 3711 Market Street, Suite 740, Philadelphia, Pennsylvania 19104, U.S.A., and its telephone number is (215) 382-9000. Through Rosetta Genomics Inc., we market our products and perform lab services in the United States. Our web site address is [www.rosettagenomics.com](http://www.rosettagenomics.com). The information on our web site is not incorporated by reference into this Annual Report and should not be considered to be a part of this Annual Report.

On February 4, 2010, we established Rosetta Green Ltd., an Israeli Company, as a controlled subsidiary. As of December 31, 2010, we owned approximately 76.2% of the outstanding ordinary shares of Rosetta Green. In February 2011, Rosetta Green completed an initial public offering in Israel on the Tel Aviv Stock Exchange, or TASE. In December 2011, we sold our complete ownership interest in Rosetta Green, which represented approximately 50.03% of the outstanding ordinary shares of Rosetta Green. We received an upfront payment of \$900,000 for the Rosetta Green ordinary shares. In addition, we were entitled to a payment of \$2,000,000 if Rosetta Green was acquired within three years and if certain other conditions were met in connection with such acquisition. In February 2013, Rosetta Green was acquired by A.B. Seeds Ltd., an affiliate of Monsanto Co., however, the conditions required to be met for us to receive the \$2,000,000 were not met.

On July 22, 2008, through Rosetta Genomics Inc., we purchased all of the shares of Parkway Clinical Laboratories, Inc., a privately held Pennsylvania corporation owning a CLIA-certified laboratory, for an aggregate purchase price of \$2,900,000 (not including \$207,000 of transaction expenses), consisting of \$1,900,000 in cash and \$1,000,000 of our ordinary shares, plus an additional \$300,000 payable upon the achievement of certain milestones, which were not met. Parkway remained an indirect wholly owned subsidiary until May 18, 2009, when we sold Parkway for up to \$2,500,000, to be paid as a fixed percentage from the revenues over six years. With its CLIA certification, Parkway helped us to obtain CLIA certification for our laboratory in Philadelphia, Pennsylvania.

### **Principal Capital Expenditures**

We had net capital expenditures and repayment of capital lease of \$298,000 in 2012, \$89,000 in 2011, and \$579,000 in 2010. Our capital expenditures during 2012, 2011, and 2010 consisted primarily of laboratory equipment, computer equipment and leasehold improvements. We have financed our capital expenditures with cash generated from financing activities. We are currently making further capital improvements in our laboratory in Philadelphia. We are also in the process of redesigning our corporate website.

## **B. BUSINESS OVERVIEW**

### **Overview**

We are seeking to develop and commercialize new diagnostic tests and therapeutics based on a group of genes known as microRNAs. MicroRNAs are naturally expressed, or produced, using instructions encoded in DNA and are believed to play an important role in normal function and in various pathologies. We have established a CLIA-certified laboratory in Philadelphia, which enables us to commercialize our own diagnostic tests applying our microRNA technology.

We believe that we were the first commercial enterprise to focus on the emerging microRNA field, and that as a result, we have developed an early and strong intellectual property position related to the development and commercialization of microRNA-based diagnostics. Using our intellectual property, collaborative relationships with leading commercial enterprises and academic and medical institutions, and expertise in the field of microRNAs, we have initiated microRNA-based diagnostic programs for various cancers. In late-2008, we launched our first three diagnostic tests applying our microRNA technology:

1. miRview® mets - for identification of the origin of the primary tumor of metastases;
2. miRview® squamous - for differentiating squamous from non squamous non-small cell lung cancer; and
3. miRview® meso - for differentiating mesothelioma from carcinomas in the lung and pleura.

In December 2010, we launched our fourth product - miRview® mets<sup>2</sup> which expands the utility of our miRview® mets test. miRview® mets<sup>2</sup> has replaced miRview® mets as our primary CUP assay.

In July 2011, we launched our fifth product - miRview® lung – for differentiating primary lung cancers into four types: squamous lung cancer, non-squamous non-small cell lung cancer, carcinoid lung cancer and small cell lung cancer. miRview® lung has replaced miRview® squamous as our primary lung diagnostic assay.

In May 2012, we launched our sixth product - miRview® kidney – for differentiating four histological types of renal or kidney tumors.

We currently have distribution agreements with respect to some of these tests covering Australia, Canada, Greece, India, Israel, New Zealand, Qatar, Saudi Arabia, Singapore, Turkey and the United Arab Emirates. All of these distribution agreements call for samples to be sent to our CLIA-certified laboratory in Philadelphia for analysis.

On July 23, 2012 we entered into a co-marketing agreement with Precision Therapeutics Inc., which was revised on October 15, 2012, pursuant to which we have granted Precision Therapeutics the co-exclusive right, along with us, to market miRview® mets<sup>2</sup> in the United States.

In general, we are generating demand for our testing services, primarily miRview® mets<sup>2</sup>, through our direct selling effort in the United States and are successfully fulfilling that demand in our lab in Philadelphia, Pennsylvania. We are working with our reimbursement vendor and consultants to gain more consistent payment from commercial payors, as well as to secure reimbursement coverage from Medicare. In May 2012, we announced that the designated Medicare Administrative Contractor, or MAC, for the miRview® mets<sup>2</sup> test had informed us that it plans to cover this test for all Medicare beneficiaries, and in June 2012, we announced that the MAC had established a reimbursement rate for the test.

In addition, we are in the discovery stage for a body fluid-based diagnostic test for Heart Failure (HF). We have performed a proof of concept (POC) study which demonstrated that by using microRNA expression levels in serum we can identify heart failure patients. We are currently performing additional studies involving various blood fractions to assess the feasibility to develop a minimally-invasive microRNA-based stratification test for HF.

MicroRNAs also represent potential targets for the development of novel drugs. We are participating in the Rimonim Consortium, which is supported by the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor of the State of Israel, or the OCS. The aim of this consortium is to develop technologies for the use of short interfering RNA, or siRNA, and microRNA mimetics for therapeutics. In this consortium, we are attempting to develop novel microRNA mimetic molecules with novel chemical modifications, as well as novel delivery systems for microRNAs. The consortium includes five companies and five academic groups. The transfer of know-how developed in the framework of the consortium or rights to manufacture based on and/or incorporating such know-how to third parties which are not members of the consortium requires the consent of the OCS. See also “Item 4.B. Business Overview – Rimonim Consortium.

## **Background**

Rosetta Genomics was founded in 2000 with the belief that what was known as “junk DNA” actually contains hundreds, possibly thousands, of tiny RNA genes that encode small RNA molecules, later termed microRNAs, which play an important role in the regulation of protein production, and hence the onset and progression of disease. In the cell, genes are expressed through information carried from our DNA by messenger RNAs, or mRNAs, which is in turn translated into proteins. Proteins are the building blocks of all living cells. The type of cell, its function, and the timing of its death are determined by which proteins are produced in the cell, and at what quantities and time they are produced. However, the proteins are the end product of a complex process which begins with the genetic code present in DNA. Before a protein is expressed, or produced, relevant parts of the DNA are copied into a mRNA. Each mRNA holds a code with instructions on how to build a specific protein using a process called translation. Although one messenger RNA molecule is capable of translating hundreds of thousands of protein molecules, the number it actually produces is regulated by microRNAs. MicroRNAs have been found to regulate the expression of other genes by binding to the mRNA.

MicroRNAs have been shown to have varying expression levels across various pathological conditions, and thus have significant potential as a class of highly sensitive and tissue specific biomarkers. We have developed a microRNA discovery process and have demonstrated, in a work published by us in Nature Genetics, that the number of human microRNAs is significantly higher than what was previously believed. We have discovered hundreds of biologically validated human microRNAs and dozens of validated viral microRNAs and filed extensive patent applications with claims potentially covering these microRNAs, some of which have been issued.

To leverage the potential of microRNAs as a novel diagnostic platform, we have developed proprietary methods to extract microRNAs from a wide range of tissue and body fluid samples and to quantify specific microRNA expression signatures, which may be used as diagnostic panels to potentially diagnose cancers, their subtypes, as well as the origin of metastases. We have already developed and launched six diagnostic tests based on our platforms and have published several papers demonstrating how our methods can be used to develop such diagnostics (e.g. Rosenwald et al., Modern Pathology, 2010; Benjamin et al., Journal of Molecular Diagnostics, 2010). Moreover, we were able to demonstrate the utility of our developed tests in post-market studies with collaborators from leading medical centers in the United States and Europe (Bishop et al. Clinical Cancer Research, 2010; Muller et al., The Oncologist, 2010).

We believe that microRNAs are stable, sensitive and specific markers, and we are advancing diagnostic development programs in cancer and other areas, to potentially enable accurate diagnosis and improve patient care management worldwide.

## **Our Strategy**

Rosetta’s goal is to become a leader in the development and commercialization of microRNA-based diagnostic tests. Our key business strategies to achieve this goal are as follows:

- *Leverage our knowledge and experience.* We plan to leverage our extensive microRNA knowledge and experience to potentially develop additional tissue based as well as body fluid-based diagnostic tests.
- *Maximize sales of our current commercial tests through geographic partners.* We plan to maximize revenues from our four current commercial tests via corporate relationships and through our own targeted commercial efforts. To date we have entered into distribution agreements with five distributors, pursuant to which these distributors have the right to commercialize these tests in their territories. Furthermore, we have also entered into a co-promotion agreement with a partner in the U.S. We intend to support the work of these partners while pursuing other partnerships for additional geographies.
- *Build and maintain a strong intellectual property position.* We believe that we were the first commercial enterprise to focus on the emerging field of microRNAs. We also believe we have an early and strong intellectual property position (both patents we own and those we have exclusively, co-exclusively, or non-exclusively licensed) in the area of developing and commercializing microRNA-based diagnostic tests. Our patent strategy is to seek broad coverage on all of our identified microRNA sequences. We have also filed, and intend to continue to file, patent applications that claim our technical platforms and method-of-use for specific diagnostic and therapeutic applications.
- *Leverage our intellectual property position and microRNA expertise to continue to establish strategic collaborations.* We intend to continue to establish strategic collaborations with leading clinical diagnostic and pharmaceutical companies to further develop and

commercialize microRNA-based diagnostics. We believe that our strong intellectual property position and expertise in the field of microRNAs will be very attractive to additional collaboration partners.

## ***Our Diagnostic Tests***

### ***The Role of MicroRNAs in Diagnostic Products***

Ideally, diagnostic tests provide physicians and their patients with information relating to one or more of the following:

- the existence or the probability of developing disease;
- the exact type of the disease;
- the severity of the disease;
- the potential efficacy of specific therapies, such as different drugs or therapeutic procedures;
- the monitoring of success of a chosen therapy; or
- the likelihood of disease recurrence.

We believe that using microRNAs as diagnostic biomarkers will enable the development of diagnostic products that can provide more accurate and comprehensive information to doctors and patients. Currently, many diagnostic tests are designed to detect abnormal levels of messenger RNAs or proteins. We believe microRNA-based tests have the potential to be superior to these tests because it is believed that microRNAs are closer to the biological origin of disease and many studies have shown their involvement in disease processes, including the demonstration that microRNAs are both diagnostic and prognostic markers. A change in the expression level of a single microRNA may affect the activity of dozens of messenger RNA genes, which in turn may affect the level of hundreds of proteins. In addition, microRNAs are very tissue specific and very stable in body fluids and tissue samples. Thus, we expect that by focusing our efforts on microRNAs, we can develop a less complex biomarker panel, resulting in a more specific and sensitive test. Furthermore, extracting microRNAs from tissue and body fluid samples is more reliable than extracting messenger RNAs because of the greater stability of microRNAs. In addition, amplification technologies, such as PCR, can potentially increase the sensitivity of a microRNA-based diagnostic test by generating millions of copies of a particular microRNA and thereby making it easier for the test to detect the presence of the microRNA. Since amplification technologies cannot be used with proteins, we believe microRNA-based diagnostic tests have the potential to be more sensitive than protein-based diagnostic tests.

### ***Our Diagnostic Product Development Process***

Our development process for diagnostic products consists of the following important steps:

- *Access to samples.* As a prerequisite for the development and clinical validation of diagnostic products, evaluation of clinical samples is critical. Accordingly, we have entered into collaborations with several institutions in Israel, Europe and the United States that provide us high quality clinical samples. These relationships provide us the opportunity to study thousands of well-characterized samples relevant to different disease areas such as cancer, cardiovascular indications, women's health, and neurodegenerative diseases. The sample collections include solid tumor samples and various body fluids such as blood, as well as high quality tissue samples from archival pathology banks. Where relevant, samples are accompanied by a database of medical history and clinical information, such as diagnosis, treatment and response to treatment, recurrence and survival, which for the samples from the archival pathology banks can be as long as 20 years.
- *RNA extraction.* We utilize both commercial and our proprietary technologies to extract microRNAs from both tissue and body fluid samples.
- *Expression profiling.* The identification of microRNA biomarkers requires sensitive and specific measurements of the levels of the microRNAs extracted from the tissue or body fluid samples. We have developed proprietary methods to rapidly, robustly and accurately perform these measurements. Our methods allow us to perform simultaneous profiling of multiple samples, and we believe result in more accurate measurements of expression levels for each of the analyzed samples.
- *Analysis.* We analyze expression profiles to identify microRNA signatures which detect the existence of disease and provide information on certain disease parameters, such as tumor subtype, tumor origin, tumor aggressiveness, response to treatment, and risk of recurrence. Identifying microRNA signatures is a complex task, and we believe our analytical expertise is one of our key advantages.

### ***Current Commercial Tests***

We are currently marketing and selling the following four diagnostic tests based on our proprietary microRNA technologies:

- *miRview<sup>®</sup> mets<sup>2</sup>* – This test is our second-generation microRNA-based diagnostic for the identification of the primary site of metastatic cancer, specifically metastatic cancer of unknown primary (CUP). miRview<sup>®</sup> mets<sup>2</sup> has replaced miRview<sup>®</sup> mets as our primary CUP assay. CUP is a heterogeneous group of cancers that constitutes 3-5% of all cancers with a poor median survival of six to ten months. Each year approximately 70,000 patients in the United States are diagnosed with CUP. A patient is typically diagnosed with CUP only

after undergoing a wide range of tests, including various imaging tests such as x-ray, CT, MRI, and PET, which have failed to identify the origin of the cancer. Presently, the choice of treatment for metastatic cancer is largely dependent on the nature of the primary tumor. Patients with CUP pose a therapeutic dilemma and treatment is often empiric with a “one treatment fits all” approach. In the era of rapidly growing effective cytotoxic and targeted therapies for known cancers, quicker and more accurate methods to identify the tissue of origin of CUP cancers would permit the use of these therapies, thereby improving the chances of achieving a response and possibly extending the patient’s survival. miRview<sup>®</sup> mets<sup>2</sup> is able to identify 42 tumor types that include carcinomas, soft tissue tumors, lymphoma and other malignancies with very high accuracy.

- *miRview*<sup>®</sup> *meso* – This test leverages microRNA’s high-specificity as biomarkers to differentiate mesothelioma, a cancer connected to asbestos exposure and other risk factors, from other carcinomas in the lung and pleura, a medically and legally important differential diagnosis. Malignant pleural mesothelioma, or MPM, is a solid, locally aggressive tumor of the lung pleura that covers and later invades the lung parenchyma, which leads to a severe clinically symptomatic disease. The incidence of mesothelioma has clearly grown in recent years in all developed countries of Western Europe and North America, and most probably in developing countries as well. Exposure to asbestos is still a major factor that contributes to the continuing growth in number of cases. As mesothelioma patients require specific treatment regimens, an accurate diagnosis is critical. However, the distinction between mesothelioma and carcinomas that involve the pleura, in particular peripheral pulmonary adenocarcinoma, can be challenging. Because of the inter-observer variations between pathologists, and because of the absence of a single specific and reliable biomarker for the diagnosis of mesothelioma, there is a need for a reliable and objective assay that would help make this distinction with greater confidence. We used microRNA biomarkers we identified to develop *miRview*<sup>®</sup> *meso*, a molecular assay for the differential diagnosis of mesothelioma. This assay provides a standardized, quantitative alternative to the currently applied methods. The small number of microRNAs needed for classification, the high tissue specificity of these microRNAs and the ease of their determination from archival fixed tissues embedded in paraffin, makes this assay a practical option. The microRNA-based assay that we have developed, uses expression levels of only three microRNAs, and is able to accurately diagnose mesothelioma and distinguish it from lung adenocarcinoma and other malignancies involving the lung and pleura with very high sensitivity and specificity. This assay is simple to perform and highly reliable in its reproducibility.
- *miRview*<sup>®</sup> *lung* - This test is a microRNA-based lung cancer classification test for cytology samples, mainly fine-needle aspirate, or FNA, samples as well as pathology samples, such as small biopsies and resections. The test targets all newly diagnosed lung cancer patients, estimated to be more than 200,000 people annually in the United States alone. The test classifies primary lung cancers into Neuroendocrine vs. NSCLC and then further classifies NSCLC into squamous vs. non-squamous and Neuroendocrine into Small Cell Lung Cancer (SCLC) vs. carcinoid. The microRNA-based assay that we have developed is performed by measuring microRNA biomarkers in a sample from the tumor, where the sample can be either a cytology sample or a pathology sample. The assay measures the expression of 8 microRNAs and using that expression accurately identifies the lung cancer subtype. *miRview*<sup>®</sup> *lung* has replaced *miRview*<sup>®</sup> *squamous* as our primary lung diagnostic assay.

Lung cancer is the leading cause of cancer-related death in both men and women worldwide and in the United States. It is estimated that in the United States alone, there were 222,520 new cases of lung cancer diagnosed in 2010 and that approximately 157,300 people will die of the disease this year.

For patients with lung carcinoma, the accurate determination of tumor type significantly influences treatment decision. In general, SCLC, the main sub-type of Neuroendocrine tumors, is much more responsive to chemotherapy and consequently this comprises the mainstay of treatment. This is in contrast to NSCLC which is relatively chemoresistant and thus primarily treated with surgical resection for local disease. In addition, the recent emergence of novel biological therapies that effectively target specific cellular alterations now demands the most precise classification possible for non-small cell carcinomas. For example, lung adenocarcinomas are more likely to respond to EGFR tyrosine kinase inhibitors (e.g. erlotinib). Similarly, antibody therapy (bevacizumab) directed against vascular endothelial growth factor (VEGF) is more effective in the treatment of adenocarcinomas. Not only is bevacizumab less effective in treating squamous cell lung cancers, but the squamous phenotype is associated with much higher rates of life-threatening pulmonary hemorrhage. Thus, the distinction of squamous from non-squamous carcinomas is becoming increasingly important. Current methods for differentiating squamous from non-squamous NSCLC are not standardized, are difficult to reproduce and have an unacceptable level of variability between pathologists and laboratories, as indicated in numerous peer review publications.

- *miRview*<sup>®</sup> *kidney* - In May 2012 we launched this microRNA-based kidney tumor classification test for pathology samples. This test targets newly diagnosed kidney tumor patients, estimated to be more than 54,000 people annually in the United States. Renal cancers account for more than 3% of adult malignancies and cause more than 13,000 deaths per year in the United States. The test was designed to classify primary kidney tumors into one of the four most common types: the malignant renal cell carcinomas clear cell (conventional), papillary and chromophobe as well as the benign oncocytoma. These histological subtypes vary in their clinical course and their prognosis, and different clinical strategies have been developed for their management. In some of the kidney tumor cases it is difficult for the pathologist to distinguish between tumor types on the basis of morphology. The microRNA-based assay that we have developed is performed by measuring microRNA biomarkers in a sample from the tumor. The assay uses the expression of 24 microRNAs to accurately identify the kidney tumor subtype.

We currently have the following distribution agreements relating to miRview<sup>®</sup> mets, miRview<sup>®</sup> squamous, and miRview<sup>®</sup> meso:

- with Teva Pharmaceutical Industries Ltd., pursuant to which Teva has the right to distribute these tests in Turkey and Israel;
- with Warnex Medical Laboratories, a division of Warnex, Inc., pursuant to which Warnex has the exclusive right to distribute these tests in Canada;
- with Genekor S.A., pursuant to which Genekor has the exclusive right to distribute these tests in Greece;
- with Super Religare Laboratories Limited (SRL), pursuant to which SRL has the non-exclusive right to distribute these tests in India, Saudi Arabia, Qatar and the United Arab Emirates; and
- with Genetic Technologies Limited (GTL), pursuant to which GTL has the exclusive right to distribute these tests in Australia, New Zealand and Singapore.

We are currently in the process of amending these distribution agreements to reflect that we have replaced miRview<sup>®</sup> mets and miRview<sup>®</sup> squamous with miRview<sup>®</sup> mets<sup>2</sup> and miRview<sup>®</sup> lung, respectively. While we are amending these agreements, if we receive a sample relating to miRview<sup>®</sup> squamous, we contact the ordering physician and offer them the miRview<sup>®</sup> lung test at no extra cost. However, if they prefer, we will run the miRview<sup>®</sup> squamous test. If we receive a sample relating to miRview<sup>®</sup> mets, we offer miRview<sup>®</sup> mets<sup>2</sup>, but we will not run the “old” miRview<sup>®</sup> mets test if they do not want the miRview<sup>®</sup> mets<sup>2</sup> test.

On June 9, 2011 we entered into an agreement with PACE claims services, LLC, a wholly owned subsidiary of Navigant Inc., (PACE), according to which, PACE will provide us exclusive educational and marketing services to defendants involved in lawsuits relating to malignant pleural mesothelioma and asbestos exposure, provided the exclusivity does not apply to our own marketing efforts and to any marketing efforts of our distributors offering our tests outside of the United States. According to this agreement, PACE will be entitled to certain remuneration derived from actual sales to defendants in these lawsuits.

On July 23, 2012 we entered into a co-marketing agreement with Precision Therapeutics Inc., which was revised on October 15, 2012, pursuant to which we have granted Precision Therapeutics the co-exclusive right, along with us, to market miRview<sup>®</sup> mets<sup>2</sup> in the United States.

All of these distribution and other agreements call for samples to be sent to our CLIA-certified laboratory in Philadelphia, Pennsylvania for analysis.

### ***Our Long-term Pipeline***

We believe that body fluid-based tests for early diagnosis and/or stratification of patients in different diseases are the future of the diagnostics industry and that our highly sensitive and specific platforms are suitable for development of such tests. Thus, we expect to continue to search for microRNA biomarkers in order to develop body fluid-based tests for different indications.

We are currently working on the development of the following body fluid based diagnostic test, based on microRNA's:

- *Heart Failure* - We are seeking to discover blood-based microRNA biomarkers in order to develop a new diagnostic test for early diagnosis and refined risk stratification of patients following Myocardial Infarction (MI). Such a test has the potential to influence clinical management in a cost effective manner, by improving diagnosis, refining risk stratification and guiding therapy. Heart Failure (HF) is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricles to fill with or eject blood. It is the most prevalent disease in the western world and the only cardiovascular disease whose prevalence continues to rise. It is estimated that 5 million Americans are diagnosed with HF and each year there are approximately 500,000 new HF patients. Besides its high prevalence, HF is also the most expensive disease in western countries. We have so far performed a first study, which was published in the European Journal of Heart Failure (Goren et. al., 2012), showing that elevated serum levels of specific microRNAs identify heart failure patients.

### **Therapeutic Products**

MicroRNAs are important regulators of protein expression, and as such, they represent potential targets for the development of drugs. Important information about the role of a microRNA in a disease can be deduced by mimicking or inhibiting its activity and examining the impact this has on the phenotype of the cell or organism. If mimicking or inhibiting a microRNA leads to improvement in disease symptoms, this implies that the target microRNA plays an important role in the disease and thus, can serve as a potential drug target. Expression studies indicate significant changes in microRNA expression in different disease states in comparison to normal tissue. Inhibition or replacement of one microRNA can extensively effect a cell internally and significantly alter the cellular phenotype since it can change a number of genes that are direct targets of the

microRNA, as well as genes influenced by those direct targets, therefore influencing whole pathways. Accordingly, microRNA inhibition or replacement has the potential to be a key factor in the treatment of various disease conditions. MicroRNA replacement will strive to mimic the natural effect of a down-regulated microRNA in a specific indication. This will result in silencing the natural targets to reverse the phenotypic changes the cell experienced after the de-regulation of this specific microRNA.

Because microRNAs are natural regulators of protein expression, we believe it is possible to develop microRNA-based therapeutic products which can either increase or decrease the levels of proteins. A drug that mimics a microRNA should result in decreased levels of the proteins naturally regulated by that microRNA, while a drug that inhibits the microRNA should result in increased levels of those proteins. We believe that microRNAs can serve as a basis for a new class of therapeutic products and that we can leverage our microRNA diagnostic capabilities to help develop drugs targeting microRNAs.

We have demonstrated this in liver cancer, ovarian cancer and pancreatic cancer, where differential microRNAs that were shown in tissues of patients were used to find drug candidates that could inhibit those cancers through either microRNA inhibition or mimetics. In ovarian cancer we chose microRNAs that were over-expressed in ovarian tissues (both tumor and normal) comparing to other normal tissues, and in liver and pancreatic cancer we chose microRNAs that are over expressed in the cancerous tissue comparing to adjacent healthy tissue. Those microRNAs served to help us design modified oligonucleotides with anti-sense sequences that were used in vitro in proliferation assays. We specifically wanted to see microRNA inhibition that can lead to reduction in proliferation of cancer cell lines. The anti- microRNAs with the strongest effect over cell proliferation were chosen as the drug candidates with most potential.

### ***Rimonim Consortium***

In January 2011, we joined the Rimonim Consortium, which is supported by the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor of the State of Israel, or the OCS. The purpose of the consortium is to develop RNA interference, or RNAi, -based therapeutics. As a member of the consortium, we are entitled to certain grants to support our research and development activities. Under the terms applicable to members of the consortium, so long as we continue to meet the criteria for receiving these grants, which criteria include the payment by us of part of the expenses for the activities funded by the grants and the timely delivery to OCS of written reports regarding those activities, then we are not required to repay the grants. If we cease to meet these and other criteria, then the grant amounts for the year in which we ceased to meet the criteria become immediately due and payable to OCS. As of the date of this report, we had received total grants of \$355,000 from the OCS for our development within the consortium and continued to meet the criteria to receive grants such that we are not obligated to repay those funds. The vision of the consortium is to develop new advanced technologies that are expected to help in solving some of the key problems and deficiencies that the industry is facing in developing RNAi-based therapeutics and create a significant RNAi-based industry in Israel by using breakthrough technologies and producing RNAi therapeutics and a range of additional products (diagnostics, chemical and biological services). Since discovery, the development of RNAi to first, a powerful research tool and, more recently, to a promising therapeutic approach, has occurred very rapidly. The ability to specifically silence virtually every gene including previously non-druggable (non-amenable for development of small molecule inhibitors) targets has made RNAi-based therapeutics a very attractive approach for treating diseases in many therapeutic areas.

The main challenges in the development of siRNA/miRNA therapeutics addressed by the consortium are:

1. siRNA/miRNA drug substance: Only a very limited number of non-toxic chemical modifications to the basic structures that are suitable to make the drug active and with the desirable properties are available.
2. siRNA/miRNA drug delivery to target tissues/cells: This is the major problem in the field. Practically all RNAi drugs in development are currently delivered only locally, and even the local delivery is not optimized. Efficient and productive systemic siRNA delivery has been demonstrated only to the kidney (non-formulated) and to the liver (formulated), whereas systemic delivery is needed for many serious diseases. In addition, most formulations currently available are highly toxic, thus allowing only very narrow therapeutic windows.

Members of the consortium, are established representatives of the industry and academia in Israel that will share their expertise and experience in various fields of the technological challenges: biology, toxicology, physical and structural chemistry, formulation, and others, to establish a meaningful scientific/technological basis for what has the potential to be one of the most promising technical breakthroughs in biological research in the last decade.

The transfer of know-how developed in the framework of the consortium or rights to manufacture based on and/or incorporating such know-how to third parties which are not members of the consortium requires the consent of the OCS.

### **Our Intellectual Property Strategy and Position**

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;
- defend our patents;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.



We believe that we were the first commercial enterprise to focus on the emerging microRNA field, and as a result, we have developed an early and strong intellectual property position related to the development and commercialization of research, diagnostic and therapeutic products and other applications based on microRNAs. Our patent strategy is to seek broad coverage on all of our identified microRNA sequences. We also filed applications which claim groups of microRNAs which are grouped for example by chromosomal locations of the microRNA genes. We have filed, and will continue to file, patent applications that claim method-of-use for specific diagnostic and therapeutic applications as we or our collaborators develop them. We believe this approach will provide strong and broad patent protection for a large number of microRNAs that we have discovered and may provide us with a competitive advantage over new entrants to the field.

As of March 21, 2013, our patent portfolio included a total of 25 issued U.S. patents, one issued Australian patent, one issued European patents, two issued Israeli patents, 41 pending patent applications worldwide, consisting of 21 U.S. patent applications, three of which received notice of allowance, five PCT applications, three applications that were nationalized in Europe, three applications nationalized in Israel, two applications nationalized in Japan, two applications nationalized in Australia, two applications nationalized in Canada, two applications nationalized in China and one application that was nationalized in Korea. Of these patent applications, 35 relate to human microRNAs and their uses, three claim viral microRNAs, and three contain claims related to our discovery process. 21 applications contain claims directed to microRNA-based diagnostics in Heart Failure, Alzheimer's disease, Cancer of Unknown Origin (CUP), lung, mesothelioma and other cancers; and nine contain claims directed to microRNA-based therapeutics. The issued patents expire between 2022 and 2028. To date, patent protection related to numerous human genes has been obtained in the United States and elsewhere, and since microRNAs are derived from naturally occurring genes, we believe, are similarly patentable under U.S. and foreign patent laws. However, see "Item 3. Key Information—D. Risk Factors—If we are not able to obtain and enforce patent protection for our discoveries, our ability to develop and commercialize microRNA-based diagnostics and therapeutics will be harmed." for a description of recent U.S. case law that could affect the patentability of genes and genetic material. While a final ruling has yet to be received whether nucleic acids related to genes are patentable under U.S. patent laws nucleic acids related to genes are generally patentable under foreign patent laws.

In order to obtain maximum patent protection for composition of matter of microRNAs in the U.S. and foreign jurisdictions, our patent applications:

- provide for utility, function and disease targets for each microRNA sequence;
- claim specific microRNA sequences as opposed to general mechanism or concept; and
- identify the functional fragment of each microRNA sequence.

We believe this approach avoids common mistakes made by others in the past with respect to attempts to patent genes and, if patents are issued, will make it more difficult for competitors to design around our patents.

Our intellectual property strategy is closely coordinated with our research and development plan and we have an ongoing three-tier approach to obtaining patent protection, which is illustrated and described below:

#### ***First Tier: Composition-of-Matter Patent applications on Biologically Validated MicroRNAs***

We have filed a first tier of patent applications claiming patent coverage for the composition-of-matter of microRNAs that we have either detected by microarray or biologically validated by sequencing or qRT-PCR. In addition to the function and utility based on informatically calculated targets, microRNAs claimed in these patent applications are further described as potential markers of a disease, as supported by differential expression of these microRNAs in healthy versus diseased tissue. Our patent portfolio includes 29 issued patents and 8 patent applications with composition-of-matter claims related to validated microRNAs.

#### ***Second Tier: Technologies to detect MicroRNAs***

We have filed a second tier of patent applications claiming patent coverage for our proprietary discovery process technologies for microRNA detection, including qRT-PCR methods, microarray, in-situ hybridization and extraction methods from all body fluids. Our patent portfolio includes 3 patent applications related to discovery process technologies.

#### ***Third Tier: Method-of-Use Patents***

We have filed a third tier of patent applications claiming patent coverage for the method-of-use of microRNAs, including diagnostic and therapeutic uses for specific diseases. This tier of patent applications includes applications which we have filed ourselves and those that we have filed jointly with academic, medical and commercial partners with whom we collaborate. Our patent portfolio includes 30 patent applications with method of use claims related to diagnostic and therapeutic uses of microRNAs and we expect to file additional third tier applications in the future.

Individual patents extend for varying periods depending on the effective date of filing of the patent application or the date of patent issuance, and

the legal term of the patents in the countries in which they are obtained. Generally, patents issued in the United States are effective for:

- the longer of 17 years from the issue date or 20 years from the earliest effective filing date, if the patent application was filed prior to June 8, 1995; and
- 20 years from the earliest effective filing date, if the patent application was filed on or after June 8, 1995.

All of our current patent applications were filed after June 8, 1995.

The term of foreign patents varies in accordance with provisions of applicable local law, but typically is 20 years from the earliest effective filing date. In addition, in some instances, a patent term in the United States and outside of the United States can be extended to recapture a portion of the term effectively lost as a result of the health authority regulatory review period. These extensions, which may be as long as five years, are directed to the approved product and its approved indications. We intend to seek such extensions as appropriate. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that a patent may remain in force for a short period following commercialization, thereby reducing the advantage of the patent to our business and products.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents or if issued will assist our business. Any patents that may issue in the future may be challenged, invalidated or circumvented. This could limit our ability to stop competitors from marketing related products and reduce the length of term of patent protection that we may have for any products. In addition, the rights granted under any patents which may issue may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Our competitors may develop similar technologies, duplicate any technology developed by us, or use their patent rights to block us from taking full advantage of the market.

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect the trade secrets in our proprietary technology and processes, in part, by entering into confidentiality agreements with commercial partners, collaborators, employees, consultants, scientific advisors and other contractors and into invention assignment agreements with our employees and some of our commercial partners and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of the technologies that are developed. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

### ***In-Licensed Intellectual Property***

#### *License Agreement with The Rockefeller University (Diagnostics)*

In May 2006, we signed a royalty-bearing, co-exclusive, worldwide license agreement with The Rockefeller University. Under this agreement, we were granted the right to make, use and sell Rockefeller's proprietary microRNAs for diagnostic purposes including a limited right to sublicense. Our right to sublicense is limited to sublicenses we grant as part of a license that includes other technology or patent rights of ours. The agreement covers microRNAs and microRNA candidates, including approximately 80 biologically validated human microRNAs and approximately 30 biologically validated viral microRNAs discovered by researchers at The Rockefeller University and for which it has filed patent applications. These microRNAs can be licensed by Rockefeller in the diagnostics field to three additional parties. In consideration for this license, we paid an initiation fee and will pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of our revenues from any sublicenses. Rockefeller is obligated to notify us of any license it grants to a third party at a lower royalty rate and we will have the right to modify the terms of our license to adopt all of the material terms and conditions of that license.

Rockefeller controls prosecution, maintenance and enforcement of all the licensed patent rights; however, we are responsible for a pro rata share of associated costs. Also, if Rockefeller elects not to take action against a claim of infringement of the licensed patent rights, we may undertake such action at our own expense. We are obligated to indemnify Rockefeller against any liabilities arising from our development and use of the licensed microRNAs and any actions brought by third parties or related to clinical trials or studies. We are also required to maintain comprehensive insurance coverage.

The agreement will terminate upon the later of the expiration or abandonment of the last patent to expire or become abandoned. If no patent ever issues, the agreement will terminate ten years after the first commercial sale of the first licensed product. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$960,000 in aggregate annual license maintenance fees over the term of this agreement. Rockefeller has the right to terminate the agreement if we are more than 30 days late in meeting our payment obligations and do not pay in full within ten days of Rockefeller's written demand; or upon our uncured material breach. We can terminate the agreement by providing sixty days written notice to Rockefeller, ceasing all use of the licensed products, terminating any sublicenses granted under the agreement and paying all amounts owed to Rockefeller through the date of termination.



### *License Agreement with The Rockefeller University (Therapeutics)*

In May 2007, we signed a royalty-bearing, co-exclusive, worldwide license agreement with The Rockefeller University. Under this agreement, we were granted the right to make, use and sell Rockefeller's proprietary microRNAs for therapeutic purposes, including a limited right to sublicense. Our right to sublicense is limited to sublicenses that are for research and development of products and that are granted as part of a license that includes other technology or patent rights of ours. The agreement covers microRNAs and microRNA candidates, including approximately 80 biologically validated human microRNAs and approximately 30 biologically validated viral microRNAs discovered by researchers at The Rockefeller University for which it has filed patent applications. These microRNAs can be licensed by Rockefeller in the therapeutics field to three additional parties. In consideration for this license, we paid an initiation fee and are required to pay a fixed annual license maintenance fee, milestone payments and royalties based on net sales and a percentage of our revenues from any sublicenses. Rockefeller is obligated to notify us of any license it grants to a third party at a lower royalty rate, and we will have the right to modify the terms of our license to adopt all of the material terms and conditions of that license.

Rockefeller controls prosecution, maintenance and enforcement of all the licensed patent rights; however, we are responsible for a pro rata share of associated costs. Also, if Rockefeller elects not to take action against a claim of infringement of the licensed patent rights, we may undertake such action at our own expense. We are obligated to indemnify Rockefeller against any liabilities arising from our development and use of the licensed microRNAs and any actions brought by third parties or related to clinical trials or studies. We are also required to maintain comprehensive insurance coverage.

The agreement will terminate upon the later of the expiration or abandonment of the last patent to expire or become abandoned. If no patent ever issues, the agreement will terminate ten years after the first commercial sale of the first licensed product. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$690,000 in aggregate annual license maintenance fees over the term of this agreement. Rockefeller has the right to terminate the agreement if we are more than 30 days late in meeting our payment obligations and do not pay in full within ten days of Rockefeller's written demand; or upon our uncured material breach. We can terminate the agreement by providing 60 days written notice to Rockefeller, ceasing all use of the licensed products, terminating any sublicenses granted under the agreement and paying all amounts owed to Rockefeller through the date of termination.

### *License Agreement with The Rockefeller University (Research)*

In January 2008, we signed a royalty-bearing, nonexclusive, worldwide license agreement with The Rockefeller University. Under this agreement, we were granted the right to make, use, import, sell and offer for sale Rockefeller's proprietary microRNAs for research purposes including a limited right to sublicense. Our right to sublicense is limited to sublicenses we grant as part of a license that includes other technology or patent rights of ours. The agreement covers microRNAs and microRNA candidates, including approximately 80 biologically validated human microRNAs and approximately 30 biologically validated viral microRNAs discovered by researchers at The Rockefeller University and for which it has filed patent applications. In consideration for this license, we paid an initiation fee and will pay a minimum annual royalty, based on net sales and a percentage of our revenues from any sublicenses. Rockefeller is obligated to notify us of any license it grants to a third party at a lower royalty rate and we will have the right to modify the terms of our license to adopt all of the material terms and conditions of that license.

Rockefeller controls preparation, prosecution and maintenance of the licensed patent rights and the selection of patent council with our input; however, we are responsible for a pro rata share of associated costs. Also, if Rockefeller elects not to take action against a claim of infringement of the licensed patent rights, we may undertake such action at our own expense. We are obligated to indemnify Rockefeller against any liabilities arising from our development, testing, use, manufacture, promotion, sale of other disposition of the licensed microRNAs and any actions brought by third parties. We are also required to maintain comprehensive insurance coverage.

The agreement will terminate upon the later of the expiration or abandonment of the last patent to expire or become abandoned. If no patent ever issues, the agreement will terminate ten years after the first commercial sale of the first licensed product. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$440,000 in aggregate minimum annual royalty over the term of this agreement. Rockefeller has the right to terminate the agreement if we are more than 30 days late in meeting our payment obligations and do not pay in full within ten days of Rockefeller's written demand; or upon our uncured material breach. We can terminate the agreement by providing 60 days written notice to Rockefeller, ceasing all use of the licensed products, terminating any sublicenses granted under the agreement and paying all amounts owed to Rockefeller through the date of termination.

### *License Agreement with Max Planck Innovation GmbH (Diagnostics)*

In June 2006, we entered into a royalty-bearing, co-exclusive, worldwide license agreement with Max Planck Innovation GmbH, or Max Planck, the technology transfer agency of the Max Planck Society. This agreement was amended and restated in March 2009. Under this agreement, we licensed from Max Planck the rights to its proprietary microRNAs for diagnostics purposes. The agreement covers microRNAs and microRNA

candidates, including approximately 110 biologically validated human microRNAs, discovered by the researchers of the Max-Planck-Institute for Biophysical Chemistry in Goettingen. In consideration for this license, we paid an initiation fee, and are required to pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of our revenues from any sublicenses.

These microRNAs can be licensed by Max Planck for diagnostics purposes to three other parties. Max Planck is obligated to notify us of any more favorable license in the diagnostics field it grants for these microRNAs, in which event we shall have the right to adopt all material terms of such license. We have the right to enter into sublicense agreements, only in the event that the granted sublicense includes a license to intellectual property rights owned or co-owned by us as well, is reasonably necessary for sublicensee in order to further develop and/or commercialize or manufacture products and permits no more than one tier of sublicensing.

Max Planck is responsible, in its sole discretion, to apply for, seek issuance of, maintain and prosecute the licensed patent rights, and we have the right to comment on the documents to be filed by the patent office. We are required, however, to pay a pro rata share of associated costs. We are obligated to indemnify Max Planck against any liabilities arising from any use by us, our affiliates, sublicensees and sales partners of the patent rights, the development and use of any product, process or service under the agreement, and the use by third parties of any products, processes or services sold by us. We are also required to maintain comprehensive insurance coverage.

The agreement terminates upon the expiration or abandonment of all issued and filed licensed patents. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$514,000 in aggregate annual license maintenance fees over the term of this agreement. We have the right to terminate the agreement with three months' prior written notice. We have the obligation to use commercially reasonable efforts to develop and commercialize the products and services based on the licensed patents in the field of diagnostics. In the event we cease carrying out our business related to the agreement we must notify Max Planck and then both parties have the right to terminate the agreement with three months' prior notice. Max Planck also has the right to terminate the agreement if we challenge one of the licensed patents; if we fail to cure a breach within 60 days of receiving notice of such breach; or if we fail to pay within 30 days of a notice requiring a payment. The agreement will terminate automatically upon filing of bankruptcy or insolvency proceedings by or against us, or upon the assignment of all or a substantial portion of our assets for the benefit of creditors.

#### *License Agreement with Max Planck Innovation GmbH (Research)*

In December 2006, we entered into a royalty-bearing, non-exclusive, worldwide license agreement with Max Planck. Under this agreement, we licensed from Max Planck the rights to its proprietary microRNAs for research purposes. The agreement covers microRNAs and microRNA candidates, including approximately 110 biologically validated human microRNAs, discovered by the researchers of the Max-Planck-Institute for Biophysical Chemistry in Goettingen. In consideration for this license, we will pay an initiation fee, and are required to pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of our revenues from any sublicenses.

Max Planck is obligated to notify us of any more favorable license in the research field it grants for these microRNAs, in which event we shall have the right to adopt all material terms of such license. We have the right to enter into sublicense agreement, but only if the granted sublicense includes a license to microRNAs owned by us as well.

Max Planck is responsible, in its sole discretion, to apply for, seek issuance of, maintain and prosecute the licensed patent rights, and we have the right to comment on the documents to be filed with the patent office. We are obligated to indemnify Max Planck against any liabilities arising from any use by us, our affiliates, sublicensees and sales partners of the patent rights, the development and use of any product, process or service under the agreement, and the use by third parties of any products, processes or services sold by us. We are also required to maintain comprehensive insurance coverage.

The agreement terminates upon the later of the expiration or abandonment of the last patent to expire or become abandoned of the patent rights contemplated under the agreement, or, if no patent ever issues from the patent rights, ten years after the first commercial sale of the first licensed product, as contemplated under the agreement. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$316,000 in aggregate annual license maintenance fees over the term of this agreement. We have the right to terminate the agreement with 60 days prior written notice. Max Planck also has the right to terminate the agreement if we fail to cure a breach within 60 days of receiving notice of such breach; or if we fail to pay within 30 days of a notice requiring a payment.

#### *License Agreement with Johns Hopkins University*

In August 2006, we signed a royalty-bearing, exclusive, worldwide license agreement with Johns Hopkins University. This agreement was amended and restated in August 2011. Under the restated agreement, we have licensed from Johns Hopkins the rights to its proprietary microRNAs for all fields and applications on a non-exclusive basis. The agreement covers approximately 130 biologically validated microRNAs. We also have the right to further sublicense these rights, provided that such sublicense includes a license to substantial intellectual property rights owned or co-owned by us and is consistent with the terms of our license agreement. In consideration for the restated license we paid an amendment fee, and are required to pay minimum annual royalties, royalties based on net sales and a percentage of our revenues from any sublicense. We are obligated to perform commercially reasonable diligent efforts in the development of products, including or using the licensed microRNAs.

Johns Hopkins is responsible for filing, prosecuting and maintaining the licensed patent rights, and we have the right to comment on and advise Johns Hopkins with respect to such matters. We are required to pay all expenses related to filing, prosecution and maintenance of the licensed patent rights; unless we provide Johns Hopkins notice that we elect not to do so. If we so elect, Johns Hopkins may file, prosecute or maintain such patent rights at its own expense and any license we have with respect to such patent rights shall terminate. We have the right but not the obligation to enforce the patent rights against infringement.

We are obligated to indemnify Johns Hopkins against any liabilities arising out of use by us, our affiliates or sublicensees of the licensed microRNAs. We are also obligated to establish and maintain product liability or other appropriate insurance prior to initial human testing or first commercial sale of any product incorporating the licensed microRNAs.

The agreement terminates with respect to each country in which a patent has issued upon the expiration of the last to expire patent covered by the terms of the agreement in such country. If no patents ever issue in a country but patent applications are filed in such country, the agreement will expire with respect to such country upon the cancellation, abandonment, withdrawal or disallowance of all claims under all patent applications in that country or at such time as there is no claim that has been pending in such country for less than six years from the date such claim was filed in a non-provisional patent application in that country. Based on an estimate of the date of expiration of the last patent to expire, we estimate that we will pay a minimum of approximately \$320,000 in aggregate annual royalties over the term of the agreement. In addition, either party may terminate the agreement (1) upon the filing of bankruptcy or insolvency proceedings with respect to the other party or (2) if the other party is in material breach of the agreement and such breach is not cured within 30 days of notice. We also have the right to terminate the agreement for any reason upon 90-day notice.

## **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. All of the tests and products we are developing or may develop in the future, if approved, will compete against existing non-microRNA-based diagnostic tests and therapies. In addition, we believe a significant number of non-microRNA-based diagnostic tests and drug candidates are currently under development and may become available for the diseases we are targeting or may target. In addition to the competition we face from non-microRNA-based competing tests and products from companies such as Pathwork Diagnostics, Inc. and Biotheranostics, Inc. that have developed or are developing diagnostic tests based on other non-microRNA technologies, we also face competition from other companies working to develop novel tests and products using technology that competes more directly with our microRNAs. We are aware of several other companies that are working to develop microRNA diagnostics and therapeutics, including Combimatrix Corporation, Alnylam Pharmaceuticals, Inc., Asuragen Inc., Exiqon A/S, Life Technologies Corporation, Isis Pharmaceuticals, Merck & Co., Inc., Santaris Pharma A/S, Regulus Therapeutics and others. We believe the key competitive factors affecting the commercial success of our potential tests and products will be:

- the safety and effectiveness of our products;
- the timing and scope of regulatory approvals, if required, for these tests and products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- reimbursement coverage; and
- patent position.

Many of our potential competitors, either alone or with their collaborative partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of diagnostics and therapeutics, obtaining FDA and other regulatory approvals of tests and products and the commercialization of those tests and products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval and achieving widespread market acceptance. Our competitors' tests or products may be more effective, or more effectively marketed and sold, than any test or product we may commercialize and may render our tests and products obsolete or non-competitive before we can recover the expenses of developing and commercializing them. We anticipate that we will face intense and increasing competition as advanced technologies become available.

## **Manufacturing**

We currently intend to rely on contract manufacturers or our collaborative partners to produce materials for diagnostic tests and drug substances and drug products required for preclinical studies and clinical trials. We plan to continue to rely upon contract manufacturers and collaboration partners to manufacture commercial quantities of these materials for any marketed diagnostic or therapeutic.

## **Regulatory**

### ***Diagnostics***

#### *CLIA and Other Laboratory Licensure*

Laboratories that perform testing on human specimens for the purpose of providing information for diagnosis, prevention or treatment of disease or assessment of health are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA. This law imposes quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. The FDA is responsible for the categorization of commercially marketed IVD tests under CLIA into one of three categories based upon the potential risk to public health in reporting erroneous results. The categories were devised on the basis of the complexity of the test and include waived tests, tests of moderate complexity, and tests of high complexity. Laboratories performing moderate or high-complexity testing must meet the CLIA requirements for proficiency testing, patient test management, quality control, quality assurance and personnel.

Under CLIA, certified laboratories are required to hold a certificate applicable to the type of work they perform and to comply with standards covering personnel, facilities administration, quality systems and proficiency testing. CLIA-certified laboratories are typically subject to survey and inspection every two years to assess compliance with program standards. In addition to CLIA certification, laboratories offering clinical testing services are required to hold certain federal, state and local licenses, certifications and permits. Clinical laboratories are licensed by the states in which they are located. In addition, some states require any clinical laboratory that analyzes samples from residents of that state to also be licensed by it. Many CLIA-certified laboratories also seek accreditation by the College of American Pathologists, or CAP, and licensure by states that require that state specific licensure for a laboratory that intends to test clinical samples from residents of that state. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA and state certification requirements.

### *Food and Drug Administration*

#### Laboratory Developed Tests

Although the FDA has consistently stated that it has the authority to regulate clinical laboratory tests as medical devices, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and validated at the high complexity CLIA-certified laboratory at which the test is performed. These tests are known as LDTs. More recently, the FDA has indicated that it is reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting in 2010, to obtain input from stakeholders on how it should apply its authority to implement a reasonable risk-based and effective regulatory framework for LDTs. In 2012, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs, and held a public meeting to obtain input from stakeholders on how it should apply its authority to implement a reasonable risk-based and effective regulatory framework for LDTs. The FDA has not indicated when or how those changes will be implemented, but it left little doubt that changes are forthcoming.

#### In Vitro Diagnostics

The type of regulation to which our tests and diagnostics may be subject will depend in large part on how we intend to commercialize them. Diagnostics that will be commercialized through direct product sales as *in vitro* diagnostic kits are subject to review by the FDA as medical devices and must be cleared or approved before they can be marketed. Most tests that are offered as LDTs by a CLIA-certified laboratory have generally not been subject to regulation by the FDA, however, this may change after the FDA announces the new requirements that will apply to LDTs.

The FDA regulates the sale or distribution of medical devices, including *in vitro* diagnostic test kits and some *in vitro* diagnostic tests. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, pre-market notification and adherence to FDA's quality system regulation, which are device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to pre-market approval. Nearly all Class I devices are exempt from premarket review; most Class II devices require 510(k) clearance and all Class III devices must receive premarket approval before they can be sold in the United States. The payment of a fee is usually required when a 510(k) notice or premarket approval application is submitted.

*510(k) Premarket Notification.* A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device", that is legally marketed in the United States and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device.

The FDA is supposed to issue a decision letter within 90 days of receipt of the 510(k) if it has no additional questions or send a first action letter requesting additional information within 75 days. However, in 2012, the FDA issued a guidance document in which it indicated that it will conduct a preliminary review of a 510(k) based on an acceptance checklist within 15 business days of the submission of the 510(k). If the FDA determines that the 510(k) is not administratively complete, it will refuse to accept the application until a complete response is submitted in response to the refuse to accept, or RTA, notification. Most 510(k)s do not require clinical data for clearance, but a minority will. Requests for additional data, including clinical data, will increase the time necessary to review the notice. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may petition the FDA to make a risk-based determination of the new device and reclassify the new device as a Class I or Class II device. The FDA continues to reevaluate the 510(k) review process, and we cannot predict what if any changes will occur.



*Premarket Approval.* The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a “significant risk,” the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA that is 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. The total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved.

Any products sold by us pursuant to FDA clearances or approvals will be subject to pervasive and continuing regulation by the FDA, including record keeping requirements, reporting of adverse experiences with the use of the device and restrictions on the advertising and promotion of our products. Device manufacturers are required to register their establishments and list their devices with the FDA and are subject to periodic inspections by the FDA and certain state agencies. Noncompliance with applicable FDA requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the FDA to grant 510(k) clearance or PMA approval for devices, withdrawal of 510(k) clearances and/or PMA approvals and criminal prosecution.

### *European Regulations*

In the European Union, IVD medical devices are regulated under EU-Directive 98/79/EC, or the IVD Directive, and corresponding national provisions. The IVD Directive requires that medical devices meet the essential requirements set out in an annex of the directive. These requirements include the safety and efficacy of the devices. According to the IVD Directive, the Member States presume compliance with these essential requirements in respect of devices which are in conformity with the relevant national standards transposing the harmonized standards of which the reference numbers have been published in the Official Journal of the European Communities. These harmonized standards include ISO 13485:2003, the quality standard for medical device manufacturers.

IVD medical devices, other than devices for performance evaluation, must bear the CE marking of conformity when they are placed on the market. The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation implementing the relevant European Directive. As a general rule, the manufacturer must follow the procedure of the EC Declaration of conformity to obtain this CE marking.

Each European country must adopt its own laws, regulations and administrative provisions necessary to comply with the IVD Directive. Member States may not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking according to the conformity assessment procedures. In September 2012, the European Commission adopted a proposal for a regulation which if adopted will change the way that most medical devices are regulated in the European Union, and may subject our products to additional requirements.

### *Therapeutics*

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, at each institution participating in a clinical trial, which must review and approve the plan for any clinical trial before it commences at that institution;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application, or NDA, if the drug is a small molecule, or a biologics license application, or BLA, if the drug is a biologic;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, and applicable clinical data or literature, among other things, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to, among other things, safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. An IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative and must monitor the study until completed.

Each new clinical protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2:* Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3:* Involves studies undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug within required specifications and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug does not undergo unacceptable deterioration over its shelf life.

### *United States Review and Approval Processes*

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The FDA initially reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee.

The review process is lengthy and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the approved indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a company to conduct post-approval testing, including Phase 4 clinical trials, to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

#### *Post-approval Requirements*

Approved drugs are subject to extensive and continuing regulation by the FDA, including, among other things, cGMP compliance, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, and complying with FDA promotion and advertising requirements. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

#### *Non-U.S. Regulations*

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our tests and products outside the United States. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, the approval process, product licensing, pricing and reimbursement vary greatly from country to country.

#### *HIPAA and Other Privacy and Security Laws*

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive United States protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Covered Entities must have in place administrative, physical, and technical safeguards to guard against the misuse of protected health information. Specifically, Title II of HIPAA, the administrative Simplification Act, contains four provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of data content, codes and formats used in healthcare transactions. The privacy regulations protect medical records and other personal health information by limiting their use and release and giving patients the right to access their medical records. The HIPAA security standards require the adoption of administrative, physical and technical safeguards and the adoption of written security policies and procedures. Additionally, some state laws impose privacy protections more stringent than HIPAA and many impose security standards and breach notification requirements that apply in addition to HIPAA. Most of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We are a Covered Entity to the extent that our U.S. operations involve standard transactions conducted electronically (such as billing) in connection with clinical testing. Accordingly, we have implemented privacy and security policies and procedures consistent with HIPAA standards and taken other steps to comply.

In 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009. Final HITECH regulations were published in January, 2013. HITECH amends HIPAA and, among other things, creates significant new regulatory compliance obligations for "business associates" or organizations that provide services to Covered Entities involving the use or disclosure of protected health information and downstream entities providing services to business associates. Additionally, HITECH expands and strengthens HIPAA enforcement, imposes new penalties for noncompliance and establishes new breach notification requirements for Covered Entities and business associates. Under HITECH's new breach notification requirements, Covered Entities must, within 60 days of discovery, notify each individual whose information has been or is reasonably believed to have been, accessed, acquired or disclosed as a result of a breach. Covered Entities must also report breaches to the U.S. Department of Health and Human Services, or HHS, and in some cases, publish information about the breach in local or prominent media outlets. Consequently, it is important that breaches of PHI are promptly detected and reported within the company, so that we can make all required notifications. Most states have adopted data security laws protecting the personal data of state residents. Personal data subject to protection typically includes name coupled with social security number, state-issued identification number, or financial account number. Most states require specific, technical security measures for the protection of all

personal data, including employee data, and impose their own breach notification requirements in the event of a loss of personal data. State data security laws generally overlap and apply simultaneously with HIPAA. In the event of a data breach affecting individuals from more than one state, we must comply with all relevant state notification requirements as well as HIPAA and are subject to enforcement by all relevant state and federal authorities as well as fines and penalties imposed by each state.

## *Federal Prohibitions on Health Care Fraud and False Statements Related to Health Care Matters*

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act, or HIPAA, the U.S. Department of Health and Human Services, or HHS, issued regulations for protecting the privacy and security of protected health information. Additional administrative simplification provisions created new federal crimes: health care fraud, false statements relating to health care matters, theft or embezzlement in connection with a health benefit program and obstruction of criminal investigation of health care offenses. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including a private insurer. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. The theft or embezzlement statute prohibits knowingly and willfully embezzling, stealing or otherwise converting or misapplying the money or property of a health care benefit program. The obstruction of criminal investigations of health care offenses statute prohibits willfully preventing, obstructing, misleading or delaying the communication of information and records relating to a violation of a federal health care offense to a criminal investigator. A violation of any of these laws is a felony and may result in fines, imprisonment, or exclusion from the federal health care programs.

We are currently subject to the HIPAA regulations and maintain an active program designed to address regulatory compliance issues. Regulations and guidance in this area are evolving so we must regularly evaluate and update our regulatory compliance measures to remain in compliance with the law. We are subject to audit by federal authorities and subject to prosecution or administrative enforcement and increased civil and criminal penalties for non-compliance, including monetary penalties. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH and who also enforce state data security laws.

Our activities must also comply with other applicable privacy laws. For example, there are international privacy laws that impose restrictions on the access, use, and disclosure of health and other personal information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue samples and associated patient information or to conduct clinical testing could significantly impact our business and our future business plans.

### **Compliance with Fraud and Abuse Laws**

We have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid.

#### ***Anti-Kickback Statute***

The federal Anti-Kickback Statute prohibits persons from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or
- purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by a government-sponsored healthcare program.

The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as gifts, certain discounts, waiver of payments, and providing anything at less than its fair market value. In addition, several courts have interpreted the law to mean that if “one purpose” of an arrangement is intended to induce referrals, the statute is violated.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services, or OIG, has issued regulations, commonly known as “safe harbors.” These safe harbors set forth certain requirements that, if fully met, will assure healthcare providers, including medical device manufacturers, that they will not be prosecuted under the Anti-Kickback Statute. Although full compliance with these safe harbor provisions ensures against prosecution under the Anti-Kickback Statute, full compliance is often difficult and the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. The statutory penalties for violating the Anti-Kickback Statute include imprisonment for up to five years and criminal fines of up to \$25,000 per violation. In addition, through application of other laws, conduct that violates the Anti-Kickback Statute can also give rise to False Claims Act lawsuits, civil monetary penalties and possible exclusion from Medicare and Medicaid and other federal healthcare programs. In addition to the Federal Anti-Kickback Statute, many states have their own kickback laws. Often, these laws closely follow

the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payment made by a government health care program but also with respect to other payors, including commercial insurance companies.

## ***Physician Self-Referral Laws***

The federal ban on physician self-referrals, commonly known as the "Stark Law," prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member of the physician has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing for any good or service furnished pursuant to an unlawful referral, and any person collecting any amounts in connection with an unlawful referral is obligated to refund such amounts. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to \$15,000 per service and possible exclusion from federal healthcare programs. In addition to the Stark Law, many states have their own self-referral laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states these anti-referral laws apply not only to payment made by a federal health care program but also with respect to other payors, including commercial insurance companies. In addition, some state laws require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider even if the referral itself is not prohibited.

## ***Other Fraud and Abuse Laws***

The federal False Claims Act, or FCA prohibits any person from knowingly presenting, or causing to be presented, a false claim or knowingly making, or causing to made, a false statement to obtain payment from the federal government. Those found in violation of the FCA can be subject to fines and penalties of three times the damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim. Actions filed under the FCA can be brought by any individual on behalf of the government, a "qui tam" action, and such individual, known as a "relator" or, more commonly, as a "whistleblower," who may share in any amounts paid by the entity to the government in damages and penalties or by way of settlement. In addition, certain states have enacted laws modeled after the FCA, and this legislative activity is expected to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies, including medical device manufacturers, to defend false claim actions, pay damages and penalties or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of investigations arising out of such actions.

The OIG also has authority to bring administrative actions against entities for alleged violations of a number of prohibitions, including the Anti-Kickback Statute and the Stark Law. The OIG may seek to impose civil monetary penalties or exclusion from the Medicare, Medicaid and other federal healthcare programs. Civil monetary penalties can range from \$2,000 to \$50,000 for each violation or failure plus, in certain circumstances, three times the amounts claimed in reimbursement or illegal remuneration. Typically, exclusions last for five years.

In addition, we must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, all of which can also be triggered by violations of federal anti-kickback laws; the Health Insurance Portability and Accounting Act of 1996, which makes it a federal crime to commit healthcare fraud and make false statements; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

## **Reimbursement**

### ***United States***

In the United States, payments for diagnostic tests come from several sources, including third party payors such as insurance companies and health maintenance organizations; government health programs such as Medicare and Medicaid; and patients; and, in certain circumstances, hospitals or referring laboratories (who then bill health third-party payors for testing).

*Code Assignment.* In the United States, a third-party payor's decisions regarding coverage and payment are driven, in large part, by the specific Current Procedural Terminology, or CPT, code used to identify a test. The American Medical Association, or AMA, publishes the CPT, which is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of the CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services and therefore to ensure reliable nationwide communication among healthcare providers, patients, and third-party payors.

A manufacturer of in vitro diagnostic kits or a provider of laboratory services may request establishment of a Category I CPT code for a new product. Assignment of a specific CPT code ensures routine processing and payment for a diagnostic test by both private and government third-party payors.

The AMA has specific procedures for establishing a new CPT code and, if appropriate, for modifying existing nomenclature to incorporate a new test into an existing code. If the AMA concludes that a new code or modification of nomenclature is unnecessary, the AMA will inform the requestor how to use one or more existing codes to report the test.



While the AMA's decision is pending, billing and collection may be sought under an existing, non-specific CPT code. A manufacturer or provider may decide not to request assignment of a CPT code and instead use an existing, non-specific code for reimbursement purposes. However, use of such codes may result in more frequent denials and/or requests for supporting clinical documentation from the third-party payor and in lower reimbursement rates, which may vary based on geographical location.

*Coverage Decisions.* When deciding whether to cover a particular diagnostic test, private and government third-party payors generally consider whether the test is a covered benefit and, if so, whether it is reasonable and necessary for the diagnosis or treatment of illness and injury. Most third-party payors do not cover experimental services. Coverage determinations often are influenced by current standards of practice and clinical data, particularly at the local level. The Centers for Medicare & Medicaid Services, or CMS, which is the government agency responsible for overseeing the Medicare program, has the authority to make coverage determinations on a national basis, but most Medicare coverage decisions are made at the local level by contractors that administer the Medicare program in specified geographic areas. Private and government third-party payors have separate processes for making coverage determinations, and private third-party payors may or may not follow Medicare's coverage decisions. If a third-party payor has a coverage determination in place for a particular diagnostic test, billing for that test must comply with the established policy. Otherwise, the third-party payor makes reimbursement decisions on a case-by-case basis.

*Payment.* Payment for covered diagnostic tests is determined based on various methodologies, including prospective payment systems and fee schedules. In addition, private third-party payors may negotiate contractual rates with participating providers or set rates as a percentage of the billed charge. Diagnostic tests furnished to Medicare inpatients generally are included in the bundled payment made to the hospital under Medicare's Inpatient Prospective Payment System. Payment for diagnostic tests furnished to Medicare beneficiaries in most other circumstances is made based on the Clinical Laboratory Fee Schedule, under which a payment amount is assigned to each covered CPT code. The law technically requires fee schedule amounts to be adjusted annually by the percentage increase in the consumer price index, or CPI, for the prior year, but Congress has frozen payment rates in certain years. For the 2011 calendar year the Clinical Laboratory Fee Schedule, or CLFS, was reduced across all listed tests by 1.75%. Currently, the ceiling for established tests is set at 74% of the median of all contractor fee schedule amounts for a particular test and 100% of the median for diagnostic tests for which no limitation amount was established prior to 2001. Medicaid programs generally pay for diagnostic tests based on a fee schedule, but reimbursement varies by state.

### ***European Union***

In the European Union the reimbursement mechanisms used by private and public health insurers vary by country. For the public systems reimbursement is determined by guidelines established by the legislator or responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the healthcare system. Acceptance for reimbursement comes with cost, use and often volume restrictions, which again can vary by country.

### **C. ORGANIZATIONAL STRUCTURE**

Rosetta Genomics Ltd. is organized under the laws of the State of Israel and has a wholly owned subsidiary, Rosetta Genomics Inc., which is a Delaware corporation, and a controlled subsidiary. In December 2011, we sold our complete ownership interest in Rosetta Green Ltd., a public Israeli company whose shares are traded on the Tel Aviv Stock Exchange, which represented approximately 50.03% of the outstanding ordinary shares of Rosetta Green.

### **D. PROPERTY, PLANTS AND EQUIPMENT**

We currently rent approximately 4,715 square feet of office and laboratory space in Rehovot, Israel, under a lease that expires in October 2017. Our wholly owned subsidiary, Rosetta Genomics Inc., rents approximately 3,649 square feet of office space in Jersey City, New Jersey under a lease that expires in March 2013. In addition, Rosetta Genomics Inc. rents approximately 6,233 square feet of laboratory space in Philadelphia, Pennsylvania under a lease that expires in December 2018. If our business grows we may need additional space, but expect that alternate facilities will be available on reasonable terms as and when needed.

#### **ITEM 4.A UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with “Item 3. Key Information — A. Selected Consolidated Financial Data” and our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under “Forward-Looking Statements,” “Item 3. Key Information — D. Risk Factors” and elsewhere in this Annual Report.*

## Overview

We are seeking to develop and commercialize new diagnostic products based on a recently discovered group of genes known as microRNAs. MicroRNAs are naturally expressed, or produced, using instructions encoded in DNA and are believed to play an important role in regulating protein production. Proteins control most biological processes and thus we believe that microRNAs as their regulators have the potential to form the basis of a novel class of diagnostic tests and therapies for many serious illnesses.

Since our inception in March 2000, we have generated significant losses. As of December 31, 2012, we had an accumulated deficit of \$95.5 million. We funded our operations through December 31, 2012 primarily through proceeds received from the sale of equity securities to investors in the aggregate amount of approximately \$128 million, including the following recent transactions:

- On January 26, 2012, we entered into a Secured Loan Agreement, pursuant to which on January 27, 2012, we sold and issued a \$1,750,000 senior secured debenture (the "Debenture") with a maturity date of January 26, 2013 and that accrued interest at a rate between 10% and 18%. On March 15, 2012, an aggregate of \$300,000 in principal amount of the Debenture became convertible, into our ordinary shares at a conversion price of \$1.416 per share. The Debenture was secured by a security interest in all of our current and future assets and of any current or future subsidiary. On June 21, 2012, we entered into an agreement and release with the Debenture holders, pursuant to which we prepaid an aggregate of \$1,450,000 in principal and \$288,000 in interest and the Debenture holders agreed to convert the remaining \$300,000 in principal into ordinary shares no later than July 31, 2012. Following the prepayment of the \$1,450,000 in principal and \$288,000 in interest, all of our obligations (other than the obligation to convert the remaining \$300,000 in principal into ordinary shares) were satisfied or terminated and the security interest in all of our assets terminated. The agreement also contained a mutual release and discharge of all claims

On July 27, 2012, we issued 211,865 ordinary shares, following the conversion of the remaining \$300,000 in principal amount of the Debenture. As a result of the revaluation of the conversion of the Debenture and the release of the secured loan, we recorded expense of \$1,547,000 and an interest expense of \$288,000 which were attributed to financial expenses.

- On April 17, 2012, we completed a registered direct offering with several institutional investors (referred to herein as the "April 2012 registered offering"). Under the terms of the financing, we sold 540,000 ordinary shares at a price of \$2.55 per share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 13,500 ordinary shares at an exercise price of \$3.1875 per share, which expires on April 12, 2017. Net proceeds to us from the April 2012 registered offering, after fees and expenses, were approximately \$1.2 million.
- On May 22, 2012, we completed a registered direct offering with several institutional investors (referred to herein as the "May A -2012 registered offering"). Under the terms of the financing, we sold 632,057 ordinary shares at a price of \$3.50 per share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 15,802 ordinary shares at an exercise price of \$4.375 per share, which expires on May 16, 2017. Net proceeds to us from the May A- 2012 registered offering, after fees and expenses, were approximately \$1.9 million.
- On May 31, 2012, we completed a registered direct offering with several institutional investors (referred to herein as the "May B -2012 registered offering"). Under the terms of the financing, we sold 570,755 ordinary shares at a price of \$11.50 per share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 14,269 ordinary shares at an exercise price of \$14.375 per share, which expires on May 24, 2017. Net proceeds to us from the May B- 2012 registered offering, after fees and expenses, were approximately \$5.9 million.
- On August 8, 2012, we closed an underwritten public offering of 5,500,000 ordinary shares at a public offering price of \$5.00 per share (referred to herein as the "2012 public offering"). Under the terms of the underwriting agreement, we granted the underwriter an option (referred to herein as the "over-allotment option") exercisable for 45 days, to purchase up to an additional 825,000 of our ordinary shares at the same price, solely to cover over-allotments.

On August 28, 2012, the underwriter exercised its over-allotment option in full, and on August 29, 2012, we closed the sale of an additional 825,000 ordinary shares at a price to the public of \$5.00 per share. For its services in the offering, the underwriter received a Purchase Option Agreement to purchase 148,937 ordinary shares at an exercise price of \$6.25 per share, which expires on August 2, 2017. In addition, our former placement agent received a warrant to purchase up to 26,481 ordinary shares at an exercise price of \$5.5769 per share, under its fee-tail agreement. This warrant expires on November 24, 2014. Net proceeds to us from the 2012 public offering, including from the exercise of the over-allotment option, after fees and expenses, were approximately \$28.8 million.

We have focused our efforts since inception primarily on research and development, building and maintaining our intellectual property, business planning and raising capital. We have not achieved profitability and we expect to incur significant additional losses over the next several years. We expect our net losses to continue primarily due to research and development activities relating to our internal product development, collaborations, business development, commercialization, and other general corporate activities. We anticipate that our operating results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods. Our sources of potential funding for the next several years are expected to include our existing cash and cash equivalents, as well as product revenues, additional equity and/or debt financings, funded research and development payments, and license fees and/or milestone payments under potential future collaborative arrangements.

Research and development expenses represented 15%, 40%, and 42% of our total operating expenses for the years ended December 31, 2012, 2011 and 2010, respectively. We have not tracked our historical research and development costs on a project-by-project basis because the majority of our efforts have been focused on the development of capabilities associated with our microRNA discovery process rather than on specific projects. Major components of the \$1.25 million in research and development expenses for the year ended December 31, 2012 included payroll and related expenses, research materials and related expenses, costs associated with license fees and intellectual property-related costs.

On July 2008, through our wholly owned subsidiary Rosetta Genomics Inc., we purchased all of the shares of Parkway Clinical Laboratories, Inc., a privately held Pennsylvania corporation owning a CLIA-certified laboratory, for an aggregate purchase price of \$2,900,000 (not including \$207,000 of transaction expenses), consisting of \$1,900,000 in cash and \$1,000,000 of our ordinary shares, plus an additional \$300,000 payable upon the achievement of certain milestones, which were not met. Parkway remained an indirect wholly owned subsidiary until May 2009, when we sold Parkway for a purchase price of up to \$2,500,000, to be paid as a fixed percentage of revenues over six years. During the years ended December 31, 2012, December 31, 2011, and December 31, 2010, we received an amount of \$30,000, \$0, and \$148,000, respectively, in respect of this consideration. These payments are lower than the amounts due to us under Parkway's sale agreement and we have been experiencing collection problems with Parkway's buyer since the sale. Operating results for Parkway have been classified as discontinued operations for all presented periods.

On February 4, 2010, we established Rosetta Green Ltd., an Israeli Company, as a controlled subsidiary. As of December 31, 2010, we owned approximately 76.2% of the outstanding ordinary shares of Rosetta Green. In February 2011, Rosetta Green completed an initial public offering in Israel on the Tel Aviv Stock Exchange, or TASE. In December 2011, we sold all our holdings in Rosetta Green (approximately 50.03% of the outstanding shares of Rosetta Green). We received an upfront payment of \$900,000 for the Rosetta Green ordinary shares. In addition, we were entitled to a payment of \$2.0 million if Rosetta Green was acquired within three years and if certain other conditions were met in connection with such acquisition. In February 2013, Rosetta Green was acquired by A.B. Seeds Ltd., an affiliate of Monsanto Co., however, the conditions required to be met for us to receive the \$2.0 million were not met.

On November 22, 2010, we and Prometheus Laboratories Inc., or Prometheus, entered into a Settlement Agreement and Mutual Release (the "Settlement Agreement") to resolve the various disputes between the parties relating to the License Agreement, the Laboratory Services Agreement, dated April 10, 2009, and the Stock Purchase Agreement, dated April 10, 2009, including all claims relating to the arbitration proceeding. Pursuant to the Settlement Agreement, all licenses and commercialization rights granted to Prometheus were terminated. In consideration of the termination of the licenses and the return of the commercialization rights, we agreed to pay Prometheus \$3.1 million as follows: (a) \$1.2 million to be paid on December 2, 2010, (b) \$500,000 to be paid on or before February 28, 2011, (c) \$650,000 to be paid on or before November 22, 2011, and (d) \$750,000 to be paid on or before May 22, 2012. Rosetta granted Prometheus a non-interest bearing note with respect to the \$500,000 payment due on or before February 28, 2011 and a note bearing interest at 12% per year with respect to the \$650,000 payment due on or before November 22, 2011 and the \$750,000 payment due on or before May 22, 2012. We paid the \$1.2 million payment due December 2, 2010 and the \$500,000 payment due on or before February 2011 in a timely manner. However, we defaulted on the \$650,000 payment due on November 22, 2011, but cured the default by paying \$650,000 principal payment, plus accrued and unpaid interest within five business days of November 22, 2011. The final payment of \$750,000 due May 22, 2012 was paid on a timely basis.

## **Financial Operations Overview**

### ***Revenues***

Revenues from continuing operations consist primarily of revenues from sales of our diagnostic tests processed in our laboratory in Philadelphia. Our first diagnostic products applying our microRNA technology that were launched in late 2008 began generating revenues in 2009. We have generated revenues from continuing operations for the years ended December 31, 2012, 2011, and 2010, in the amounts of \$201,000, \$103,000, and \$279,000, respectively.

Our ability to continue to operate is dependent on the successful execution of our commercial business plan as well as further development of our current and future products, and our ability to obtain additional financing until profitability is achieved.

### ***Cost of Revenues***

Cost of revenues related to services consists primarily of the operational costs of our subsidiary, Rosetta Genomics Inc., which mainly include salaries and employee benefits, consulting costs, costs related to rent and maintenance costs. Cost of revenues related to products consists primarily of expenses related to the cost of purchasing or manufacturing our products.

### ***Research and Development Expenses, net***

We expense research and development costs as incurred. Our research and development expenses currently include costs of salaries and related expenses, activities related to intellectual property and licensing, tissue samples and other research materials, supplies, equipment depreciation, outsourced clinical and other research activities, consultants, utilities expenses and an allocation of corporate administrative costs. Due to the restructuring that we underwent in 2010 and 2011, these expenses decreased in 2012.

We are currently conducting a number of studies analyzing microRNA expression profiles in healthy and diseased samples and expect we will continue such studies in 2013. As a result, we expect that our expenses related to the purchase of tissue and body fluid samples, as well as other research consumables, will increase in the future. We have entered into several license agreements for rights to utilize certain technologies. The terms of the licenses provide for up-front payments, annual maintenance payments and royalties on product sales. Costs to acquire and maintain licensed technology are expensed as incurred.

### ***Marketing and Business Development Expenses***

Marketing and business development expenses consist primarily of salaries and related expenses, costs of post marketing validation studies, and expenses related to advertising, marketing campaigns, and commercialization. As we continue to explore new collaborations to develop and commercialize diagnostic and therapeutic products based on microRNAs, we anticipate that these expenses will increase.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related expenses, professional fees and expenses related to general corporate activities. We anticipate that general and administrative expenses will continue to grow in 2013 due to the continued growth and activities of our business.

### ***Financial Expenses (Income)***

Financial expenses for the year ended December 31, 2012 consisted primarily of amortization of the discount and the changes of the fair value of the embedded conversion feature in the convertible debenture described above as well as the revaluation of warrants related to share purchase agreements. The revaluation of warrants related to share purchase agreements provided us with financial income for the years ended December 31, 2011 and 2010. In addition, financial expenses and income include expenses and income related to the impact of fluctuations in the exchange rate between the NIS and the U.S. dollar, as well as interest income and expense.

### ***Critical Accounting Policies and Estimates***

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements included in this annual report, we believe the following accounting policies to be the most critical in understanding our consolidated financial statements and the assumptions management used.

### ***Fair Value Measurements and Disclosures***

The fair value of the liability for each class of warrants issued in certain financing transactions in 2011 and 2012 was calculated using the Black Scholes Model. We accounted for these warrants according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity" and based on certain terms of the warrants classified them as liabilities, measured at fair value each reporting period until they are exercised or expire, with changes in the fair values being recognized in our statement of operations as financial income or expense.

The above approach to valuation uses estimates, which are consistent with the plans, and estimates that we use to manage our business. There is inherent uncertainty in making these estimates.

### ***Revenue Recognition***

We generate revenues from diagnosing patient tissue received from private patients or third-party distributors. We perform the diagnostic testing in our laboratory in the United States.

Revenues from sales of our diagnostic services are recognized in accordance with ASC 605 "Revenue Recognition in Financial Statements" ("ASC 605") when (1) persuasive evidence of an agreement exists, (2) delivery of test results has occurred or services have been rendered, (3) the vendor's fee is fixed or determinable, and (4) no further obligation exists and collectability is probable. In arrangements with private patients, in which prior to delivery the patient's third-party insurance provider has not contractually set the sale prices, we do not recognize revenue until the fees are fixed and determinable and collectability assured.

Criterion (1) is satisfied when we have an arrangement to pay or a contract with the payor in place addressing reimbursement for the test. In the absence of such arrangements, we consider that criterion (1) is satisfied when a third-party payor pays us for the test performed. Criterion (2) is satisfied when we perform the test and generate and deliver to the physician, or make the patient report available to the patient. Determinations of criteria (3) and (4) are based on management's judgments regarding whether the fee charged for products or services delivered is fixed or determinable, and the collectability of those fees under any contract or arrangement. When evaluating collectability, we consider whether it has sufficient history to reliably estimate a payor's individual payment patterns. To the extent all criteria set forth above are not met when test results are delivered, service revenues are recognized when cash is received from the payor. Under the arrangements with distributors, once delivery of a test result has occurred, the distributor is obligated to pay us the fixed price for such test pursuant to the relevant distribution agreement.

Royalties from licensing the right to use our products are recognized when earned and when written sales confirmation from the licensee is received and no future obligation exists. Non-refundable, up front advancements of royalties from licensing the right to use our products which are fully chargeable against royalties, are recorded as deferred revenue until the above mentioned criteria for recognizing revenue are met. As of December 31, 2012, we have deferred revenue in an amount of \$228,000.

### ***Accounting for Stock-Based Compensation***

We account for stock-based compensation in accordance with ASC 718 "Compensation- stock compensation" ("ASC 718") (formerly Statement of Financial Accounting Standard No. 123 (revised 2004), "Share-Based Payment"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our consolidated income statements.

We recognize compensation expenses for the value of awards granted based on the straight line method over the requisite service period of each of the awards, net of estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Estimated forfeitures are based on actual historical pre-vesting forfeitures. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option. We currently expect, based on future expected forfeitures, that approximately 90% of our options will actually vest, and therefore have applied an annual forfeiture rate of 10% to all options that are not vested as of December 31, 2012. Ultimately, the actual expenses recognized over the vesting period will only be for those shares that vest.

We selected the Black-Scholes option pricing model as the most appropriate fair value method for stock-option awards and value restricted stock based on the market value of the underlying shares at the date of grant. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. The computation of expected volatility is based on realized historical stock price of our stock starting from the IPO date. As a result of the above-mentioned calculations, the volatility used for the twelve months ended December 31, 2012 and 2011 was 122% and 88%, respectively. The risk-free interest rate assumption is the implied yield currently available on United States treasury zero-coupon issues with a remaining term equal to the expected life term of our options. We determined the expected life of the options according to the simplified method, average of vesting and the contractual term of the options.

We apply ASC 718 and ASC 505-50 "Equity-Based Payments to Non-Employees" (formerly EITF No. 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services"), with respect to options and warrants issued to non-employees. ASC 718 requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option pricing model,

was re-measured using the then current fair value of our ordinary shares. Since the fair market value of the ordinary shares to non-employees is subject to change in the future, the compensation expense recognized during the years ended December 31, 2012, 2011, and 2010 may not be indicative of future compensation charges.

### ***Impairment of Long-Lived Assets***

The long-lived assets of us and of our subsidiary and all identifiable intangible assets that are subject to amortization are reviewed for impairment in accordance with ASC 360, "Property, plant and equipment"/ ASC 250 "Presentation of Financial Statement" (Formerly Statement of Financial Accounting Standard No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets"), 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 assets. 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 assets exceeds the fair value of the assets. As of December 31, 2012 and 2011, no impairment losses have been identified.

### ***Discounted Future Cash Flow Method (DCF) - Future consideration from Parkway***

To determine the fair value of the receivable that is related to Parkway's sale as of December 31, 2012, 2011 and 2010, we performed a valuation using DCF methodology at each valuation date. Under the DCF method, the fair value of receivable asset is estimated based on the stream of future benefits we expect to receive, the timing of such benefits and the risk borne by Parkway.

## **A. OPERATING RESULTS**

### ***Years Ended December 31, 2012 and 2011 - Continuing Operations***

***Revenues.*** In the years ended December 31, 2012 and December 31, 2011, we recognized \$201,000 and \$103,000, respectively, as revenues from continuing operations. This increase resulted primarily from our increased commercial activities and investments in our commercial infrastructure.

***Cost of revenues.*** Cost of revenues were \$258,000 for the year ended December 31, 2012, including \$15,000 of non-cash stock-based compensation, compared to \$324,000 for the year ended December 31, 2011, which included \$19,000 of non-cash stock-based compensation. This decrease resulted primarily from a decrease in depreciation expense attributable to lab equipment as well as an overall decrease in travel, office, and maintenance expenditures related to cost-cutting initiatives.

***Research and development expense, net.*** Research and development expenses were \$1.2 million for the year ended December 31, 2012, including \$26,000 of non-cash stock-based compensation, compared to \$3.4 million for the year ended December 31, 2011, including \$180,000 of non-cash stock-based compensation. Research and development expenses for the year ended December 31, 2012 have reduced significantly as a result of our restructuring efforts during 2011.

Royalty bearing grants from the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor of the State of Israel, or the OCS, for funding approved research and development projects are presented as a reduction from the research and development expenses. We received grants in an amount of \$165,000 and \$206,000, for the years ended December 31, 2012 and 2011, respectively.

***Marketing and business development expenses.*** Marketing and business development expenses were \$3.9 million for the year ended December 31, 2012, including \$326,000 of non-cash stock-based compensation, as compared to \$2.6 million for the year ended December 31, 2011, including \$266,000 of non-cash stock-based compensation. This increase resulted primarily from increased commercial activities and investments in our commercial infrastructure.

***General and administrative expenses.*** General and administrative expenses were \$3.0 million for the year ended December 31, 2012, including \$182,000 of non-cash stock-based compensation, as compared to \$2.5 million for the year ended December 31, 2011, including \$138,000 of non-cash stock-based compensation. This increase is a result of increased corporate activities due to the growth and expansion of the business.

***Financial expenses (income), net.*** Net financial loss was \$2.4 million for the year ended December 31, 2012, as compared to a net financial income of \$1.4 million for the year ended December 31, 2011. Financial expenses for 2012 primarily consisted of the change in fair value of the embedded conversion feature of \$1.5 million and interest of \$288,000 related to the \$1.75 million convertible debenture described above, as well as the revaluation of warrants related to share purchase agreements of \$635,000. Financial income for 2011 included \$1.6 million for revaluation of warrants related to share purchase agreements which was partially offset by \$251,000 expenses related to issuance cost derived from warrants related to share purchase agreements.

### ***Years Ended December 31, 2011 and 2010 - Continuing Operations***

*Revenues.* In the years ended December 31, 2011 and December 31, 2010, we recognized \$103,000 and \$279,000, respectively, as revenues from continuing operations. This decrease resulted primarily from cessation of sales by Prometheus, our former distributor in the United States, in late 2010.

*Cost of revenues.* Cost of revenues were \$324,000 for the year ended December 31, 2011, including \$19,000 of non-cash stock-based compensation, as compared to \$628,000 for the year ended December 31, 2010, including \$11,000 of non-cash stock-based compensation. This decrease resulted primarily from a decrease in the revenues.

*Research and development expense, net.* Research and development expenses were \$3.4 million for the year ended December 31, 2011, including \$181,000 of non-cash stock-based compensation, as compared to \$5.7 million for the year ended December 31, 2010, including \$231,000 of non-cash stock-based compensation. Research and development expenses for the year ended December 31, 2011 have been reduced significantly compared to 2010. This decrease resulted primarily from our restructuring efforts in October 2010 and during 2011.

Royalty bearing grants from the Bi-national Industrial Research and Development Foundation and from the OCS for funding approved research and development projects are presented as a reduction from the research and development expenses (see also Note 9.1 of our Consolidated Financial Statements). We received grants in an amount of \$ 206,000 and \$ 0, in the years 2011 and 2010, respectively.

*Marketing and business development expenses.* Marketing and business development expenses were \$2.6 million for the year ended December 31, 2011, including \$266,000 of non-cash stock-based compensation, as compared to \$4.9 million for the year ended December 31, 2010, including \$272,000 of non-cash stock-based compensation. This decrease resulted primarily from our restructuring efforts in October 2010 and during 2011.

*General and administrative expenses.* General and administrative expenses were \$2.5 million for the year ended December 31, 2011, including \$138,000 of non-cash stock-based compensation, as compared to \$2.4 million for the year ended December 31, 2010, including \$243,000 of non-cash stock-based compensation.

*Other operating expenses related to the settlement with Prometheus.* Other operating expenses related to the settlement with Prometheus were \$0 for the year ended December 31, 2011, as compared to \$554,000 for the year ended December 31, 2010. These expenses in 2010 reflect the fair value of certain payments due to Prometheus pursuant to the settlement agreement, net of the \$1,700,000 deferred revenues and the development fund recognized.

*Financial expenses (income), net.* Net financial income was \$1.4 million for the year ended December 31, 2011, as compared to net financial income of \$1.0 million for the year ended December 31, 2010. Financial income in 2011 included \$1.6 million for revaluation of warrants that was partially offset by \$251,000 expenses related to issuance cost derived from warrants related to share purchase agreements.

### ***Years Ended December 31, 2012, 2011 and 2010 - Discontinuing Operations***

According to ASC 360, "Property, Plant, and Equipment" / ASC 205, "Presentation of Financial Statements" when a component of an entity, as defined in ASC 360, has been disposed of, the results of its operations, including the gain or loss on its disposal should be classified as discontinued operations when the operations and cash flows of the component have been eliminated from the company's consolidated operations and the company will no longer have any significant continuing involvement in the operations of the component.

Since Rosetta Green was consolidated prior to the disposal it met the criteria for reporting as discontinued operations and, therefore, the results of operations of the business and the loss on the sale have been classified as discontinued operations loss in the Statement of Comprehensive Loss and prior periods results have been reclassified accordingly. In addition, the comparative data of the assets and liabilities have been reclassified as assets and liabilities attributed to discontinued operations in the balance sheets as described in more detail in Note 2i to our Consolidated Financial Statements.

The sale of Parkway met the criteria for reporting as discontinued operations and, therefore, the results of operations of the business and the loss on the sale have been classified as discontinued operations in the statement of operations and prior periods results have been reclassified accordingly. In addition, the comparative data of the assets and liabilities have been reclassified as assets and liabilities attributed to discontinued operations in the balance sheets, as described in more detail in Note 2i to the Consolidated Financial Statements.

## ***B. LIQUIDITY AND CAPITAL RESOURCES***

Since our inception, we have generated significant losses and expect to continue to generate losses for the foreseeable future. As of December 31,

2012, we had an accumulated deficit of \$95.5 million. We have funded our operations primarily through the proceeds from the sales of our equity and debt securities. As of December 31, 2012, we had cash, cash equivalents and short-term bank deposit of \$30.9 million, compared to \$884,000 as of December 31, 2011.

The total aggregate amount of debt and equity capital that was raised from January 1, 2012 through December 31, 2012 was \$43.5 million of which \$1,450,000 was used to prepay the January 2012 convertible debenture outlined above and as further described in Note 3 to the Consolidated Financial Statements.

## **Cash Flows**

*Net cash used in operating activities.* Net cash used in operating activities from continuing operations was \$8.7 million in 2012, compared to \$10.0 million in 2011, and \$14.0 million in 2010. These amounts were used to fund our net losses for these periods, adjusted for non-cash expenses and changes in operating assets and liabilities. Net cash provided by (used in) operating activities from discontinued operations for the years ended 2012, 2011 and 2010 were \$30,000, \$(1.2 million), and \$268,000, respectively.

*Net cash provided by (used in) investing activities.* Net cash used in investing activities from continuing operations was \$225,000 in 2012, compared to net cash provided by investing activities from continuing operations in 2011 of \$1.2 million and \$6.2 million in 2010. Net cash used in investing activities during 2012 primarily relates to the purchase of property and equipment. Net cash provided by investing activities in 2011 is primarily from the sales net of purchases of marketable securities, net of purchase of property and equipment and the sale of Rosetta Green shares. Net cash provided by investing activities in 2010 is primarily from the decrease in bank deposits and restricted cash and sales net of purchases of marketable securities, net of purchase of property and equipment. Net cash used in investing activities from discontinued operations in 2012 was \$0, compared to \$3.7 million in 2011 and \$15,000 in 2010.

*Net cash provided by financing activities.* Net cash provided by financing activities from continuing operations was \$38.9 million in 2012, compared to \$9.6 million in 2011 and \$7.0 million in 2010. In 2012, net cash provided by financing activities consisted primarily of proceeds from the issuance of shares and warrants. In 2011, net cash provided by financing activities consisted primarily of proceeds from the issuance of shares. In 2010, net cash provided by financing activities consisted primarily of proceeds from the issuance of shares. Net cash provided by financing activities from discontinued operations in 2012 was \$0, compared to \$2.2 million in 2011 and \$0 in 2010.

## **Funding Requirements**

We expect to incur continuing and increasing losses from operations for at least the next several years. In particular, we expect to incur significant marketing and business development expenses, research and development expenses, and general and administrative expenses in the future as we expand our operations and product development efforts and continue operating as a public company. We believe that our existing cash, cash equivalents, short term bank deposits, and potential future revenue will be sufficient to fund our operations for approximately the next 24 months. However, our funding requirements may change and will depend upon numerous factors, including but not limited to:

- the timing, receipt and amount of sales of our products;
- progress in our research and development programs;
- the resources, time and costs required to initiate and complete development and any required preclinical studies and clinical trials, and obtain regulatory approvals for our products;
- the timing, receipt, and amount of milestone, royalty and other payments from present and future collaborators, if any; and
- costs necessary to protect our intellectual property.

We will require substantial additional funding and expect to augment our cash balance through financing transactions, including the issuance of debt or equity securities and further strategic collaborations. On December 7, 2012, we filed a shelf registration statement on Form F-3 with the SEC for the issuance of ordinary shares, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$75 million, from time to time at prices and on terms to be determined at the time of such offerings. The filing was declared effective on December 19, 2012. However there can be no assurance that we will be able to obtain adequate levels of additional funding on favorable terms, if at all. If adequate funds are not available, we may be required to:

- delay, reduce the scope of or eliminate certain research and development programs;
- obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain technologies or products that we might otherwise seek to develop or commercialize independently;
- monetizing certain of our assets;
- pursue merger or acquisition strategies; or
- seek protection under the bankruptcy laws of Israel and the United States.

## **C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.**

Our research and development expenditures were \$1.2 million, \$3.4 million, and \$5.7 million, in the years ended December 31, 2012, 2011 and 2010, respectively. See also "Item 5. Operating and Financial Review and Prospects - Financial Operations Overview - Research and Development Expenses."



#### D. TREND INFORMATION

See “Item 5. Operating and Financial Review and Prospects.”

#### E. OFF-BALANCE SHEET ARRANGEMENTS

We are not party to any material off-balance-sheet arrangements.

#### F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

Set forth below is a description of our contractual cash obligations as of December 31, 2012. Operating and capital lease obligations consist of rent payable under our existing facility leases and lease payments for company automobiles and equipment. Other long-term obligations consist of cash obligations under various license agreements.

(In thousands)	Total	2013	2014	2015	2016	2017	Thereafter
Operating and capital lease obligations	\$ 2,108	\$ 427	\$ 395	\$ 382	\$ 344	\$ 325	\$ 235
Other long-term liabilities	\$ 2,322	\$ 159	\$ 159	\$ 159	\$ 159	\$ 159	\$ 1,527

Under our license agreements as of December 31, 2012, we are obligated to pay an aggregate amount of approximately \$159,000 annually after 2017 and until 2022, \$100,000 annually after 2022 and until 2029 and \$10,000 annually after 2029 and until 2032. Each of these agreements terminates upon the expiration of all patents relating to such agreement, including patents to be filed and potentially issued at an indeterminable date in the future, and, thus, such termination dates cannot be determined at this time. Accordingly, we are also unable to determine the aggregate amount of such payments due after 2017 at this time. However, based on current facts and circumstances, we estimate that our obligations under these agreements will be through at least 2032. See “Item 4. Information on the Company” for more information on our contractual obligations.

### ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

#### A. DIRECTORS AND SENIOR MANAGEMENT

The following table sets forth information regarding our corporate and executive officers and directors:

Name	Age	Position
Kenneth A. Berlin	48	Chief Executive Officer and President
Ron Kalfus	39	Chief Financial Officer
Dganit Bar, Ph.D.	44	Chief Scientific Officer
E. Robert Wassman, M.D.	62	Chief Medical Officer
Guy C. Malchi	44	Executive Vice President, Corporate Development
Oded Biran	34	General Counsel
Eti Meiri, Ph.D.	44	Vice President, Research
Brian Markison (3)	53	Chairman of the Board of Directors
Roy N. Davis (4)	66	Director
Yitzhak Peterburg, M.D., Ph.D. (3) (4)	62	Director
Joshua Rosensweig, Ph.D. (3)	60	Director
Dr. David Sidransky, M.D. (1) (4)	52	Director
Gerald Dogon (1)(2)	73	External Director
Tali Yaron-Eldar (1)(2)	49	External Director

(1) Member of our Audit Committee

(2) Member of our Compensation Committee

(3) Member of our Nominating and Corporate Governance Committee

(4) Member of our Research and Development Committee

*Kenneth A. Berlin* joined us in November 2009 as our President and Chief Executive Officer. He was later appointed by our shareholders in December 2009 as a member of our board of directors, and resigned as a director in March 2011. Prior to joining us, Mr. Berlin, served as Worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. Under his leadership the organization grew to over 100 employees, and he spearheaded the launch of three cancer diagnostic products, the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from a research and development entity to a commercial provider of oncology diagnostic products and services. During Mr. Berlin's tenure, Veridex received numerous awards including recognition from the Cleveland Clinic and Prix Galien for the use of its innovative CellSearch® technology in the fight against cancer. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. He then held positions of increasing responsibility within Johnson & Johnson and a number of its subsidiary companies. From 2001 until 2004, he served as Vice President, licensing and new business development in the pharmaceuticals group, and from 2004 until 2007 was Worldwide Vice President, franchise development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California, Los Angeles School of Law.

*Ron Kalfus* joined us in May 2012 as our Chief Financial Officer. Prior to joining Rosetta, Mr. Kalfus served as the Chief Financial Officer and Treasurer of MabCure Inc., a publicly-traded biotechnology startup company in the field of early cancer detection using antibodies, from 2008 to 2012. From 2003 to 2007, Mr. Kalfus held various positions with Toys "R" Us, Inc., being responsible for the company's financial reporting to the Securities and Exchange Commission and being responsible for the Toys "R" Us division's annual budget. Prior to joining Toys "R" Us, Inc., Mr. Kalfus worked as an auditor for two large public accounting firms, specializing in audits of medium-sized enterprises as well as public companies. Mr. Kalfus holds an MSc in Accounting from Fairleigh Dickinson University and a BBA in Finance from the University of Georgia.

*Dganit Bar, Ph.D.* joined us in October 2012, as our Chief Scientific Officer. Dr. Bar joined Rosetta with more than 10 years of experience in drug development. Prior to joining Rosetta, from 2004 to 2012 she served in various positions, including Executive Director Science & Technology at BioLineRx, Ltd, a biopharmaceutical company, where she led the development and out-licensing of several drug candidates spanning different therapeutic areas, including oncology, cardiovascular and CNS. From 2000 to 2004 Dr. Bar was with QBI Enterprises, Ltd, where she held several positions including Head of Cancer Research working on the company's oncology pipeline. Dr. Bar received her B.Sc. in Life Science from The Hebrew University, Jerusalem. She holds a M.Sc. in Biotechnology and a Ph.D. in Biotechnology Engineering from Ben-Gurion University of the Negev.

*E. Robert Wassman, M.D.* joined us in October 2012, as our Chief Medical Officer. Dr. Wassman joined Rosetta with more than 30 years of experience in genetics-based diagnostics. Prior to joining Rosetta, he served in various positions focused on advancing the translation and delivery of cutting-edge diagnostic technology into clinical service, including Chief Medical and Chief Genomics Officer at Generation Health; SVP/CMO of Helicos BioSciences; Co-Founder and CMO of Good Start Genetics, and President/CMO of Celula, Inc. Prior to leading these start-up ventures, he was the Vice President and National Medical Director of Genzyme Genetics after helping lead Alfigen/The Genetics Institute for many years. In addition he has served as a consultant to numerous companies introducing other key innovations to the market. Dr. Wassman received his B.S. from Yale University, and his M.D. from Albany Medical College. He took post-graduate training in Pediatrics and Medical Genetics at NY Hospital-Cornell University Medical Center and UCLA respectively, and is Board certified in these disciplines.

*Guy C. Malchi* joined us in September 2012, as our Executive Vice President, Corporate Development. Prior to joining Rosetta, from August 2008 to January 2012 he was with Champions Oncology, Inc. where he was General Manager, UK Diagnostic Subsidiary and Head of Pharma Business. At Champions he designed and implemented the drug pipeline strategy and business plan, and signed several licensing deals and strategic partnerships with leading biotechnology firms and academic institutions. Previously, from March 2005 to June 2008 he was CEO of Optimata, Ltd., an Israeli biotechnology company that developed and marketed biosimulation predictive software. Mr. Malchi spent seven years at TEFEN Ltd., Management Consulting in London, where he was a Founding Partner and Head of European Life Science Practice. Mr. Malchi holds a B.Sc. in Industrial Engineering from Tel-Aviv University and an Executive MBA from the London Business School. Guy focuses on leading the Company's effort to leverage its microRNA platform in partnerships with pharmaceutical and biotechnology companies, as well as with medical technology and diagnostic companies. In addition he will lead efforts aimed at licensing and/or acquiring new opportunities.

*Oded Biran, Adv.* has served as our General Counsel since November 2011. Mr. Biran was an independent attorney between the years 2010-2011, after previously working for us as legal counsel between June and November 2010. Prior to that, Mr. Biran was an associate in the law offices of Sharon Raviv and Co., a boutique law firm specializing in technology and communications, between December 2009 and June 2010. During the years of 2008 and 2009, Mr. Biran was an associate in Raved Magriso, Benkel, Lahav and Co.'s, where he practiced in the corporate and securities department, specializing in corporate, technology, IP and complex mergers and acquisitions transactions. During 2006-2007, Mr. Biran was an associate at Gabriel Reubinoff and Co.'s Tel Aviv office where he co-headed the firm's class action department. Mr. Biran holds a L.L.B degree from the Hebrew University in Jerusalem and is a member of the Israeli Bar Association.

*Eti Meiri, Ph.D.* has served as our Vice President, Research since May 2012. She previously served as our Senior Scientist, Molecular Biology since 2003. She has been contributing to our science and was extremely instrumental in all of the R&D activities throughout the years. Her contributions included the development of our microRNA array platform as well as the development of RNA extraction protocols suitable for microRNA extraction from clinical samples. Prior to joining us, from 2001 to 2002, Dr. Meiri served as Senior Scientist in ViroGene Ltd. She is the author of 20 papers published in peer reviewed journals. Dr. Meiri earned her Ph.D. from the Department of Plant Sciences in the Weizmann Institute of Science in Rehovot, her M.Sc. from The Hebrew university of Jerusalem, and her B.Sc. from the Faculty of life sciences, in Tel Aviv University.

*Brian Markison* has served as a member of our board of directors since March 2011. Mr. Markison was appointed by our board of directors to fill the vacancy created by the resignation of Mr. Berlin. Mr. Markison's appointment was approved by the general meeting dated July 6, 2011. Mr. Markison was appointed as chairman of the board on April 12, 2011. Mr. Markison is President, Chief Executive Officer and a member of the Board of Directors of Fougera Pharmaceuticals Inc., since July 2011. Previously, he had been with King Pharmaceuticals since 2004 and led the company through its acquisition by Pfizer for \$3.6 billion in 2010. Previously Mr. Markison was with Bristol-Myers Squibb from 1982 to 2004, where he served in various commercial and executive positions rising from an oncology sales representative to become President, BMS Oncology/Virology and Oncology Therapeutics Network. Mr. Markison serves on the board of directors of Immunomedics, Inc. and PharmAthene Inc.. He also serves on the board of directors for the Komen Foundation and on the Board of Trustees for the Pennington School. Mr. Markison received a B.S. from Iona College in New Rochelle, New York.

*Roy N. Davis* has served as a member of our board of directors since June 2012. Mr. Davis joined Johnson & Johnson (J&J) in 1984, where he moved through leadership positions of increasing responsibility in the organization in the U.S., Europe and Asia for 27 years prior to his retirement in January 2012. Most recently, from January 2008 through January 2012 Mr. Davis was President, J&J Development Corporation, J&J's wholly owned venture group, and Vice President of Corporate Development for all of J&J. In these roles Mr. Davis was responsible for acquisition and licensing in areas outside of current J&J business sectors, venture capital investing on behalf of J&J and management of J&J's wholly owned ventures. These efforts focused on developing new companies for J&J that offer transformational health care solutions. From 2003 to 2007, Mr. Davis held the positions of Company Group Chairman, J&J and Worldwide Franchise Chairman, Ortho Clinical Diagnostics with responsibilities for Ortho Clinical Diagnostics, Inc., Veridex LLC and Therakos, Inc. Mr. Davis received a Bachelor of Science from the State University of New York and a Master of Science from Rensselaer Polytechnic Institute. He currently is a member of the Innovations Advisory Board for the Cleveland Clinic, the Advisory Board for the Wake Forest Institute for Regenerative Medicine and in March 2012 was named to the Board of Directors of Innosight, an innovation consulting firm.

*Dr. Yitzhak Peterburg* has served as a member of our board of directors since December 2012. Dr. Peterburg has also served as a consultant to Rosetta since October 2012. He currently serves on the Board of Directors of TEVA Pharmaceuticals, prior to which he served as TEVA's Senior Vice President, Head of Global Branded Products, prior to which he served on the board of TEVA. Prior to his positions with TEVA, Dr. Peterburg was President and CEO of Cellcom, one of Israel's leading cellular companies. Between the years of 1990 to 2002, Dr. Peterburg was with Clalit Health Services, a non-governmental, not-for-profit organization that provides comprehensive health services to more than 55% of the Israeli population. From 1997 to 2002 he served as General Manager (CEO) for Clalit Health Services and from 1990 to 1997 he held a series of senior executive positions including Head, Health Policy Division and Chief Information Officer, Medical Division. Among his many positions at Clalit, from 1995-1997, Dr. Peterburg served as CEO of Soroka University Medical Center, Beer-Sheba, Israel, one of the biggest university hospitals in Israel. Dr. Peterburg received an M.D. from the Hebrew University of Jerusalem, and holds a Ph.D. in health services administration from the Columbia University School of Public Health in New York and a master's degree in information systems from the London School of Economics.

*Joshua Rosensweig* has served as a member of our board of directors since May 2004. Since November 2010, he has served as a member of the board of directors of *Bezeq Israel Telecommunication Corp. Ltd.* (Israel's leading communications group) and of *Alrov Real Estate and Hotels Ltd.*, a publicly-traded property development company. From September 2003 to September 2006, Dr. Rosensweig served as the Chairman of the Board of Directors of the First International Bank of Israel. From 1998 to July 2005, Dr. Rosensweig was a senior partner at Gornitzky and Co., a law firm where he specialized in international transactions and taxation. Dr. Rosensweig lectured at Bar-Ilan University, Law School from 1980 to 1995 and at Tel Aviv University, School of Business from 1983 to 1995. Dr. Rosensweig received his J.S.D. (International Taxation), and LL.M. (Taxation) from New York University Law School.

*David Sidransky, M.D.*, has served as a member of our board of directors since December 22, 2009. Dr. Sidransky is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. He serves as Executive Officer of Biomerk, Inc. and as Director of the Head and Neck Cancer Research Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University. He is a Professor of Oncology, Otolaryngology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at John Hopkins University and Hospital. Dr. Sidransky has written over 400 peer-reviewed publications, and has contributed to more than 50 cancer reviews and chapters. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents. He has been the recipient of many awards and honors, including the 1997 Sarstedt International prize from the German Society of Clinical Chemistry, 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians and the 2004 Hinda Rosenthal Award presented by the American Association of Cancer Research. Dr. Sidransky has served as Vice Chairman of the Board of Directors, and presently is a director of ImClone. He serves on the board of directors of KV Pharmaceutical Co., Champions Biotechnology, Inc. and Morria Biopharmaceuticals Plc. and is Chairman of Tamir Biotechnology, Inc. (also known as Alfacell Corp.). He is serving and has served on scientific advisory boards of corporations and institutions, including Amgen, MedImmune, Roche and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. In Addition, Dr. Sidransky served as Director of American Association for Cancer Research from 2005 to 2008. Dr. Sidransky received his B.A. from Brandeis University and his M.D. from the Baylor College of Medicine.

*Gerald Dogon* has served as a member of our board of directors since February 2007. From December 2004 to December 2006, Mr. Dogon served as a director and a member of the audit, investment and nomination committees of Scailex Corporation (previously Scitex Corporation). From October 2005 until it was acquired by PMC-Sierra, Inc. in May 2006, he served as a member of the board of directors of Passave, Inc., a semiconductor company. From 1999 to 2000, he served as a director and as chairman of the audit committee of Nogatech, Inc. Mr. Dogon has also served as a member of the board of directors of Fundtech Ltd. and was a member of its audit and nominating committees. From 1994 to 1998, Mr. Dogon served as Executive Vice President and Chief Financial Officer of DSPC Inc., and in addition, from November 1997 until December 1999, as a member of its board of directors. Mr. Dogon holds a B.A. in Economics from the University of Cape Town.

*Tali Yaron-Eldar* has served as a member of our board of directors since February 2007. Since January 2013, Ms. Yaron-Eldar has served as founder of her own private practice. Between March 2007 and December 2012, Ms. Yaron-Eldar had been a partner with the law firm of Tadmor & Co. From January 2004 to March 2007, she was a partner at the law firm of Cohen, Yaron-Eldar & Co. From January 2004 to January 2008, Ms. Yaron-Eldar served as the Chief Executive Officer of Arazim Investment Company. She has also served in a variety of public positions, including as the Chief Legal Advisor of the Customs and V.A.T department of the Finance Ministry of the State of Israel from 1998 to 2001 and as the Commissioner of Income Tax and Real Property Tax Authority of the State of Israel from 2002 to 2004. Ms. Yaron-Eldar holds an M.B.A. specializing in finance and an LL.M. from Tel Aviv University and is a member of the Israeli Bar Association.

## **B. COMPENSATION**

### ***Executive Officers' Remuneration***

The aggregate direct compensation we paid to our corporate and executive officers as a group (seven persons) as of the year ended December 31, 2012) was approximately \$1,561,000 of which approximately \$65,000 was set aside or accrued to provide for pension, retirement, severance or similar benefits. These amounts do not include expenses we incurred for other payments, including dues for professional and business associations, business travel and other expenses, and other benefits commonly reimbursed or paid by companies in Israel.

In 2012, we paid bonuses to certain of our executive officers in an aggregate amount of \$625,000 for performance during the year. Other employee's bonuses had not yet been determined or awarded. During 2012, we granted to our executive officers:

- Options to purchase an aggregate amount of 1,000 ordinary shares, at an exercise price of \$2.48 per share with an expiration date of February 5, 2022, of which none were vested as of December 31, 2012.
- Options to purchase an aggregate amount of 1,000 ordinary shares, at an exercise price of \$5.38 per share with an expiration date of September 2, 2022, of which none were vested as of December 31, 2012.
- Options to purchase an aggregate amount of 144,000 ordinary shares, at an exercise price of \$5.37 per share with an expiration date of October 12, 2022, of which none were vested as of December 31, 2012.
- Options to purchase an aggregate amount of 20,000 ordinary shares, at an exercise price of \$5.35 per share with an expiration date of October 22, 2022, of which none were vested as of December 31, 2012.
- Options to purchase an aggregate amount of 20,000 ordinary shares, at an exercise price of \$5.21 per share with an expiration date of October 25, 2022, of which none were vested as of December 31, 2012.

In addition, during 2012, the Company's Board of Directors approved the granting of 50,000 Restricted Share Units ("RSUs") to certain employees. The RSU's were granted during 2012 and will vest one year after the grant date.

### ***Directors' Remuneration***

Under the directors' compensation package approved by our board of directors and shareholders (at its meeting held on July 12, 2006), as of our initial public offering, (i) each member of the board of directors was entitled to receive an annual fee of \$10,000, payable in equal quarterly installments (ii) each member of our board of directors, other than the external directors, who served on board committees received an additional annual fee of \$10,000, payable in equal quarterly installments. On October 12, 2012, our shareholders approved the following remuneration to our directors who are not external directors: (i) the chairman of our board is entitled to (a) an annual fee of \$25,000, (b) an annual fee of \$10,000 for every committee on which he serves, and (c) a participation fee of \$250 for attendance of every meeting of the board or of a committee on which he serves and (ii) all other directors who are not external directors are entitled to (a) an annual fee of \$20,000, (b) an annual fee of \$7,500 for every committee on which such director serves, and (c) a participation fee of \$250 for attendance of every meeting of the board or of a committee on which such director serves.

The Companies Law and the regulations promulgated pursuant thereto governing the terms of compensation payable to external directors require that external directors receive annual payment as well as payment for participation in meetings as set forth in the regulations, and further provides that such remuneration may generally be determined relative to that of "other directors" (as such term is defined in the Companies Law). Due to a clerical error, the above-mentioned company approval excluded external directors from receiving the participation fee, which should have been identical to the compensation payable to the other directors. In compliance with the Companies Law and the regulations promulgated thereunder, our audit committee, our board of directors and our shareholders (at its meeting held on July 14, 2010) resolved to (i) ratify and approve the payments made by us to the external directors over the three years prior to such meeting as participation remuneration in an amount of \$10,000 annually and (ii) amend the remuneration and benefits of the external directors so that each external director shall be entitled to an annual fee of NIS 40,000 and to an additional participation fee of NIS 2,800 per meeting. According to the Companies Law and the regulations promulgated pursuant thereto, an external director shall be entitled to 60% of the participation fee in the event that such external director remotely participates in a meeting and to 50% of the participation fee in the event a resolution is adopted by the board of directors or a board committee on which such

external director serves as a member, without a meeting.

In addition, it was resolved that, in the event that during their term as external directors we increase the remuneration payable, whether by way of annual compensation or on a per meeting basis, to any "other directors", each external director will be entitled, to receive additional remuneration, if necessary, so that his or her annual compensation and/or compensation for participation in meetings, as the case may be, will be equivalent to the average compensation payable to such "other directors" as annual compensation or as compensation for participation in meetings, respectively.

We paid an aggregate of \$131,000 in direct compensation to our directors for their services as directors for the year ended December 31, 2012.

As of December 31, 2012, there were outstanding options to purchase 215,727 ordinary shares that were granted to our 14 directors and officers, at a weighted average exercise price of \$13.60 per share.

During 2012, the Company's shareholders approved the annual granting of 25,000 RSUs to certain members of the Company's Board of Directors. The RSU's were granted during 2012 and will vest one year after the grant date.

### **C. BOARD PRACTICES**

We are incorporated in Israel, and, therefore, subject to various corporate governance practices under Israeli law relating to such matters as external directors, independent directors, the audit committee, independent auditor and the internal auditor. These matters are in addition to the requirements of The NASDAQ Capital Market and other relevant provisions of U.S. securities laws. Under The NASDAQ Capital Market rules, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable NASDAQ Capital Market requirements, except for certain matters such as composition and responsibilities of the audit committee and the independence of its members. For U.S. domestic companies, NASDAQ Capital Market rules specify that the board of directors must contain a majority of independent directors within 12 months of its initial public offering. We currently comply with this requirement as well as the committee composition and responsibility requirements with respect to our committees. In addition, under the Companies Law, we are required to appoint at least two external directors. Gerald Dogon and Tali Yaron-Eldar were appointed as our external directors, each of whom is also independent under the rules of The NASDAQ Capital Market. Mr. Dogon and Ms. Yaron-Eldar were re-elected as external directors by a general meeting on July 14, 2010, and their current terms expire on July 13, 2013.

#### **Board of Directors**

Our board of directors currently consists of seven directors, including two external directors. Our directors, apart from the external directors, are elected at an annual meeting or an extraordinary meeting, as stated in our Articles of Association (the "Articles") by a vote of the holders of a majority of the voting power represented at a meeting of our shareholders and voting on the election of directors. The Articles provide that we may have no less than two and no more than 11 directors.

In accordance with our Articles, our board of directors, apart from our external directors, is divided into three classes of directors, with one class being elected each year for a term of approximately three years. At each annual general meeting of shareholders, the successors to directors whose term then expires will be elected to serve from the time of election and qualification until the third annual meeting of shareholders following election. Our directors are divided among the three classes as follows:

- ★ the Class I directors are Brian A. Markison and Dr. Yitzhak Peterburg, and their terms expire at the annual general meeting of shareholders to be held in 2014;
- ★ the Class II directors are Dr. David Sidransky and Dr. Joshua Rosensweig, and their terms expire at the annual general meeting of shareholders to be held in 2015; and
- ★ the Class III director is Roy N. Davis, and his term expires at the annual general meeting of shareholders to be held in 2013.

In accordance with our Articles, the approval of at least 75% of the voting rights represented at a general meeting is generally required to remove any of our directors from office, elect directors in their stead or fill any vacancy created in our board of directors. In addition, in case of vacancies on the board of directors may generally continue to act in every matter and may appoint directors to temporarily fill any such vacancy. See "—External Directors" below for a description of the procedure for election of external directors.

In addition, our two external directors, Gerald Dogon and Tali Yaron-Eldar, were re-elected on July 14, 2010 for three-year terms, and their current terms expire on July 13, 2013. See "—External Directors" below.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. For that matter, external directors are excluded.



Our Articles provide, as allowed by Israeli law, that any director may, by written notice to us, appoint another person to serve as an alternate director (subject to the consent of the board of directors) and may cancel such appointment. Unless the appointing director limits such appointment to a specified period of time or restricts it to a specified meeting or action of the board of directors, or otherwise restricts its scope, the appointment shall be for all purposes and for a period of time concurrent with the term of the appointing director. Currently, no alternate directors have been appointed. The Companies Law stipulates that a person not qualified to be appointed as a director, shall not be appointed and shall not serve as alternate director. In addition, a person who serves as a director shall not be appointed and shall not serve as an alternate director except under very limited circumstances, which are not relevant to our company. An alternate director has the same responsibilities as a director. Under the Companies Law, and our Articles, a director that is a member of a committee of the board of directors, may appoint as his alternate director on such committee of the board of directors another member of the board of directors, provided that such director is not already a member of such committee, and provided that if such person is appointed as an alternate director for an external director, such alternate director shall have the same accounting and financial expertise or other professional expertise as possessed by the appointing director. In addition, an independent director cannot appoint as his alternate director a person who is not qualified to be appointed as an independent director.

## **External Directors**

### ***Qualifications of External Directors***

Companies incorporated under the laws of the State of Israel whose shares are listed on a stock exchange, including The NASDAQ Capital Market, are required to appoint at least two natural persons as "external directors". We have appointed Gerald Dogon and Tali Yaron-Eldar, who qualify as external directors under the Companies Law. Our external directors were re-elected on July 14, 2010. The Companies Law provides that no person may be appointed as an external director if such person is a controlling shareholder or a relative of a controlling shareholder, or if such person, a relative, partner or employer of such person, or anyone to whom such person is directly or indirectly subordinate, or any entity under such person's control, has or had, on or within the two years preceding the date of such person's appointment to serve as an external director, any affiliation to the company to whose board such external director is proposed to be appointed or any other entity (which its controlling shareholder, on or within the two years preceding the date of such person's appointment, is the said company or which its controlling shareholder),, with any controlling shareholder of the company, with a relative of such controlling shareholder, at the date of appointment, or with any entity controlled by the company or by a controlling shareholder of the company, or, if the company has no controlling shareholder or a shareholder holding 25% or more of the company's voting rights, any affiliation, at the time of the appointment, to the chairman of the board of directors, the chief executive officer, the most senior financial officer of the company, or to a shareholder holding 5% or more of the outstanding shares or voting rights of the company.

The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; as well as
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the public offering.

The term "office holder" is defined in the Companies Law as a managing director, chief executive officer, executive vice president, vice president, any other person fulfilling or assuming any of the foregoing positions without regard to such person's title, as well as a director, or a manager directly subordinate to the managing director.

In addition, no person may serve as an external director if: (a) the person's position or other business activities create, or may create, a conflict of interest with the person's duties as a director or may interfere with the person's ability to serve as an external director; (b) at the time such person serves as a non-external director of another company on whose board of directors a director of the reciprocal company serves as an external director; (c) the person is an employee of the Israel Securities Authority or of an Israeli stock exchange; (d) such person or such person's relative, partner, employer or anyone to whom such person is directly or indirectly subordinate, or any entity under such person's control, has business or professional relations with any person or entity he or she should not be affiliated with, as described above, even if such affiliation is not on a regular basis, unless such relations are negligible; or (e) such person received compensation, directly or indirectly, in connection with such person's services as an external director, other than as permitted under the Companies Law and the regulations promulgated thereunder. If, at the time of election of an external director, all other directors, who are not controlling shareholders of such company or their relatives, are of the same gender, the external director to be elected must be of the other gender.

Under the Companies Law, a person may only be appointed as an external director if he or she has professional qualifications or if he or she has accounting and financial expertise, provided that at least one of the external directors must have accounting and financial expertise. However, according to regulations promulgated pursuant to the Companies Law, which were amended on and effective as of January 2013, companies whose shares are listed for trading on specified exchanges outside of Israel, including the NASDAQ Capital Market, may appoint external directors who

have professional qualifications only (and not accounting and financial expertise) provided that an existing member of the board of directors has accounting and financial expertise and is considered as an independent director under the relevant non-Israeli rules, relating to independence standards for audit committee membership. In addition, the board of directors of publicly traded companies, such as us, are required to make a determination as to the minimum number of directors who must have financial and accounting expertise in addition to the external director, based among other things, on the type and size of the company and the scope and complexity of its operations, and subject to the number of directors that may be appointed by the company as set forth in its articles of associations.

The conditions and criteria for possessing accounting and financial expertise or professional qualifications were determined in regulations promulgated by the Israeli Minister of Justice in consultation with the Israeli Securities Authority. The regulations mandate that a person is deemed to have “expertise in finance and accounting” if his or her education, experience and qualifications provide him or her with expertise and understanding in business matters, accounting and financial statements, in a way that allows him or her to understand, in depth, the company’s financial statements and to encourage discussion about the manner in which the financial data is presented.

The company’s board of directors must evaluate the proposed external director’s expertise in finance and accounting, by considering, among other things, his or her education, experience and knowledge in the following: (i) accounting and auditing issues typical to the field in which the company operates and to companies of a size and complexity similar to such company; (ii) a company’s external public accountant’s duties and obligations; and (iii) preparing company financial statements and their approval in accordance with the Companies Law and the Israeli Securities Law.

A director is deemed to be “professionally qualified” if he or she meets any of the following criteria: (i) has an academic degree in any of the following professions: economics, business administration, accounting, law or public administration; (ii) has a different academic degree or has completed higher education in a field that is the company’s main field of operations, or a field relevant to his or her position; or (iii) has at least five years of experience in any of the following, or has a total of five years of experience in at least two of the following: (A) a senior position in the business management of a corporation with significant operations, (B) a senior public position or a senior position in public service, or (C) a senior position in the company’s main field of operations. The board of directors here too must evaluate the proposed external director’s “professional qualification” in accordance with the criteria set forth above.

The board of directors has determined that other than one external director no other directors are required to have financial and accounting expertise. Our board of directors further determined that our external director, Mr. Dogon, possesses the requisite financial and accounting expertise and that both of our external directors possess the requisite professional qualifications.

Following termination of service as an external director, a public company, a controlling shareholder thereof and any entity controlled by a controlling shareholder, may not grant any benefit, directly or indirectly, to any person who served as an external director of such public company, or to his or her spouse or child, including, not appointing such person, or his or her spouse or child, as an office holder of such public company or of an entity controlled by a controlling shareholder of such public company, not employing such person and not receiving professional services for pay from such person, either directly or indirectly, including through a corporation controlled by such person, or his or her relative, all until the lapse of two years from termination of office with respect to the external director, his or her spouse or child and until the lapse of one year from termination of office with respect to other relatives besides spouse or child of the former external director.

### ***Election of External Directors***

External directors are elected at the general meeting of shareholders by a simple majority, provided that:

- the majority includes at least a majority of the shares of shareholders who are not controlling shareholders and who do not have a personal interest in the matter (other than a personal interest which is not the result of an affiliation with a controlling shareholder), who are present and voted on the matter of the election of the external director (disregarding abstentions); or
- the non-controlling shareholders or shareholders that do not have a personal interest in the matter (other than a personal interest which is not the result of an affiliation with a controlling shareholder), who are present and voted against the election of the external director hold two percent or less of the voting power of the company.

External directors are elected for a term of three years and may be re-elected to two additional terms of three years each, provided that with respect to the appointment for each such additional three-year term, one of the following has occurred: (a) the reappointment of the external director has been proposed by one or more shareholders holding together one percent or more of the aggregate voting rights in the company and the appointment was approved at the general meeting of the shareholders by a simple majority, provided that: (i) in calculating the majority, votes of controlling shareholders or shareholders having a personal interest in the appointment (other than a personal interest which is not the result of an affiliation with a controlling shareholder) and abstentions are disregarded, and (ii) the total number of shares of shareholders who do not have a personal interest in the appointment (other than a personal interest which is not the result of an affiliation with a controlling shareholder) and/or who are not controlling shareholders, present and voting in favor of the appointment exceed two percent of the aggregate voting rights in the company; or (b) the reappointment of the external director has been proposed by the board of directors and the appointment was approved by the majority required for the initial appointment of an external director.

However, under regulations promulgated pursuant to the Companies Law, companies whose shares are listed for trading on specified exchanges outside of Israel, including the NASDAQ Global Market, NASDAQ Global Select Market, and, as of January 14, 2013, the NASDAQ Capital Market, may elect external directors for additional terms that do not exceed three years each, beyond the three three-year terms generally applicable, provided that, if an external director is being re-elected for an additional term or terms beyond three three-year terms: (i) the audit committee and board of directors must determine that, in light of the external director's expertise and special contribution to the board of directors and its committees, the reelection for an additional term is to the company's benefit; (ii) the external director must be re-elected by the required majority of shareholders and subject to the terms specified in the Companies Law; and (iii) the term during which the nominee has served as an external director and the reasons given by the audit committee and board of directors for extending his or her term of office must be presented to the shareholders at the shareholder's meeting prior to their approval.

An external director cannot be removed from office unless: (i) the board of directors determines that the external director no longer meets the statutory requirements for holding the office, or that the external director is in breach of his or her duty of loyalty to the company, and the shareholders vote, by the same majority of shareholders as is required for his or her appointment, to remove the external director after the external director has been given the opportunity to present his or her position; (ii) a court determines, upon a request of a director or a shareholder, that the external director ceases to meet the statutory requirements for his or her appointment or that the external director is in breach of his or her fiduciary duties to the company; or (iii) a court determines, upon a request of the company or a director, shareholder or creditor of the company, that the external director is unable to fulfill his or her duty, or has been convicted of specified crimes. If an external directorship becomes vacant and the number of external directors serving in the company is less than two, then a company's board of directors is required under the Companies Law to call a shareholders' meeting immediately to appoint a new external director.

Each committee of a company's board of directors that has the right to exercise a power delegated by the board of directors cannot include any person who is not a director, and is required to include at least one external director. The audit committee must consist of at least three members, is required to include all of the external directors, and most of its members must be independent directors, as defined below.

In addition to the concept of "external" directors, the Companies Law also includes the concept of "independent" directors. An independent director is either an external director or a director appointed or classified as such who meets the same non-affiliation criteria as an external director, as determined by the subject company's audit committee, and who has not served as a director of the company for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service. An independent director may be removed from office in the same manner that an external director may be removed.

Pursuant to the Companies Law, a public company, such as us, may include in its articles of association a provision providing that a specified number of its directors be independent directors or may adopt a standard provision providing that a majority of its directors be independent directors or, if there is a controlling shareholder or a 25% or more shareholder, that at least one-third of its directors be independent directors.

Regulations promulgated pursuant to the Companies Law provide that a director in a company whose shares are listed for trading on specified exchanges outside of Israel, including the NASDAQ Global Market, NASDAQ Global Select Market and as of January 14, 2013, the NASDAQ Capital Market, who qualifies as an independent director under the relevant non-Israeli rules relating to independence standards for audit committee membership and who meets certain non-affiliation criteria, which are less stringent than those applicable to external directors, would be deemed an "independent" director pursuant to the Companies Law provided he or she has not served as a director for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service. Furthermore, pursuant to these regulations, such company may re-appoint a person as an independent director for additional terms, beyond nine years, which do not exceed three years each, if the audit committee and the board of directors determine that in light of the independent director's expertise and special contribution to the board of directors and its committees, the re-appointment for an additional term is to the company's benefit.

Although the Company has not included such a provision in its Articles, it believes that Brian A. Markison, Joshua Rosensweig, Gerald Dogon and Tali Yaron-Eldar could qualify as independent directors under the Companies Law. In addition, the Company believes that Brian A. Markison, Joshua Rosensweig, Gerald Dogon, Tali Yaron-Eldar and David Sidransky qualify as "independent directors" as defined by The NASDAQ Stock Market.

An external director is entitled to compensation only as provided in regulations adopted under the Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with services provided as an external director. For this matter, the term "compensation" shall not include the grant of an exemption, an undertaking to indemnify, indemnification or insurance.

## **Board Committees**

Our board of directors has established an audit committee, a compensation committee, a nominating and governance committee and a research and development committee.

### ***Audit Committee***

Under the listing requirements of The NASDAQ Capital Market, a foreign private issuer is required to maintain an audit committee that operates under a formal written charter and has certain responsibilities and authority, including being directly responsible for the appointment, compensation, retention and oversight of the work of the issuer's independent auditors. The members of the audit committee are required to meet the independence requirements established by the SEC in accordance with the requirements of the Sarbanes-Oxley Act. The rules of The NASDAQ Capital Market also require that at least one member of the audit committee be a financial expert. Our audit committee is comprised of three members and meets the listing requirements of The NASDAQ Capital Market and the SEC.

The Companies Law requires public companies to appoint an audit committee comprised of at least three directors, including all of the external directors, and further stipulates that the chairman of the board of directors, any director employed by or providing other services to a company on an ongoing basis, and a controlling shareholder or any relative of a controlling shareholder may not be members of the audit committee.

The majority of the members of the audit committee must be independent directors under the Companies Law. Additionally, the following may not be members of the audit committee: (a) the chairman of the board (b) a director employed by or providing services on an ongoing basis to the company, a controlling shareholder or an entity controlled by a controlling shareholder; (c) a director whose livelihood depends on a controlling shareholder, and (d) a controlling shareholder and its relative (as defined in the Companies law). The Companies Law further requires that (i) the chairperson of the audit committee be an external director; (ii) generally, any person who is not entitled to be a member of the audit committee may not attend the audit committees meetings; and (iii) the quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee be a majority of the members of the audit committee provided that the majority of the members present are independent directors and at least one of them is an external director.

Our audit committee provides assistance to the board of directors in fulfilling its responsibility to our shareholders relating to our accounting, financial reporting practices, and the quality and integrity of our financial reports. The audit committee also oversees consultants and experts providing the company with consulting services concerning risk management and internal control structure, pre-approves the services performed by our independent auditors and oversees that management has established and maintains processes to assure compliance by the Company with all applicable laws, regulations and corporate policies. The audit committee also oversees and ensures the independence of our independent auditors.

The responsibilities of the audit committee under the Companies Law include: (a) identifying flaws in the management of a company's business, including by consulting with the internal auditor or with the independent auditor, and making recommendations to the board of directors as to how to correct them; (b) reviewing and deciding whether to approve certain related party transactions and certain actions involving conflicts of interest; (c) with respect to certain actions involving conflicts of interest and with respect to certain related party transactions, deciding whether such actions are material actions and whether such transactions are extraordinary transactions, respectively, all for the purpose of approving such actions or transactions; (d) reviewing the internal auditor's work program; (e) examining the company's internal control structure and processes, the performance of the internal auditor and whether the internal auditor has at his or her disposal the tools and resources required to perform his or her duties, considering, *inter alia*, the special needs of the company and its size; (f) examining the independent auditor's scope of work as well as the independent auditor's fees and to provide the corporate organ responsible for determining the independent auditor's fees with its recommendations; and (g) the audit committee will also be responsible for providing for arrangements as to the manner in which the Company will deal with employee complaints with respect to deficiencies in the administration of the Company's business and the protection to be provided to such employees.

Our written audit committee charter, a copy of which is available on the "Corporate Governance" section of our website, states that in fulfilling its role, the committee is entitled to meet with our management, our internal auditor and our independent auditor.

Gerald Dogon, Tali Yaron-Eldar and Dr. David Sidransky are the current members of our audit committee. Each of these persons is an 'independent director' in accordance with the NASDAQ listing standards and, except for Dr. Sidransky, qualifies as an independent director under the Companies Law.

### ***Compensation Committee***

Our compensation committee reviews and provides our board of directors with recommendations relating to compensation and benefits of our officers and key employees and assists the board of directors with establishing, overseeing and/or administering incentive compensation and equity based plans. The compensation committee reviews corporate goals and objectives set by our board that are relevant to compensation of the Chief Executive Officer, evaluates the performance of the Chief Executive Officer in light of those goals and objectives, and recommends to the board of directors the Chief Executive Officer's compensation based on such evaluations, subject to additional approvals, to the extent required pursuant to the Companies Law. The compensation committee also reviews and makes recommendations for approvals to the board of directors, subject to additional approvals, to the extent required pursuant to the Companies Law, with respect to the compensation of directors, executive officers other

than the Chief Executive Officer and key employees. The compensation committee operates under a written compensation committee charter, a copy of which is available on the “Corporate Governance” section of our website. The members of our compensation committee are, Tali Yaron Eldar and Gerald Dogon.

Amendment no. 20 to the Companies Law was published on November 12, 2012 and became effective on December 12, 2012 ("Amendment no. 20"). In general, Amendment no. 20 requires public companies to appoint a compensation committee and to adopt a compensation policy with respect to its officers (the "Compensation Policy"). In addition, Amendment no. 20 addresses the corporate approval process required for a public company's engagement with its officers (with specific reference to a director, a non-director officer, a Chief Executive Officer and controlling shareholders and their relatives who are employed by the company).

The compensation committee shall be nominated by the board of directors and be comprised of its members. The compensation committee must consist of at least three members. All of the external directors must serve on the compensation committee and constitute a majority of its members (in some cases, a company whose shares are listed for trading on specified exchanges outside of Israel, including the NASDAQ Capital Market, may appoint a compensation committee in which the external directors do not constitute a majority). The remaining members of the compensation committee must be directors who qualify to serve as members of the audit committee (including the fact that they are independent) and their compensation should be identical to the compensation paid to the external directors of the company.

Amendment no. 20 does not set a date for the appointment of the compensation committee. However, the Compensation Policy should be approved by the general meeting of shareholders (after discussions and recommendation of the compensation committee and approval by the board of directors) by September 11, 2013. Moreover, the approval of the compensation committee is required in order to approve terms of office and/or employment of office holders.

Our current compensation committee does not qualify as "compensation committee" according to the Israeli Companies Law, as it is not currently comprised of the required members and we have yet to appoint a compensation committee that meets the requirements of Amendment no. 20.

The roles of the compensation committee are, among others, to: (1) recommend to the board of directors the Compensation Policy for office holders, and recommend to the board once every three years the extension of a Compensation Policy that had been approved for a period of more than three years; (2) recommend to the directors any update of the Compensation Policy, from time to time, and examine its implementation; (3) decide whether to approve the terms of office and of employment of office holders that require approval of the Compensation Committee; and (4) decide, in certain circumstances, whether to exempt the approval of terms of office of a CEO from the requirements of shareholders' approval.

The Compensation Policy requires the approval of the general meeting of shareholders with a Special Majority, as defined below (however, under special circumstances, the Board of Directors may approve the Compensation Policy without their approval).

Amendment no. 20 details the considerations that should be taken into account in determining the Compensation Policy and certain issues which the Compensation Policy should include.

### ***Nominating and Governance Committee***

The nominating and governance committee is responsible for making recommendations to the board of directors regarding candidates for directorships and the composition of our board of directors and its committees as well as to evaluate and consider matters relating to the qualifications of directors. In addition, the nominating and governance committee is responsible for reviewing and reassessing our corporate governance guidelines and making recommendations to the board of directors concerning governance matters. The nominating and governance committee operates under a written charter, a copy of which is available on the "Corporate Governance" section of our website. The members of our nominating and governance committee are Brian Markison, Dr. Joshua Rosensweig and Dr. Yitzhak Peterburg. Our board of directors has determined that the members of our nominating and governance committee are independent under the applicable NASDAQ Capital Market rules.

Pursuant to our Articles, nominations for the election of directors may be made by the board of directors or a committee appointed by the board of directors or by any shareholder holding at least 1% of the outstanding voting power in the Company. However, any such shareholder may nominate one or more persons for election as directors at a general meeting only if a written notice of such shareholder's intent to make such nomination or nominations has been delivered to us as required under our Articles.

### ***Research and Development Committee***

The research and development committee is responsible for liaising between the Company's research and development team and the board of directors. This committee is also responsible for reviewing proposed research and development projects for Rosetta, as well as the research and development focus of Rosetta and making recommendations to the board of directors regarding the research and development projects which we intend to undertake as well as recommendations relating to our pipeline. The members of our research and development committee are Roy Davis, Dr. Yitzhak Peterburg and Dr. David Sidransky.



## **Internal Auditor**

Under the Companies Law, the board of directors must appoint an internal auditor recommended by the audit committee. On May, 7, 2007, we appointed Yardeni Gelfend as our internal auditor. The role of the internal auditor is to examine, among other things, whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be an interested party or an office holder, or a relative of an interested party or an office holder, nor may the internal auditor be the company's independent auditor or anyone on his behalf. An interested party is defined in the Companies Law as a holder of 5% or more of the Company's outstanding shares or voting rights, any person or entity who has the right to designate one director or more or the chief executive officer of the company or any person who serves as a director or as a chief executive officer. The internal auditor's tenure cannot be terminated without his or her consent, nor can he or she be suspended from such position unless the board of directors has so resolved after hearing the opinion of the audit committee and after giving him or her the opportunity to present his or her case to the board and to the audit committee.

## **Approval of Specified Related Party Transactions Under Israeli Law**

See "Item 10 — Additional Information — B. Memorandum and Articles of Association — Fiduciary Duties of Office Holders", "— Disclosure of Personal Interests of an Office Holder" and "—Transactions Requiring Special Approval" for a discussion of the requirements of Israeli law regarding the fiduciary duties of the office holders of the company, including directors and executive officers, and their duties to disclose any personal interest that such person may have and all related material information known to him or her relating to any existing or proposed transaction by the company, as well as transactions that require special approval.

## ***D. EMPLOYEES***

As of December 31, 2012 we had 28 employees. As of December 31, 2011 we had 22 employees. As of December 31, 2010, we had 54 employees who worked a four-day work week. Of the 28 employees as of December 31, 2012, 14 were engaged in research and development and in our CLIA lab activities and 14 were engaged in management, administration, business development, marketing and finance. 12 employees were located in the United States and 16 were located in Israel.

The Israeli labor laws govern the employment of employees located in Israel. These statutes cover a wide range of subjects and provide certain minimum employment standards including the length of the workday, minimum wage, hiring and dismissal procedures, determination of severance pay, annual leave, sick days and other terms of employment.

We contribute (usually following a trial period of three months) monthly amounts for the benefit and on behalf of all our employees located in Israel to a Managers Insurance plan and/or a Pension Plan. The severance pay liability of the company to its Israeli employees is based upon the number of years of employment and the latest monthly salary. Since our contributions to the Managers Insurance plan and/or the Pension Plan are made pursuant to section 14 of the Israeli Severance Pay Law (except with respect to two employees), our liability for severance pay is covered by our regular contributions to the Managers Insurance plan and the Pension Plan.

We have never experienced labor-related work stoppages and believe that our relations with our employees are good.

## ***E. SHARE OWNERSHIP***

The following table sets forth, as of March 1, 2013, the number of our ordinary shares beneficially owned by (i) each of our directors and corporate and executive officers and (ii) our current directors and corporate and executive officers as a group. The information in this table is based on 9,097,348 ordinary shares outstanding as of March 1, 2013. Beneficial ownership of shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Ordinary shares that are subject to convertible securities, warrants or options that are currently convertible or exercisable or convertible or exercisable within 60 days of March 1, 2013 are deemed to be outstanding and beneficially owned by the person holding the convertible securities, warrants or options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Outstanding Ordinary Shares
Kenneth A. Berlin (1)	19,836	*
Ron Kalfus	0	*
Dganit Bar, Ph.D.	0	*
E. Robert Wassman, M.D.	0	*
Guy C. Malchi	0	*
Oded Biran (2)	250	*
Eti Meiri (3)	177	*
Brian Markison (4)	1,666	*
Yitzhak Peterburg, M.D., Ph.D.	0	*
Roy N. Davis	0	*
Joshua Rosensweig (5)	2,634	*
Dr. David Sidransky (6)	462	*
Gerald Dogon (7)	212	*
Tali Yaron-Eldar (8)	212	*
Current directors and executive officers as a group (14 persons) (9)	25,499	*

\* Represents beneficial ownership of less than 1% of ordinary shares.

- (1) Consists of (i) 1,084 ordinary shares, which were granted to Mr. Berlin upon the start of his employment with us, and (ii) options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 8,335 ordinary shares (which have an exercise price of \$123.00 per share and expire in November 2019), 8,334 ordinary shares (which have an exercise price of \$29.4 per share and expire in November 2019), and 2,083 ordinary shares (which have an exercise price of \$6.75 per share and expire in November 2021). Does not include the following options that become exercisable after April 30, 2013: (i) options to purchase 4,584 shares (which have an exercise price of \$6.75 per share and expire in November 2021) (ii) 96,000 ordinary shares (which have an exercise price of \$5.37 per share and expire in October 2022).
- (2) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 250 ordinary shares (which have an exercise price of \$2.475 per share and expire in February 2022). Does not include the following options that become exercisable after April 30, 2013: (i) options to purchase 750 shares (which have an exercise price of \$2.475 per share and expire in February 2022) (ii) 9,000 ordinary shares (which have an exercise price of \$5.37 per share and expire in October 2022).
- (3) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 38 ordinary shares (which have an exercise price of \$0.00 per share and expire during the years 2014 and 2015), 21 ordinary shares (which have an exercise price of \$209.78 per share and expire in April 2016), and 34 ordinary shares (which have an exercise price of \$249.6 per share and expire in June 2018), and 84 ordinary shares (which have an exercise price of \$84 per share and expire in October 2020). Does not include the following options that become exercisable after April 30, 2013: options to purchase 10,000 shares (which have an exercise price of \$5.37 per share and expire in October 2022).
- (4) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 1,666 ordinary shares (which have an exercise price of \$16.2 per share and expire in July 2021). Does not include the following options that become exercisable after April 30, 2013: options to purchase 3,334 shares (which have an exercise price of \$16.2 per share and expire in July 2021).
- (5) Consists of (i) 2,306 ordinary shares held by Dr. Rosensweig and (ii) options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 212 ordinary shares (which have an exercise price of \$368.67 per share and expire in July 2016) and 116 ordinary shares (which have an exercise price of 209.78 per share and expire in July 2016).
- (6) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 250 ordinary shares (which have an exercise price of \$342 per share and expire in January 2018) and 212 ordinary shares (which have an exercise price of \$99 per share and expire in December 2019).
- (7) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 212 ordinary shares (which have an exercise price of \$528.01 per share and expire in March 2017).
- (8) Consists of options currently exercisable or exercisable within 60 days of March 1, 2013 to purchase 212 ordinary shares (which have an

exercise price of \$528.01 per share and expire in March 2017).

(9) See notes 1 through 8 above.

## **Employee Benefit Plans**

### ***2003 Israeli Share Option Plan***

In March 2003, we adopted the Rosetta Genomics Ltd. 2003 Israeli Share Option Plan, or the 2003 Plan. The 2003 Plan provided for the grant of options to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiary and affiliates. Upon shareholder approval of the 2006 Global Share Incentive Plan, or 2006 Plan, in July 2006, the 2003 Plan was terminated and the 5,363 ordinary shares that were available for issuance under the 2003 Plan were transferred to the 2006 Plan. However, all outstanding options granted under the 2003 Plan remain outstanding and subject to the terms of the 2003 Plan. Any options that were granted under the 2003 plan and that are canceled are transferred to the 2006 Plan. As of March 1, 2013, options to purchase 258 ordinary shares have been granted and are still outstanding under the 2003 Plan and 6,874 shares have been issued pursuant to the exercise of options granted under the 2003 Plan.

## ***2006 Global Share Incentive Plan***

The 2006 Global Share Incentive Plan, or the 2006 Plan, was approved in July 2006. In November 2007, our board of directors approved an additional 8,333 shares under the 2006 Plan. In December 2009, our shareholders approved an additional 25,000 shares under the 2006 plan. In October 2012, our shareholders approved an additional 853,770 shares under the 2006 plan. As of March 1, 2013, there were 592,155 shares available for grant under the 2006 Plan, 2,652 shares have been issued pursuant to the exercise of options granted under the 2006 Plan and options to purchase 305,193 ordinary shares have been granted and are outstanding under the 2006 Plan. The 2006 Plan, and its appendices for grantees subject to U.S. taxation and grantees subject to Israeli taxation, provides for the grant of options to our directors, employees, consultants and office holders and those of our subsidiary and affiliates.

## ***Administration of Our Employee Benefit Plans***

Our employee benefit plans are administered by our compensation committee, which makes recommendations to our board of directors regarding the grant of options and the terms of the grant, including, exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Options granted under the 2003 Plan and the 2006 Plan to eligible employees and office holders who are Israeli residents may be granted under Section 102(b)(2) of the Israel Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be allocated or issued to a trustee and be held in trust for a minimum requisite period, which is currently two years from the date of grant. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares and gains are generally subject to a capital gains tax of 25%, provided, however, that in accordance with Section 102(b)(3) of the Israel Income Tax Ordinance, if the exercise price of the options is lower than the average closing price of the shares in the 30 trading days preceding the grant, the difference between such average closing price and the exercise is taxed as ordinary employment income rates.

Options to be granted under the 2006 Plan to U.S. residents may qualify as incentive stock options within the meaning of Section 422 of the Code. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, unless otherwise approved by our board of directors and shareholders, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

Options granted under our employee benefit plans generally vest over three or four years, and they generally expire ten years from the date of grant. If we terminate the employment or engagement of a participant under the 2006 Plan for cause, all of such participant's vested and unvested options expire immediately upon the date of such termination for cause unless specified otherwise in the award agreement. Upon termination of employment for any other reason, including due to death or disability of the participant, vested options may be exercised within three months of the date of termination, unless otherwise determined in the award agreement. Vested options not exercised within the prescribed period and options which have expired prior to vesting are available for future grants under the 2006 plan.

In the event of a change of control, or merger, consolidation, reorganization or similar transaction resulting in the acquisition of at least 50% of our voting power, or the sale of all or substantially all of our shares or assets, the options will be assumed or substituted by the acquiring entity, or if the acquiring party does not provide for such assumption or substitution, then the options shall be subject to acceleration.

## **ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

### ***A. MAJOR SHAREHOLDERS***

Based on a review of required SEC filings, we are not aware of any person or entity that is the beneficial owner of more than 5% of our outstanding ordinary shares.

Our ordinary shares are traded on the NASDAQ Capital Market in the United States. A significant portion of our shares are held in street name, therefore we generally have no way of determining who our shareholders are, their geographical location or how many shares a particular shareholder owns.

### ***Significant Changes in Share Ownership***

The following table shows changes over the last three years in the percentage ownership by major shareholders:

	<b>Percentage of Outstanding</b>	<b>Percentage of</b>	<b>Percentage of</b>
--	--------------------------------------	----------------------	----------------------

<b>Name of Beneficial Owner</b>	<b>Ordinary Shares Owned as of March 1, 2011</b>	<b>Outstanding Ordinary Shares Owned as of March 1, 2012</b>	<b>Outstanding Ordinary Shares Owned as of March 1, 2013</b>
Isaac Bentwich, M.D. (1)	4.9%	3.1%	-
Prometheus Laboratories Inc. (2)	6.3%	-	-
Becker Drapkin Management (3)	9.7%	2.9%	-
Perkins Capital Management, Inc.(4)	-	9.3%	-

(1) Percentage of shares outstanding as of March 1, 2013 is unknown.

(2) Percentage of outstanding shares owned as of March 1, 2011 is based solely on a Schedule 13G filed with the SEC on February 14, 2011. Percentage of shares outstanding as of March 1, 2012 and March 1, 2013 is unknown.

(3) Percentage of outstanding shares owned as of March 1, 2011 is based solely on a Schedule 13G filed with the SEC on February 24, 2011. Percentage of outstanding shares owned as of March 1, 2012 is based solely on a Schedule 13G filed with the SEC on February 10, 2012. Percentage of shares outstanding as of March 1, 2013 is unknown.

(4) Percentage of outstanding shares owned as of March 1, 2012 is based solely on a Schedule 13G filed with the SEC on February 8, 2012. Percentage of shares outstanding as of March 1, 2013 is unknown.

### ***Control of Registrant***

To our knowledge, we are not directly or indirectly owned or controlled by another corporation, by any foreign government, or by any other natural or legal person. As of March 1, 2013, our officers and directors as a group beneficially owned less than 1% of our outstanding ordinary shares.

### ***B. RELATED PARTY TRANSACTIONS***

Other than transactions related to compensation of our officers and directors as described under “Item 6. Directors, Senior Management and Employees—B. Compensation,” since January 1, 2012, we have not entered into any related party transactions.

### ***Exculpation, Indemnification and Insurance***

Our Articles permit us to exculpate, indemnify and insure our directors and officers to the fullest extent permitted by the Companies Law. An undertaking provided in advance by an Israeli company to indemnify an office holder with respect to a financial liability imposed on or incurred by him or her in favor of another person pursuant to a judgment, settlement or arbitrator’s award approved by a court must be limited to events which in the opinion of the board of directors can be foreseen based on the company’s activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned events and amount or criteria. In addition, a company may indemnify an office holder against the following liabilities incurred for acts performed as an office holder:

- reasonable litigation expenses, including attorneys’ fees, incurred by the office holder as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) either (A) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, (B) if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent or with respect to monetary sanction; and
- reasonable litigation expenses, including attorneys’ fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for a crime that does not require proof of criminal intent.

An Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder:

- a breach of duty of loyalty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care to the company or to a third party; and
- a financial liability imposed on the office holder in favor of a third party.

An Israeli company may not indemnify or insure an office holder against any of the following:

- a breach of duty of loyalty, except to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction, forfeit or penalty levied against the office holder.

As of the effective date of Amendment no. 20 to the Companies Law, exculpation, indemnification and insurance of office holders are included in the definition of "terms of office and of employment" and as such must be approved in a specific manner, as noted below under “Item 10 – Additional Information – B. Memorandum and Articles of Association - Directors’ and Officers’ Compensation.”

Our directors and officers are currently covered by a directors' and officers' liability policy and our General Counsel is currently covered by a legal professional liability policy as well. We have also resolved to provide directors and certain other office holders with indemnification from any liability for damages caused as a result of a breach of duty of care and to provide such directors and other office holders with an exemption, to the fullest extent permitted by law, all in accordance with and pursuant to the terms set forth in our standard indemnification undertaking.

### ***C. INTERESTS OF EXPERTS AND COUNSEL***

Not applicable.

## **ITEM 8. FINANCIAL INFORMATION**

### ***A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION***

#### **Consolidated Financial Statements**

Our consolidated financial statements and related notes are included in this Annual Report beginning on page F-1. See also Item 18.

#### **Legal Proceedings**

We are currently not a party to any material legal proceedings.

#### **Dividend Policy**

To date, we have not declared or paid cash dividends on any of our shares, and we have no current intention of paying any cash dividends in the near future.

The Companies Law also restricts our ability to declare dividends. We can only distribute dividends from profits (as defined in the Companies Law), or, if we do not meet the profits test, with court approval provided in each case that there is no reasonable concern that the dividend distribution will prevent the company from meeting its existing and foreseeable obligations as they come due. The payment of dividends may be subject to Israeli withholding taxes.

### ***B. SIGNIFICANT CHANGES***

See "Note 13. Subsequent Events" to our consolidated financial statements included in this Annual Report beginning on page F-1 for a discussion of significant events that have occurred since December 31, 2012.

## **ITEM 9. THE OFFER AND LISTING**

### ***A. OFFER AND LISTING DETAILS***

Our ordinary shares began trading on The NASDAQ Global Market on February 27, 2007 under the symbol "ROSG." On June 30, 2010, we transferred the listing of our ordinary shares from The NASDAQ Global Market to The NASDAQ Capital Market. Prior to February 27, 2007, there was no established public trading market for our ordinary shares. The high and low sales prices per share of our ordinary shares for the periods indicated are set forth below. This information reflects the 1-for-4 reverse stock split effected on July 6, 2011 and the 1-for 15 reverse stock split effected on May 14, 2012.

<b>Year Ended</b>		<b>High</b>		<b>Low</b>
December 31, 2008	\$	374.98	\$	64.80
December 31, 2009	\$	227.99	\$	70.79
December 31, 2010	\$	208.79	\$	54.00
December 31, 2011	\$	61.80	\$	1.95
December 31, 2012	\$	23.43	\$	1.40
<b>Quarter Ended</b>				
March 31, 2011	\$	61.80	\$	30.00
June 30, 2011	\$	33.00	\$	12.00

September 30, 2011	\$	36.45	\$	13.65
December 31, 2011	\$	20.55	\$	1.95
March 31, 2012	\$	11.25	\$	2.43
June 30, 2012	\$	23.43	\$	1.40
September 30, 2012	\$	12.87	\$	3.88
December 31, 2012	\$	7.34	\$	3.92

**Month Ended**

September 30, 2012	\$	7.73	\$	5.15
October 31, 2012	\$	7.34	\$	4.55
November 30, 2012	\$	5.39	\$	3.92
December 31, 2012	\$	5.05	\$	4.16
January 31, 2013	\$	5.98	\$	4.40
February 28, 2013	\$	5.48	\$	4.36

***B. PLAN OF DISTRIBUTION***

Not applicable.

***C. MARKETS***

Our ordinary shares are traded only in the United States on The NASDAQ Capital Market.

***D. SELLING SHAREHOLDERS***

Not applicable.

***E. DILUTION***

Not applicable.

***F. EXPENSES OF THE ISSUE***

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

***A. SHARE CAPITAL***

Not applicable.

***B. MEMORANDUM AND ARTICLES OF ASSOCIATION***

**Objects and Purposes**

We were first registered under Israeli law on March 9, 2000. Our registration number with the Israel Registrar of Companies is 51-292138-8. The objective stated in Section 3 of our Articles is to carry on any business and perform any act which is not prohibited by law.

**Fiduciary Duties of Office Holders**

An “office holder” is defined in the Companies Law as a managing director, chief executive officer, executive vice president, vice president, or any other person fulfilling or assuming any of the foregoing positions without regard to such person’s title, as well as a director, or a manager directly subordinate to the managing director.

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care requires an office holder to act with the standard of skills with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means to obtain, considering the relevant circumstances:

- ★ information regarding the business advisability of a given action brought for his or her approval or performed by him or her by virtue of his or her position; and
- ★ all other information of importance pertaining to the aforesaid actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company and includes a duty to:

- ★ refrain from any act involving a conflict of interest between the fulfillment of his or her role in the company and the fulfillment of any other role or his or her personal affairs;
- ★ refrain from any activity that is competitive with the business of the company;
- ★ refrain from exploiting any business opportunity of the company with the aim of obtaining a personal gain for himself or herself or others; and
- ★ disclose to the company all information and provide it with all documents relating to the company's affairs which the office holder has obtained due to his position in the company.

Each person listed in the table under "Item 6 - Directors, Senior Management and Employees - A. Directors and Senior Management" is an office holder.

### **Disclosure of Personal Interests of an Officer Holder**

The Companies Law requires that an office holder disclose to the company any personal interest that he or she may have, and all related material information and documents known to him or her, in connection with any existing or proposed transaction by the company. The disclosure is required to be made promptly and in any event, no later than the board of directors meeting in which the transaction is first discussed. "Personal interest", is defined by the Companies Law, as a personal interest of a person in an act or transaction of the company, including a personal interest of his or her relative or of a corporate body in which that person or a relative of that person is a holder of 5% or more of that corporate body's outstanding shares or voting rights, is a director or general manager, or in which he or she has the right to appoint at least one director or the general manager. "Personal interest" does not apply to a personal interest stemming merely from the fact that the office holder is also a shareholder in the company. The term "personal interest" also includes the personal interest of a person voting under a proxy given by another person, even if such appointing person has no personal interest in the proposed act or transaction. In addition, the vote of a person voting under a proxy given by a person having a personal interest in the proposed act or transaction, even if the person voting under the proxy has no personal interest, shall be deemed as a vote made by a person having a personal interest in the proposed act or transaction. The Companies Law defines a "relative" as a person's spouse, sibling, parent, grandparent or descendent, as well as the descendant, sibling or parent of a person's spouse, or the spouse of any of the foregoing.

Notwithstanding the above, if the transaction is not an extraordinary transaction, the office holder is not required to disclose any personal interest that he or she has solely as a result of a personal interest of his or her relative in the transaction.

### **Transactions Requiring Special Approval**

Under the Companies Law, an extraordinary transaction is a transaction:

- ★ not in the ordinary course of business of the company;
- ★ not on market terms; or
- ★ likely to have a material impact on the company's profitability, assets or liabilities.

Under the Companies Law, certain transactions require special approvals, provided however that such transactions are not adverse to the company's interest. A transaction, between the company and an office holder, or a third party in which the office holder has a personal interest, must be approved by the board, subject to the provisions of applicable law and the company's articles of association. If the transaction is an extraordinary transaction, then it also must be approved by the audit committee, prior to the approval of the board of directors. Any engagement between a company and any one of its office holders with respect to terms of office and/or employment by the company, including with respect to the grant of exculpation, indemnification or insurance would generally require compensation committee and board of directors' approval, and in some cases followed by approval of the general assembly, all as noted below under "Directors' and Officers' Compensation." Generally, any person having a personal interest in the approval of a transaction which is considered at a meeting of the board of directors or the audit committee, may not be present at such meeting or participate in the vote on such transaction, provided however that an office holder having a personal interest in a transaction may be present in order to present such transaction, if the chairman of the audit committee or of the board of directors, as applicable, determine that the presence of such office holder is required for the presentation of the transaction. Notwithstanding the foregoing, a director may be present at such meeting and may participate in the vote on such transaction, if the majority of the board of directors or the audit committee, as

applicable, has a personal interest in the transaction. If a majority of the directors have a personal interest in a transaction, shareholder approval is also required.

Under the Companies Law, the disclosure requirements which apply to an office holder also apply to a controlling shareholder of a public company. For these purposes, a controlling shareholder is any shareholder that has the ability to direct the activities of the company, including a shareholder holding 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights in the company, but excluding a shareholder whose power derives solely from his or her position on the board of directors or any other position with the company. If two or more shareholders are interested parties in the same transaction, their shareholdings are combined for the purposes of calculating percentages.

Under the Companies Law, extraordinary transactions of a public company with a controlling shareholder or in which a controlling shareholder has a personal interest, as well as any engagement between a public company and a controlling shareholder thereof or such controlling shareholder's relative, whether directly or indirectly, including through a company controlled by such person with respect to the provision of services to the company, and if such person is also an office holder of such company - with respect to such person's terms of service and employment as an office holder, and if such person is an employee of the company but not an office holder with respect to such person's employment by the company, generally requires the approval of the audit committee, or if the transaction is with respect to terms of employment and or office – the compensation committee, the board of directors and the shareholders of the company. If such shareholder approval is required, it must satisfy either of the following criteria ("Special Majority"):

- the majority of the votes for the approval includes the votes of at least a majority of the total votes of shareholders who are present at the meeting and who have no personal interest in the transaction; the votes of abstaining shareholders shall not be included in the number of the said total votes; or
- the total number of votes against the approval of the transaction, among the shareholders who are present at the meeting and who have no personal interest in the transaction shall not exceed 2% of the aggregate voting rights in the company.

Such transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, that are for a period of more than three years generally need to be brought for approval in accordance with this above procedure every three years.

In those circumstances in which shareholders' approval is required, shareholders have the right to review any documents in the company's possession related to the proposed transaction. However, the company may prohibit a shareholder from reviewing the documents if the company believes the request was made in bad faith, the documents include trade secrets or patents or their disclosure could otherwise harm the company's interests.

For information concerning the direct and indirect personal interests of certain of our office holders and principal shareholders in certain transactions with us, see "Item 7 — Major Shareholders and Related Party Transactions — B. Related Party Transactions."

### **Directors' and Officers' Compensation**

As of the effective date of Amendment no. 20 to the Companies Law, directors' and officers' compensation, including exculpation, indemnification and insurance are included in the definition of "terms of employment and of office", and as such must be approved in the following manner:

- Office holder (or "Officer") (neither a director nor the CEO) – generally, by the compensation committee, followed by the board of directors.
- CEO – generally, by the compensation committee, followed by the board of directors and the general meeting with a Special Majority.
- Director – generally, by the compensation committee, followed by the board of directors and the general meeting; if in accordance with the Compensation Policy –with a simple majority, if not in accordance with the Compensation Policy – with a Special Majority.
- Controlling shareholder - generally, by the compensation committee, followed by the board of directors and the general meeting, with a Special Majority.

Until such time that a company adopts a compensation policy, compensation of office holders must be approved in accordance with transition rules set forth in Amendment no. 20 which apply to the approval of officer compensation prior to the adoption and approval of a compensation policy by a company.

### **Directors Borrowing Powers**

Our board of directors may from time to time, in its discretion, cause the Company to borrow or secure the payment of any sum or sums of money for the purposes of the Company.

## **Rights Attached to Our Shares**

*Dividend Rights.* Our Articles provide that our board of directors may, subject to the applicable provisions of the Companies Law, from time to time, declare such dividend as may appear to the board of directors to be justified by the profits of the Company. Subject to the rights of the holders of shares with preferential or other special rights that may be authorized in the future, holders of ordinary shares are entitled to receive dividends according to their rights and interest in our profits. Dividends, to the extent declared, are distributed according to the proportion of the nominal (par) value paid up on account of the shares held at the date so appointed by the Company, without regard to the premium paid in excess of the nominal (par) value, if any. Under the Companies Law, a company may distribute a dividend only if the distribution does not create a reasonable concern that the company will be unable to meet its existing and anticipated obligations as they become due. A company may only distribute a dividend out of the company's profits, as defined under the Companies Law. If the company does not meet the profit requirement, a court may allow it to distribute a dividend, as long as the court is convinced that there is no reasonable concern that such distribution might prevent the company from being able to meet its existing and anticipated obligations as they become due.

*Voting Rights.* Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. These voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future. The ordinary shares do not have cumulative voting rights in the election of directors. As a result, holders of ordinary shares that represent more than 50% of the voting power at the general meeting of shareholders, in person or by proxy, have the power to elect all the directors whose positions are being filled at that meeting to the exclusion of the remaining shareholders. With respect to the election of external directors see Item 6. "Directors, Senior Management and Employees– C. Board Practices - External Directors."

*Liquidation Rights.* In the event of our liquidation, subject to applicable law, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to their respective holdings. This liquidation right may be affected by the grant of preferential dividends or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

*Redemption Provisions.* We may, subject to applicable law and to our Articles, issue redeemable preference shares and redeem the same.

*Capital Calls.* Under our Articles and the Companies Law, the liability of our shareholders is limited to the nominal (par) value of the shares held by them.

*Transfer of Shares.* Fully paid ordinary shares are issued in registered form and may be transferred pursuant to our Articles, unless such transfer is restricted or prohibited by another instrument and subject to applicable securities laws.

## **Modification of Rights**

Pursuant to our Articles, if at any time our share capital is divided into different classes of shares, the rights attached to any class, unless otherwise provided by our Articles, may be modified or abrogated by the Company, by a resolution of the shareholders, subject to the consent in writing of the holders of at least a majority of the issued shares of such class or the adoption of a resolution passed at a separate meeting of the holders of the shares of such class.

## **Shareholders' Meetings and Resolutions**

Pursuant to our Articles, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy, who hold shares conferring in the aggregate more than 25% of the voting power of the Company. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place or any time and place as the chairman of the meeting may designate. At such reconvened meeting, the required quorum consists of any two shareholders present in person or by proxy.

Under the Companies Law, each shareholder of record will be provided at least 21 calendar days' prior notice of any general shareholders meeting or 35 days prior notice to the extent required under regulations promulgated under the Companies Law.

Under the Companies Law and our Articles, all resolutions of our shareholders require a simple majority of the shares present, in person or by proxy or by written ballot, and voting on the matter, subject to certain exceptions provided for in our Articles namely: (a) the amendment of the provisions of our Articles relating to the election of directors, which require the approval of the greater of (i) holders of not less than seventy-five percent (75%) of the voting power represented at a meeting in person or by proxy and voting thereon, or (ii) holders of a majority of the outstanding voting power of all shares of the Company voting on such matter at a general meeting; (b) the removal of any director from office, the election of a director in place of a director so removed or the filling of any vacancy, however created, on the board of directors, which require the vote of the holders of at least 75% of the voting power represented at the meeting; and (c) the consummation of a merger (as defined in the Companies Law) which requires the approval of the holders of at least a majority of the voting power of the Company.



Under the Companies Law, each and every shareholder has a duty to act in good faith and in customary manner in exercising his or her rights and fulfilling his or her obligations towards the company in which he or she holds shares and other shareholders, and refrain from abusing his or her power in the company, including in voting in the general meeting of shareholders on the following matters:

- any amendment to the articles of association;
- an increase of our authorized share capital;
- a merger; or
- approval of interested party transactions that require shareholder approval.

In addition, each and every shareholder has the general duty to refrain from discriminating against other shareholders. In addition, any controlling shareholder, any shareholder who knows that it possesses the power to determine the outcome of a shareholder or class vote and any shareholder who, pursuant to the company's articles of association has the power to appoint or prevent the appointment of an office holder in the company is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty of fairness.

Our annual general meetings are held once in every calendar year at such time (within a period of not more than fifteen months after the last preceding annual general meeting) and at such place determined by our board of directors. All general meetings other than annual general meetings are called extraordinary general meetings.

Our board of directors may, in its discretion, convene additional meetings as "extraordinary general meetings." In addition, the board of directors must convene an extraordinary general meeting upon the demand of two of the directors, one fourth of the directors in office, one or more shareholders having at least 5% of the outstanding share capital and at least 1% of the voting power in the company, or one or more shareholders having at least 5% of the voting power in the company. The chairperson of the board of directors shall preside at each of our general meetings, or if at any meeting the chairperson is not present within fifteen (15) minutes after the time fixed for holding the meeting or is unwilling to act as chairperson, then if there is a co-chairperson, such co-chairperson shall preside at the meeting, or in the absence of both, the shareholders present shall choose someone of their number to be chairperson. The chairperson of the board of directors is not entitled to a vote at a general meeting in his capacity as chairperson.

### **Limitation on Owning Securities**

Our Articles and Israeli law do not restrict in any way the ownership or voting of ordinary shares by non-residents or persons who are not citizens of Israel, except with respect to subjects of nations which are in a state of war with Israel.

### **Mergers and Acquisitions and Tender Offers under Israeli Law**

The Companies Law includes provisions that allow a merger transaction and requires that each company that is a party to a merger have the transaction approved by its board of directors and by a simple majority of shares present, in person or by proxy, at a general meeting and voting on the transaction (including the separate vote of each class of shares of the party to the merger which is not the surviving entity) at a shareholders' meeting called on at least 35 days' prior notice. In addition, under our Articles, approval of a merger transaction requires that holders of at least a majority of the voting power of the Company vote in favor of the merger transaction. In determining whether the required majority under the Companies Law has approved the merger, if shares of a company are held by the other party to the merger, or by any person holding 25% or more of the voting rights or 25% or more of the means of appointing directors of the other party to the merger, then a vote against the merger by holders of the majority of the shares present and voting, excluding shares held by the other party to the merger or by such person, or by any person or entity acting on behalf of either of them, including their relatives or entities controlled by any of them, is sufficient to reject the merger transaction. If the transaction would have been approved but for the separate approval of each class or exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders. Notwithstanding the foregoing, a merger that is also an extraordinary transaction with a controlling shareholder or with another person in which a controlling shareholder has a personal interest, requires approval as an extraordinary transaction with a controlling shareholder. See "—Transactions Requiring Special Approval".

Under the Companies Law, each merging company must inform its creditors of the proposed merger plans. Upon the request of a creditor of either party of the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger and may further give instructions to secure the rights of creditors. In addition, a merger may not be completed unless at least 50 days have passed from the time that a proposal for the

approval of the merger has been filed with the Israel Registrar of Companies and 30 days have passed from the time that the approval of the merging parties' shareholders has been received.

The Companies Law also provides that, subject to certain exceptions, an acquisition of shares of a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company and there is no existing holder of 25% or more of the voting rights in the company. Similarly, the Companies Law provides that, subject to certain exceptions, an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company that holds more than 45% of the voting rights in the company.

Under the Companies Law, a person may not acquire shares in a public company if, following the acquisition, the acquirer will hold more than 90% of the company's shares or more than 90% of any class of shares, other than by means of a tender offer to acquire all of the shares or all of the shares of the particular class.

The Companies Law also provides that as long as a shareholder in a public company holds more than 90% of the company's shares or of a class of shares, that shareholder shall be precluded from purchasing any additional shares. In order that all of the shares that the acquirer offered to purchase be transferred to him by operation of law, one of the following needs to have occurred: (i) the shareholders who declined or do not respond to the tender offer hold less than 5% of the company's outstanding share capital or of the relevant class of shares and the majority of offerees who do not have a personal interest in accepting the tender offer accepted the offer, or (ii) the shareholders who declined or do not respond to the tender offer hold less than 2% of the company's outstanding share capital or of the relevant class of shares.

A shareholder that had its shares so transferred, whether he or she accepted the tender offer or not, has the right, within six months from the date of acceptance of the tender offer, to petition the court to determine that the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, the acquirer may provide in its offer that shareholders who accept the tender offer will not be entitled to such rights.

If the conditions set forth above are not met, the acquirer may not acquire additional shares of the company from shareholders who accepted the tender offer to the extent that following such acquisition the acquirer would own more than 90% of the company's issued and outstanding share capital.

The above restrictions apply, in addition to the acquisition of shares, to the acquisition of voting power. In addition, the provisions regarding tender offers shall also apply to the acquisition of any other securities of the company.

Notwithstanding the above, Israeli antitrust laws require that certain mergers be announced and receive approval of the Israeli Antitrust authority.

### ***C. MATERIAL CONTRACTS***

Please see "Item 4. Information on the Company — B. Business Overview — Our Intellectual Property Strategy and Position — In-Licensed Intellectual Property for a discussion of our material strategic alliances and research and license agreements.

### ***D. EXCHANGE CONTROLS***

There are currently no exchange controls in effect in Israel that restrict the repatriation by non-residents of Israel in non-Israeli currency of any dividends, if any are declared and paid, and liquidation distributions.

### ***E. TAXATION***

## **ISRAELI TAX CONSIDERATIONS AND GOVERNMENT PROGRAMS**

The following contains a description of material relevant provisions of the current Israeli income tax regime applicable to companies in Israel, with special reference to its effect on us. To the extent that the discussion is based on new tax legislation which has not been subject to judicial or administrative interpretation, we cannot assure you that the views expressed in the discussion will be accepted by the appropriate tax authorities or the courts.

This discussion does not address all of the tax consequences that may be relevant to purchasers of our ordinary shares in light of their particular circumstances or certain types of purchasers of our ordinary shares subject to special tax treatment. Examples of this kind of investor include residents of Israel and traders in securities who are subject to special tax regimes not covered in this discussion. Because individual circumstances may differ, you should consult your tax advisor to determine the applicability of the rules discussed below to you and the particular tax effects of the offer, including the application of Israeli or other tax laws. The discussion below is not intended, and should not be construed, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

## **Taxation of Companies**

### ***General Corporate Tax Structure***

In December 2010, the "Knesset" (Israeli Parliament) passed the Law for Economic Policy for 2011 and 2012 (Amended Legislation), 2011, which prescribes, among others, amendments to the Law. The amendment became effective as of January 6, 2011. According to the amendment, the benefit tracks in the Law were modified and a flat tax rate applies to the Company's entire preferred income. The Company will be able to opt to apply (the waiver is non-recourse) the amendment and from then on it will be subject to the amended tax rates that are: 2011 and 2012 - 15% (in development area A - 10%), 2013 and 2014 - 12.5% (in development area A - 7%) and in 2015 and thereafter - 12% (in development area A - 6%).

We examined the possible effect of the amendment on the financial statements, if at all, and at this time do not believe it will opt to apply the amendment.

On November 5, 2012, the "Knesset" (Israeli Parliament) passed amendment No. 69 to the Law which prescribed reduction of the corporate tax rate applied to undistributed retained earnings. Under the new structure, companies can elect to account for tax on undistributed earnings prior to distribution. Depending on their election, companies will pay a corporate income tax ranging from 6% to 17.5%, with no change to the dividend withholding tax rate. The change is temporary and will expire one year from the date of enactment.

### ***Tax Benefits for Research and Development***

Israeli tax law allows, under specified conditions, a tax deduction for R&D expenditures, including capital expenditures, for the year in which they are incurred. These expenses must relate to scientific research and development projects and must be approved by the relevant Israeli government ministry, determined by the field of research. Furthermore, the research and development must be for the promotion of the company and carried out by or on behalf of the company seeking such tax deduction. However, the amount of such deductible expenses is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. Expenditures not so approved are deductible over a three-year period. Such deductions are limited to an amount equal to 40% of the Company's taxed income, at the year of expenditures. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Income Tax Ordinance, 1961.

### ***Tax Benefits Under the Law for the Encouragement of Industry (Taxes), 1969***

Under the Law for the Encouragement of Industry (Taxes), 1969, industrial companies, as defined under the law, are entitled to the following tax benefits, among others:

- Deduction of purchases of know-how and patents over an eight-year period for tax purposes;
- Right to elect, under specified conditions, to file a consolidated tax return with additional related Israeli Industrial Companies;
- Accelerated depreciation rates on equipment and buildings; and
- Deductions over a three-year period of expenses involved with the issuance and listing of shares on a stock market.

Eligibility for benefits under the Law for the Encouragement of Industry is not subject to receipt of prior approval from any governmental authority. Under the law, an "industrial company" is defined as a company resident in Israel, at least 90.0% of the income of which, in any tax year, determined in Israeli currency, exclusive of income from government loans, capital gains, interest and dividends, is derived from an "industrial enterprise" owned by it. An "industrial enterprise" is defined as an enterprise whose major activity in a given tax year is industrial production activity.

We believe that we currently qualify as an industrial company within the definition under the Law for the Encouragement of Industry. No assurance can be given that we will continue to qualify as an industrial company or that the benefits described above will be available in the future.

### ***Special Provisions Relating to Taxation under Inflationary Conditions***

According to the Income Tax law (Inflationary Adjustments), 1985, until 2007 (inclusive), the results for tax purposes were measured based on the changes in the Israeli CPI.

Starting 2008, the results for tax purposes are measured in nominal values, excluding certain adjustments for changes in the Israeli CPI carried out in the period up to December 31, 2007. The amendment to the law includes, inter alia, the elimination of the inflationary additions and deductions and the additional deduction for depreciation starting 2008.

***Tax Benefits under the Law for the Encouragement of Capital Investments, 1959***

The Company benefits from certain government programs and tax legislation, particularly as a result of the ‘Approved Enterprise’ or ‘Benefiting Enterprise’ status of substantially all of the Company’s existing production facilities in Israel under the Law for the Encouragement of Capital Investment, 1959 (an “Approved Enterprise”, a “Benefiting Enterprise” and the “Investment Law” respectively) provides that a proposed capital investment in production facilities or other eligible facilities may be designated as an “Approved Enterprise.” To obtain “Approved Enterprise” status, an application to the Investment Center of the Ministry of Industry and Trade (the “Investment Center”) needs to be submitted. Each instrument of approval for an Approved Enterprise relates to a specific investment program that is defined both by the financial scope of the investment, including sources of funds, and by the physical characteristics of the facility or other assets.

The tax benefits available under any instrument of approval relate only to taxable profits attributable to the specific program and are contingent upon meeting the criteria set out in the instrument of approval. If a company has more than one approval or only a portion of its capital investments are approved, its effective tax rate is the weighted average of the applicable rates. Subject to certain qualifications, however, if a company with one or more approvals distributes dividends, the dividends are deemed attributable to the entire enterprise. As explained below, following the amendment of the Investment Law which became effective on April, 1, 2005, companies may receive tax benefits under the law without applying for an Approved Enterprise status.

The Investments Law also provides that an Approved Enterprise is entitled to accelerated depreciation on its property and equipment that are included in an Approved Enterprise program in the first five years of using the equipment.

#### ***Tax Benefits for Income from Approved Enterprises Approved Before April 1, 2005***

Before April 1, 2005 an Approved Enterprise was entitled to either receive investment grants and certain tax benefits from the Government of Israel or an alternative package of tax benefits (“Alternative Benefits”). We have elected to forego the entitlement to grants and have applied for the Alternative Benefits, under which undistributed income that we generate from our Approved Enterprises will be completely tax exempt (a “tax exemption”) for two years commencing from the year that we first produce taxable income and will be subject to a reduced tax rate of 10%-25% for an additional five to eight years, depending on the extent of foreign investment in the company.

Alternative Benefits are available until the earlier of (i) seven consecutive years, commencing in the year in which the specific Approved Enterprise first generates taxable income, (ii) 12 years from commencement of production and (iii) 14 years from the date of approval of the Approved Enterprise status.

Dividends paid out of income generated by an Approved Enterprise (or out of dividends received from a company whose income is generated by an Approved Enterprise) are generally subject to withholding tax at the rate of 15%. This tax is withheld at source by the Approved Enterprise. The 15% tax rate is limited to dividends and distributions out of income derived during the benefits period and actually paid at any time up to 12 years thereafter. Since we elected the Alternative Benefits track, we will be subject to pay corporate tax at the rate of 10% - 25% in respect of the gross amount of the dividend that we may distribute out of profits which were exempt from corporate tax in accordance with the provisions of the Alternative Benefits track. However, we are not obliged to attribute any part of dividends that we may distribute to exempt profits, and we may decide from which year’s profits to declare dividends. We currently intend to reinvest any income that we may in the future derive from our Approved Enterprise programs and not to distribute the income as a dividend.

If we qualify as a “Foreign Investors’ Company” or “FIC”, our Approved Enterprises will be entitled to additional tax benefits. Subject to certain conditions, a FIC is a company with a level of foreign investment of more than 25%. The level of foreign investment is measured as the percentage of rights in the company (in terms of shares, rights to profits, voting and appointment of directors), and of combined share and loan capital, that are owned, directly or indirectly, by persons who are not residents of Israel. Such a company will be eligible for an extension of the period during which it is entitled to tax benefits under its Approved Enterprise status (so that the benefit periods may be up to ten years) and for further tax benefits if the level of foreign investment exceeds 49%. The tax rate for the remainder of the benefits period will be 25%, unless the level of foreign investment exceeds 49%, in which case the tax rate will be 20% if the foreign investment is more than 49% and less than 74%; 15% if more than 74% and less than 90%; and 10% if 90% or more. The benefits available to an Approved Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations and the criteria in the specific certificate of approval, as described above. If a company does not meet these conditions, it would be required to refund the amount of tax benefits, together with consumer price index linkage adjustment and interest.

#### ***Tax Benefits under an Amendment that became effective on April 1, 2005***

On April 1, 2005, a significant amendment to the Investment Law became effective (the “2005 Amendment”). The Investment Law provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment came into effect will remain subject to the provisions of the Investment Law as they were on the date of such approval.

The 2005 Amendment changed certain provisions of the Law. As a result of the 2005 Amendment, a company is no longer obliged to acquire Approved Enterprise status in order to receive the tax benefits previously available under the Alternative Benefits provisions, and therefore generally there is no need to apply to the Investment Center for this purpose (Approved Enterprise status remained mandatory for companies seeking grants). Rather, the company may claim the tax benefits offered by the Investments Law directly in its tax returns, provided that its facilities meet the criteria for tax benefits set out by the 2005 Amendment. A company is also granted a right to approach the Israeli Tax Authority for a pre-ruling regarding their eligibility for benefits under the 2005 Amendment.

Tax benefits are available under the Amendment to production facilities (or other eligible facilities), which are generally required to derive more than 25% of their business income from export (referred to as a “Benefited Enterprise”). In order to receive the tax benefits, the 2005 Amendment states that the company must make an investment which meets all the conditions set out in the 2005 Amendment for tax benefits and exceeds a minimum amount specified in the Investment Law. Such investment allows the company to receive a “Benefiting Enterprise” status, and may be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Benefiting Enterprise (the “Year of Election”). Where the company requests to have the tax benefits apply to an expansion of existing facilities, only the expansion will be considered to be a Benefiting Enterprise and the company’s effective tax rate will be the weighted average of the applicable rates. In this case, the minimum investment required in order to qualify as a Benefiting Enterprise is required to exceed a certain amount or certain percentage of the value of the company’s production assets before the expansion.

The duration of tax benefits is subject to a limitation of the earlier of 7 (or 10 years) from the commencement year, or 12 years from the first day of the Year of Election. The tax benefits granted to a Benefiting Enterprise are determined, as applicable to its geographic location within Israel, according to one of the following new tax routes, which may be applicable to us:

- Similar to the previous Alternative Benefits package, exemption from corporate tax on undistributed income for a period of two to ten years, depending on the geographic location of the Benefiting Enterprise within Israel, and a reduced corporate tax rate of 10% to 25% for the remainder of the benefits period, depending on the level of foreign investment in each year. Benefits may be granted for a term of seven or ten years, depending on the level of foreign investment in the company. If the company pays a dividend out of income derived from the Benefiting Enterprise during the tax exemption period, such income will be subject to corporate tax at the applicable rate (10%-25%). The company is required to withhold tax at the source at a rate of 15% from any dividends distributed from income derived from the Benefiting Enterprise; and
- A special tax route, which enables companies owning facilities in certain geographical locations in Israel to pay corporate tax at the rate of 11.5% on income of the Benefiting Enterprise. The benefits period is ten years. Upon payment of dividends, the company is required to withhold tax at source at a rate of 15% for Israeli residents and at a rate of 4% for foreign residents.

Generally, a company which has a sufficiently high level of foreign investment (as defined in the Investments Law) is entitled to an extension of the benefits period by an additional five years, depending on the extent of its income that is derived from exports.

Dividends paid out of income derived by a Benefiting Enterprise will be treated similarly to payment of dividends by an Approved Enterprise under the Alternative Benefits track. Therefore, dividends paid out of income derived by a Benefiting Enterprise (or out of dividends received from a company whose income is derived from a Benefiting Enterprise) are generally subject to withholding tax at the reduced rate of 15% (deductible at source). The reduced rate of 15% is limited to dividends and distributions out of income derived from a Benefiting Enterprise during the benefits period and actually paid at any time up to 12 years thereafter. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income derived by its Benefiting Enterprise during the tax exemption period will be subject to tax in respect of the gross amount of the dividend at the otherwise applicable rate of 10%-25%.

The 2005 Amendment changed the definition of “foreign investment” in the Investment Law so that the definition now requires a minimal investment of NIS 5 million by foreign investors. Furthermore, such definition now also includes the purchase of shares of a company from another shareholder, provided that the company’s outstanding and paid-up share capital exceeds NIS 5 million. Such changes to the aforementioned definition are retroactive from 2003.

As a result of the 2005 Amendment, tax-exempt income generated under the new provisions will subject us to taxes upon distribution of the tax-exempt income to shareholders or upon liquidation of the company, and we may be required to record a deferred tax liability with respect to such tax-exempt income.

Additional amendments to the Investment Law became effective in January 2011 (the “2011 Tax Amendment”). Under the 2011 Tax Amendment, income derived by ‘Preferred Companies’ from ‘Preferred Enterprises’ (both as defined in the 2011 Tax Amendment) would be subject to a uniform rate of corporate tax as opposed to the current incentives that are limited to income from Approved or Benefiting Enterprises during their benefits period. According to the 2011 Tax Amendment, the uniform tax rate on such income, referred to as ‘Preferred Income’, would be 10% in areas in Israel that are designated as Development Zone A and 15% elsewhere in Israel during 2011-2012, 7% and 12.5%, respectively, in 2013-2014, and 6% and 12%, respectively, thereafter. Income derived by a Preferred Company from a ‘Special Preferred Enterprise’ (as defined in the Investment Law) would enjoy further reduced tax rates for a period of ten years of 5% in Zone A and 8% elsewhere. As with dividends distributed from taxable income derived from an Approved Enterprise or Benefiting Enterprise during the applicable benefits period, dividends distributed from Preferred Income would be subject to a 15% tax (or lower, if so provided under an applicable tax treaty), which would generally be withheld by the distributing company. While the Company may incur additional tax liability in the event of distribution of dividends from tax exempt income generated from its Approved and Benefiting Enterprises, no additional tax liability will be incurred by the Company in the event of

distribution of dividends from income taxed in accordance with the 2011 Tax Amendment.

Under the transitional provisions of the 2011 Tax Amendment, the Company may elect whether to irrevocably implement the 2011 Tax Amendment with respect to its existing Approved and Benefiting Enterprises while waiving benefits provided under the legislation prior to the 2011 Tax Amendment or keep implementing the legislation prior to the 2011 Tax Amendment during the next years.

We do not expect the 2011 Tax Amendment to have a material effect on the tax payable in respect of our Israeli operations.

As of December 31, 2011, we did not generate income under any of the above mentioned laws.

### **Israeli Transfer Pricing Regulations**

On November 29, 2006, Income Tax Regulations (Determination of Market Terms), 2006, promulgated under Section 85A of the Tax Ordinance, came into effect (the "TP Regs"). Section 85A of the Tax Ordinance and the TP Regs generally require that all cross-border transactions carried out between related parties be conducted on an arm's length basis and be taxed accordingly. The TP Regs are not expected to have a material effect on us.

### **Taxation of our Shareholders**

To the extent that the following discussion is based on new or existing tax or other legislation that has not been subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will be accepted by the tax or other authorities in question. The summary below does not address all of the tax consequences that may be relevant to all purchasers of ordinary shares in light of each purchaser's particular circumstances and specific tax treatment. For example, the summary below does not address the tax treatment of residents of Israel and traders in securities who are subject to specific tax regimes. As individual circumstances may differ, holders of ordinary shares should consult their own tax advisors as to United States, Israeli or other tax consequences of the purchase, ownership and disposition of ordinary shares. This discussion is not intended, nor should it be construed, as legal or professional tax advice and it is not exhaustive of all possible tax considerations. Each individual should consult his or her own tax or legal advisor.

#### **(a) Israeli Taxation**

##### **(i) Taxation of Capital Gains Applicable to Non-Israeli Shareholders**

Israeli law generally imposes a capital gains tax on the sale of securities and any other capital assets located in Israel. Pursuant to an amendment of the Tax Ordinance in 2005, effective as of January 1, 2006, the capital gains tax rate applicable to individuals upon the sale of securities acquired after that date is 20%. A 25% tax rate will apply to an individual who meets the definition of a 'Substantial Shareholder' on the date of the sale of the securities or at any time during the 12 months preceding such date. A 'Substantial Shareholder' is defined as a person who, either alone or together with any other person, holds, directly or indirectly, at least 10% of any of the means of control of a company (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director). Pursuant to an amendment of the Tax Ordinance in 2011, effective as of January 1, 2012, the capital gains tax rate applicable to individuals upon the sale of securities acquired after that date is 25% (instead of 20%), and a 30% tax rate will apply to an individual who meets the definition of a 'Substantial Shareholder' on the date of the sale of the securities or at any time during the 12 months preceding such date (instead of 25%). For sake of good order, securities acquired before January 1, 2012 and sold after that date, the profit received from such sale will be taxed as follows: from the purchase date until January 1, 2012 – 20% (or 25% - for Substantial Shareholder), and from January 1, 2012 until sales date – 25% (or 30% for Substantial Shareholder).

In addition, shareholders who bought their securities before January 1, 2003, will be taxed for the profit made from the purchase date until January 1, 2003 in accordance with their marginal rate of income.

With respect to corporate investors capital gain tax of 25% will be imposed on the sale of traded shares. This rate is subject to the provisions of any applicable bilateral double taxation treaty. The treaty concerning double taxation between the United States and Israel (the Convention between the Government of the State of Israel and the Government of the United States of America With Respect to Taxes on Income (the "Treaty")) is discussed below.

In addition, if the shares are traded on the Tel Aviv Stock Exchange, on an authorized stock exchange outside Israel or on a regulated market (which includes a system through which securities are traded pursuant to rules prescribed by the competent authority in the relevant jurisdiction) in or outside Israel, gains on the sale of shares held by non-Israeli tax resident investors will generally be exempt from Israeli capital gains tax. However, non-Israeli corporations will not be entitled to such exemption if Israeli residents (i) have controlling interest of 25% or more in such non-Israeli corporation, or (ii) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. Notwithstanding the foregoing, dealers in securities in Israel are taxed at regular tax rates applicable to business income. In addition,

persons paying consideration for shares, including purchasers of shares, Israeli securities dealers effecting a transaction, or a financial institution through which securities being sold are held, are required, subject to any applicable exemptions and the demonstration of the selling shareholder of its non-Israeli residency, to withhold tax upon the sale of publicly traded securities at the applicable corporate tax rate (25% in 2013) for a corporation and 25% for an individual.

Israeli law generally exempts non-resident individuals and entities from capital gains tax on the sale of securities of Israeli companies, provided that the securities were acquired on or after January 1, 2009.

#### (ii) Income Taxes on Dividend Distribution to Non-Israeli Shareholders

Non-Israeli residents (whether individuals or corporations) are generally subject to Israeli income tax on the receipt of dividends paid on the shares of companies that are not publicly traded at the rate of 25% (30% if the dividend recipient is a Substantial Shareholder, at the time of distribution or at any time during the preceding 12-month period), which tax is to be withheld at source, unless a different rate is provided under an applicable tax treaty. Dividends paid on the shares of companies that are publicly traded, like our ordinary shares, to non-Israeli residents, although generally subject to the same tax rates applicable to dividends paid on the shares of companies that are not publicly traded, are generally subject to Israeli withholding tax at a rate of 25% (whether or not the recipient is a Substantial Shareholder), unless a different rate is provided under an applicable tax treaty. The distribution of dividends to non-Israeli residents (either individuals or corporations) from income derived from an Approved Enterprise or a Benefiting Enterprise during the applicable benefits period or from Preferred Income is subject to withholding tax at a rate of 15%, unless a different tax rate is provided under an applicable tax treaty. In addition, non-Israeli residents who receive dividends may be entitled to tax refund from the Israeli Tax Authority, under certain conditions.

A non-resident of Israel who has dividend income derived from or accrued in Israel, from which the full amount of tax was withheld at source, is generally exempt from the duty to file tax returns in Israel in respect of such income, provided that: (i) such income was not derived from a business conducted in Israel by the taxpayer; and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Residents of the United States generally will have withholding tax in Israel deducted at source. Such residents may be entitled to a credit or deduction for U.S. federal income tax purposes in the amount of the taxes withheld, subject to detailed rules contained in U.S. tax legislation.

#### (iii) U.S. - Israel Tax Treaty

The Treaty is generally effective as of January 1, 1995. Under the Treaty, the maximum Israeli withholding tax on dividends paid to a holder of shares who is a Treaty U.S. Resident (as defined below) is generally 25%. However, pursuant to the Investment Law, dividends distributed by an Israeli company and derived from income eligible for benefits under the Investment Law will generally be subject to a reduced 15% dividend withholding tax rate, subject to the conditions specified in the Treaty. The Treaty further provides that a 12.5% Israeli dividend withholding tax will apply to dividends paid to a U.S. corporation owning 10% or more of an Israeli company's voting shares during, in general, the current and preceding tax year of the Israeli company. The lower 12.5% rate applies only on dividends distributed from income not derived from an Approved Enterprise or a Benefiting Enterprise in the applicable period or, presumably, from a Preferred Enterprise, and does not apply if the company has certain amounts of passive income.

Pursuant to the Treaty, the sale, exchange or disposition of shares in an Israeli company by a person who qualifies as a resident of the United States within the meaning of the Treaty and who is entitled to claim the benefits afforded to such residents under the Treaty (a "Treaty U.S. Resident") generally will not be subject to the Israeli capital gains tax unless such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of the voting power of the company during any part of the 12-month period preceding such sale, exchange or disposition subject to certain conditions. A sale, exchange or disposition of shares in an Israeli Company by a Treaty U.S. Resident who holds, directly or indirectly, shares representing 10% or more of the voting power of the company at any time during such preceding 12-month period would not be exempt under the Treaty from such Israeli tax; however, under the Treaty, such Treaty U.S. Resident would be permitted to claim a credit for such taxes against U.S. federal income tax imposed on any gain from such sale, exchange or disposition, under the circumstances and subject to the limitations specified in the Treaty. In addition, in the event that (1) the capital gains arising from the sale of shares of an Israeli company will be attributable to a permanent establishment of the shareholder located in Israel, or (2) the shareholder, being an individual, is present in Israel for a period or periods aggregating 183 days or more during a taxable year, the aforesaid exemption shall not apply.

### **CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS**

#### **General**

The following is a summary of certain material U.S. federal income tax consequences to U.S. persons holding our ordinary shares (referred to herein as U.S. holders) of purchasing, owning, and disposing of such shares. For this purpose, a U.S. person is, in each case as defined for U.S. federal income tax purposes: (a) an individual who is a citizen or resident of the United States; (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia; (c) an estate the income of which is subject to U.S. federal income tax regardless of its source; or (d) a trust that is subject to the primary supervision of a court over its administration and one or more U.S. persons control all substantial decisions, or a trust that has validly elected to be

treated as a domestic trust under applicable Treasury Regulations. This summary does not address any tax consequences to persons other than U.S. holders.

This discussion is a general summary and does not address all aspects of U.S. federal income taxation that may be relevant to particular U.S. holders based on their particular investment or tax circumstances. It does not address any tax consequences to certain types of U.S. holders that are subject to special treatment under U.S. federal income tax laws, such as insurance companies, tax-exempt organizations, financial institutions, broker-dealers, dealers in securities or currencies, traders in securities that elect to use the mark-to-market method of accounting for their securities, partnerships or other pass-through entities for U.S. federal tax purposes, regulated investment companies, real estate investment trusts, expatriates, persons liable for alternative minimum tax, persons owning, directly or by attribution, 10% or more, by voting power or value, of our ordinary shares, persons whose “functional currency” is not the U.S. dollar, persons holding ordinary shares as part of a hedging, constructive sale or conversion, straddle, or other risk-reducing transaction, or persons acquiring an interest in our shares in exchange for services.

This summary addresses only ordinary shares that (a) are held as capital assets, and (b) were acquired upon original issuance at their initial offering price.

This summary relates only to U.S. federal income taxes. With the exception of the discussion below under “—Tax on Net Investment Income,” this summary does not address any other tax, including but not limited to, state, local, or foreign taxes, or any other U.S. federal taxes other than income taxes.

The statements in this summary are based on the current U.S. federal income tax laws as contained in the Internal Revenue Code, Treasury Regulations, and relevant judicial decisions and administrative guidance. U.S. federal tax laws are subject to change, and any such change may materially affect the U.S. federal income tax consequences of purchasing, owning, or disposing of our ordinary shares. We cannot assure you that new laws, interpretations of law or court decisions, any of which may take effect retroactively, will not cause any statement in this summary to be inaccurate. No ruling or opinions of counsel will be sought in connection with the matters discussed herein. There can be no assurance that the positions we take on our tax returns will be accepted by the Internal Revenue Service.

This summary is not a substitute for careful tax planning. Prospective investors are urged to consult their own tax advisors regarding the specific U.S. federal, state, foreign and other tax consequences to them, in light of their own particular circumstances, of the purchase, ownership and disposition of our ordinary shares and the effect of potential changes in applicable tax laws.

## **Dividends**

A U.S. holder will be required to take into account as dividends any distributions with respect to our ordinary shares made out of our current or accumulated earnings and profits. The dividends received deduction will not be available to a U.S. holder that is taxed as a corporation. With certain exceptions (including but not limited to dividends treated as investment income for purposes of investment interest deduction limitations or dividends taxed as “excess distributions” as described under “Passive Foreign Investment Company” below), qualified dividends received by a non-corporate U.S. holder during a year that is not a year in which we are a passive foreign investment company (a “PFIC Year”) or preceded by a PFIC Year generally will be subject to tax at the maximum tax rate accorded to capital gains, if certain holding period and other conditions are satisfied. Dividends will generally be from a non-U.S. source and treated as “passive income” for U.S. foreign tax credit purposes.

Although, to the extent we pay dividends in the future, we intend to pay dividends to U.S. holders in U.S. dollars, the amount of any dividend paid in Israeli currency will equal its U.S. dollar value for U.S. federal income tax purposes, calculated by reference to the exchange rate in effect on the date the dividend is received by the U.S. holder, regardless of whether the Israeli currency is converted into U.S. dollars. If the Israeli currency is not converted into U.S. dollars on the date of receipt, the U.S. holder will have a basis in the Israeli currency equal to its U.S. dollar value on the date of receipt. Any subsequent gain or loss upon the conversion or other disposition of the Israeli currency will be treated as ordinary income or loss, and generally will be income or loss from U.S. sources.

A U.S. holder will not incur tax on a distribution with respect to our ordinary shares in excess of our current and accumulated earnings and profits if the distribution does not exceed the adjusted basis of the U.S. holder’s ordinary shares. Instead, the distribution will reduce the adjusted basis of the shares. Any such distribution in excess of both our current and accumulated earnings and profits and the U.S. holder’s adjusted basis will be treated as capital gain, long-term if the U.S. holder has held the shares for more than one year, and generally will be gain or loss from U.S. sources. See “—Disposition of Ordinary Shares” below for a discussion of capital gains tax rates and limitations on deductions for losses.

## **Disposition of Ordinary Shares**

In general, a U.S. holder must treat any gain or loss recognized upon a taxable disposition of our ordinary shares as capital gain or loss, long-term if the U.S. holder has held the shares for more than one year. In general, a U.S. holder will recognize gain or loss in an amount equal to the difference between the sum of the fair market value of any property and the amount of cash received in such disposition and the U.S. holder’s adjusted tax basis in such shares. A U.S. holder’s adjusted tax basis generally will equal the U.S. holder’s acquisition cost less any return of capital. Subject to certain exceptions (including but not limited to those described under “Passive Foreign Investment Company” below), long-term capital gain

realized by a non-corporate U.S. holder generally will be subject to a reduced maximum rate of 20%. The deduction of capital losses is subject to limitations, as are losses upon a taxable disposition of our ordinary shares if the U.S. holder purchases, or enters into a contract or option to purchase, substantially identical stock or securities within 30 days before or after any disposition. Gain or loss from the disposition of our ordinary shares will generally be from U.S. sources, but such gain or loss may be from a non-U.S. source under some circumstances under the U.S.-Israel Tax Treaty. U.S. holders should consult their own independent tax advisors regarding the sourcing of any gain or loss on the disposition of our ordinary shares, as well as regarding any foreign currency gain or loss in connection with such a disposition.

## **Credit for Foreign Taxes Paid or Withheld**

Payments to U.S. holders as dividends or consideration for ordinary shares may in some circumstances be subject to Israeli withholding taxes. See “—Israeli Tax Considerations and Government Programs” above. Generally, such withholding taxes in lieu of Israeli income taxes imposed on such transactions are creditable against the U.S. holder’s U.S. tax liability, subject to numerous U.S. foreign tax credit limitations, including additional limitations in the case of qualified dividends eligible for the maximum rate accorded to capital gains. A corporate U.S. holder may also be eligible for an “indirect” foreign tax credit on dividends to take account of certain Israeli taxes we previously paid to Israel. A U.S. holder should consult its own independent tax advisor regarding use of the U.S. foreign tax credit and its limitations. A U.S. holder (except an individual who does not itemize deductions) may elect to take a deduction rather than a credit for foreign taxes paid.

## **Controlled Foreign Corporation**

For U.S. federal income tax purposes, a “controlled foreign corporation” is a foreign corporation in which U.S. holders who own at least 10% of the voting power (directly or by constructive ownership through certain related persons) collectively own more than 50% of the voting power or value. If we are or become a controlled foreign corporation, such 10% U.S. holders must include in their current U.S. taxable income their share of the corporation’s undistributed “Subpart F income” (i.e., certain passive income, sales or service income, insurance, ocean activity, or oil-related income, and income from specified disfavored activities or from ostracized foreign countries) and the amount of the corporation’s investments in U.S. property. These income inclusions are not eligible for the maximum capital gains tax rate on qualified dividends to non-corporate tax payers. We believe that the corporation is not and has not been, and we expect that the corporation will not become, a controlled foreign corporation. There can be no assurance, however, that the corporation will not become a controlled foreign corporation in the future.

## **Passive Foreign Investment Company**

We believe that we were a “passive foreign investment company,” or PFIC, for the years ended December 31, 2003, 2006, 2007, 2010, and 2011. In addition, we may be a PFIC for the year ended December 31, 2012, (collectively, the “PFIC Years”). We nevertheless recognize that there are significant areas of uncertainty in the PFIC rules and the IRS may not agree with our belief. We are a PFIC if 75% or more of our gross income in a taxable year, including the pro rata share of the gross income of any company in which we are considered to own 25% or more of the shares by value, is passive income. Alternatively, we are a PFIC if at least 50% of our assets in a taxable year, averaged over the year and ordinarily determined based on fair market value, including the pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value, are held for the production of, or produce, passive income.

PFIC status is determined annually and cannot be definitively determined until the close of the year in question. If we qualify as a PFIC at any time during a U.S. holder’s holding period of our ordinary shares, any subsequent distributions to, or disposition of the shares by, the U.S. holder will be subject to the excess distribution rules (described below), regardless of whether we are a PFIC in the year of distribution or disposition, unless the U.S. holder: (1) made the qualified electing fund (“QEF”) election (described below); (2) made the mark-to-market election (described below); or (3) during a year in which the corporation is no longer a PFIC, elected to recognize all gain inherent in the shares on the last day of the last taxable year in which the corporation was a PFIC. If a U.S. holder holds our ordinary shares in a PFIC Year, such ordinary shares will henceforth be considered shares in a PFIC, regardless of whether we meet the PFIC tests in future years, unless the U.S. holder makes a timely QEF or mark-to-market election, or makes the deemed-gain election in a year in which the corporation is no longer a PFIC.

If we are a PFIC, each U.S. holder, upon certain “excess distributions” by us and upon disposition of our ordinary shares at a gain, would be liable to pay tax at the highest then-prevailing income tax rate on ordinary income plus interest on the tax, as if the distribution or gain had been recognized ratably over the holder’s holding period for the ordinary shares. Additionally, if we are a PFIC, a U.S. holder who acquires ordinary shares from a deceased person who was a U.S. holder would not receive a step-up of the income tax basis to fair market value for such ordinary shares. Instead, such U.S. holder would have a tax basis equal to the deceased’s tax basis, if lower.

If a U.S. holder has made a QEF election covering all taxable years during which the U.S. holder holds ordinary shares and in which we are a PFIC, distributions and gains will not be taxed as described above, nor will denial of a basis step-up at death described above apply. Instead, a U.S. holder that makes a QEF election is required for each taxable year to include in income the U.S. holder’s pro rata share of the ordinary earnings of the QEF as ordinary income and a pro rata share of the net capital gain of the QEF as capital gain, regardless of whether such earnings or gain have in fact been distributed. Undistributed income is subject to a separate election to defer payment of taxes. If deferred, the taxes will be subject to an interest charge. Where earnings and profits that were included in income under this rule are later distributed, the distribution is not a dividend. The basis of a U.S. shareholder’s shares in a QEF is increased by amounts that are included in income, and decreased by amounts distributed but not taxed as dividends. In addition, if a U.S. holder makes a timely QEF election, our ordinary shares will not be considered shares in a PFIC in years in which we are not a PFIC, even if the U.S. holder had held ordinary shares in prior years in which we were a PFIC.



In order to comply with the requirements of a QEF election, a U.S. holder must receive certain information from us. The QEF election is made on a shareholder-by-shareholder basis and can be revoked only with the consent of the IRS. A shareholder makes a QEF election by attaching a completed IRS Form 8621, including the information provided in the PFIC annual information statement, to a timely filed U.S. federal income tax return and by filing a copy of the form with the IRS. There is no assurance that we will provide such information as the IRS may require in order to enable U.S. holders to make the QEF election. Moreover, there is no assurance that we will have timely knowledge of our status as a PFIC in the future. Even if a shareholder in a PFIC does not make a QEF election, if such shareholder is a U.S. holder, such shareholder must annually file with the shareholder's tax return and with the IRS a completed Form 8621.

If our ordinary shares are "regularly traded" on a "qualified exchange or other market," as provided in applicable Treasury Regulations, a U.S. holder of our ordinary shares may elect to mark such shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference between the U.S. holder's adjusted tax basis in such shares and their fair market value. Losses would be allowed only to the extent of net mark-to-market gain previously included by the U.S. holder under the election in previous taxable years. The adjusted tax basis of a U.S. holder's ordinary shares is increased by the amount included in gross income under the mark-to-market regime, or is decreased by the amount of the deduction allowed under the regime. As with the QEF election, a U.S. holder who makes a mark-to-market election would not be subject to the general excess distribution rules and the denial of basis step-up at death described above.

If we are a PFIC and, at any time, have a non-U.S. subsidiary that is classified as a PFIC, U.S. holders of our ordinary shares generally would be deemed to own, and also would be subject to the PFIC rules with respect to, their indirect ownership interests in that lower-tier PFIC. If we are a PFIC and a U.S. holder of our ordinary shares does not make a QEF election in respect of a lower-tier PFIC, the U.S. holder could incur liability for the deferred tax and interest charge described above if either (1) we receive a distribution from, or dispose of all or part of our interest in, the lower-tier PFIC or (2) the U.S. holder disposes of all or part of its ordinary shares. There is no assurance that any lower-tier PFIC will provide to a U.S. holder the information that may be required to make a QEF election with respect to the lower-tier PFIC. A mark-to-market election under the PFIC rules with respect to our ordinary shares would not apply to a lower-tier PFIC, and a U.S. holder would not be able to make such a mark-to-market election in respect of its indirect ownership interest in that lower-tier PFIC. Consequently, U.S. holders of our ordinary shares could be subject to the PFIC rules with respect to income of the lower-tier PFIC the value of which already had been taken into account indirectly via mark-to-market adjustments. Similarly, if a U.S. holder made a mark-to-market election under the PFIC rules in respect of our ordinary shares and made a QEF election in respect of a lower-tier PFIC, that U.S. holder could be subject to current taxation in respect of income from the lower-tier PFIC the value of which already had been taken into account indirectly via mark-to-market adjustments. U.S. holders are urged to consult their own tax advisors regarding the issues raised by lower-tier PFICs.

**THE RULES DEALING WITH PFICs AND WITH THE QEF AND MARK-TO-MARKET ELECTIONS ARE VERY COMPLEX AND ARE AFFECTED BY VARIOUS FACTORS IN ADDITION TO THOSE DESCRIBED ABOVE, INCLUDING OUR OWNERSHIP OF ANY NON-U.S. SUBSIDIARY. AS A RESULT, U.S. HOLDERS OF OUR ORDINARY SHARES ARE STRONGLY ENCOURAGED TO CONSULT THEIR TAX ADVISORS ABOUT THE PFIC RULES IN CONNECTION WITH THEIR PURCHASING, HOLDING OR DISPOSING OF ORDINARY SHARES.**

### **Backup Withholding and Information Reporting**

A U.S. holder (excepting most corporations) may, under certain circumstances, be subject to information reporting requirements and backup withholding at a rate of 28% on payments of dividends, interest, and other reportable payments. A non-corporate U.S. holder should consult its own independent tax advisor regarding the possibility of information reporting and backup withholding on payments in connection with the purchase, ownership, or disposition of our ordinary shares.

### **Foreign Account Tax Compliance Act**

The recently enacted Foreign Account Tax Compliance Act ("FATCA") will impose a 30% withholding tax on any "withholdable payment" to (i) a "foreign financial institution," unless such institution enters into an agreement with the U.S. government to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which would include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with United States owners) or (ii) a foreign entity that is not a financial institution, unless such entity provides the withholding agent with a certification identifying the substantial U.S. owners of the entity, which generally includes any U.S. person who directly or indirectly owns more than 10% of the entity. For this purpose, we expect to be treated as a foreign entity that is not a financial institution.

"Withholdable payments" to us subject to FATCA will include U.S.-source payments otherwise subject to nonresident withholding tax, and also include the entire gross proceeds from the sale of any equity or debt instruments of U.S. issuers (in either case to exclude payments made on "obligations" that were outstanding on March 18, 2012). The withholding tax will apply regardless of whether the payment would otherwise be exempt from U.S. nonresident withholding tax (e.g., under the portfolio interest exemption or as capital gain). The IRS is authorized to provide

rules for implementing the FATCA withholding regime with the existing nonresident withholding tax rules.

Under the applicable Treasury Regulations, this withholding will apply to U.S.-source payments otherwise subject to nonresident withholding tax made on or after January 1, 2014 and to the payment of gross proceeds from the sale of any equity or debt instruments of U.S. issuers made on or after January 1, 2015.

We intend to, but provide no assurance that we will, provide information to the U.S. government sufficient to avoid FATCA withholding taxes on payments to us. U.S. holders are urged to consult with their tax advisors regarding the effect, if any, of FATCA to them based on their particular circumstances.

#### **Tax on Net Investment Income**

For tax years beginning after December 31, 2012, certain U.S. Holders that are individuals, estates or trusts whose income exceeds certain thresholds will be required to pay an additional 3.8% tax on “net investment income”, which includes, among other things, dividends and net gain from the sale or other disposition of property (other than property held in a trade or business), which may include our ordinary shares. U.S. Holders should consult their own tax advisors regarding the application of the tax on net investment income to their particular circumstances.

#### ***F. DIVIDENDS AND PAYING AGENTS***

Not applicable.

#### ***G. STATEMENT BY EXPERTS***

Not applicable.

#### ***H. DOCUMENTS ON DISPLAY***

We file annual and special reports and other information with the SEC. You may inspect and copy such material at the public reference facilities maintained by the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of such material from the SEC at prescribed rates by writing to the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings also are available to the public from the SEC’s website at [www.sec.gov](http://www.sec.gov). In addition, our annual and special reports and other information filed with the SEC is available free of charge through the Investors section of our website at [www.rosettagenomics.com](http://www.rosettagenomics.com) as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC.

#### ***I. SUBSIDIARY INFORMATION***

Not applicable.

### **ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Interest Rate Risk**

We are exposed to market risk related to changes in interest rates primarily from our investments in certain short-term investments. We maintain an investment portfolio consisting mainly of Israeli mutual fund and Israeli government bonds, directly or through managed funds. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk-sensitive instruments to manage exposure to interest rate changes. Accordingly, we believe that, while the securities we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

#### **Exchange Rate Risk**

We hold most of our cash, cash equivalents and short term bank deposits in U.S. dollars but incur a significant portion of our expenses, principally salaries and related personal expenses, in NIS. As a result, we are exposed to the risk that the U.S. dollar will be devalued against the NIS.

The following table illustrates the effect of the changes in exchange rates on our operation loss for the periods indicated:

	Year ended December 31,					
	2012		2011		2010	
	Actual	At 2009 Exchange rates (1)	Actual	At 2010 Exchange rates (1)	Actual	At 2011 Exchange rates (1)
	(In thousands)					
Operating loss	\$ 8,267	\$ 8,563	\$ 8,777	\$ 8,574	\$ 13,915	\$ 12,884

(1) Based on average exchange rates during the period.

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

Not applicable.

**PART II**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

Not applicable.

**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

**Material Modifications to the Rights of Security Holders**

Upon completion of our initial public offering in March 2007, all of our outstanding preferred shares and ordinary A shares were converted into ordinary shares. On October 21, 2010, our shareholders approved amendments to our articles of association to (i) increase our authorized share capital by NIS 300,000 and (ii) remove the requirement that notice of general meetings of our shareholders be published in two daily newspapers in Israel.

On July 6, 2011, our shareholders approved an increase to our authorized share capital by NIS 216 to NIS 576,000, divided into 57,600,000 ordinary shares with a nominal (par) value of NIS 0.01 each (prior to giving effect to the 1-for-4 reverse stock split effected on July 6, 2011), and the 1-for-4 reverse stock split effected by the consolidation of our authorized share capital into 14,400,000 ordinary shares with a nominal (par) value of NIS 0.04 each, by consolidating every four (4) ordinary shares with a nominal (par) value NIS 0.01 each into one (1) ordinary share with a nominal (par) value of NIS 0.04 each. Following these actions our registered (authorized) share capital was NIS 576,000 divided into 14,400,000 ordinary shares with a nominal (par) value of NIS 0.04 each. On July 6, 2011, our shareholders subsequently approved an increase to our registered (authorized) share capital by NIS 624,000, divided into 15,600,000 ordinary shares, nominal (par) value NIS 0.04 each, so that following such increase, the registered (authorized) share capital was NIS 1,200,000 divided into 30,000,000, ordinary shares nominal (par) value NIS 0.04 each.

On May 14, 2012, our shareholders approved a 1-for 15 reverse split of our ordinary shares effected by the consolidation of our authorized share capital into 2,000,000 ordinary shares with a nominal (par) value of NIS 0.6 each, by consolidating every fifteen (15) ordinary shares with a nominal (par) value NIS 0.04 each into one (1) ordinary share with a nominal (par) value of NIS 0.6 each. Following these actions, our registered (authorized) share capital was NIS 1,200,000 divided into 2,000,000 ordinary shares with a nominal (par) value of NIS 0.6 each. On May 14, 2012, our shareholders subsequently approved an increase to our registered (authorized) share capital by NIS 10,800,000, divided into 18,000,000 ordinary shares, nominal (par) value NIS 0.6 each, so that following such increase, the registered (authorized) share capital was NIS 12,000,000 divided into 20,000,000, ordinary shares nominal (par) value NIS 0.6 each.

The material provisions of our articles of association, as amended, are described under “Item 10. Additional Information — B. Memorandum and Articles of Association.”

**Use of Proceeds**

Not applicable.

**ITEM 15. CONTROLS AND PROCEDURES**

**A. DISCLOSURE CONTROLS AND PROCEDURES**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 20-F, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

## **B. MANAGEMENT'S ANNUAL 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 Securities Exchange Act of 1934, as amended. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012, including the remediation of the material weakness disclosed in our Annual Report on Form 20-F for the year ended December 31, 2011. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment we believe that, as of December 31, 2012, our internal control over financial reporting is effective.

## **C. ATTESTATION REPORT OF THE REGISTERED PUBLIC ACCOUNTING FIRM**

This Annual Report on Form 20-F does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Because we are neither an accelerated filer nor a large accelerated filer, management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the SEC.

## **D. CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2011, our management identified the following material weakness in our internal control over financial reporting as of December 31, 2011:

- *Lack of management and Audit Committee oversight and evaluation of internal controls over financial reporting.* Preparations for the implementation of the internal control and evaluation of the internal controls over financial reporting effectiveness, required under Section 404 of the Sarbanes-Oxley Act of 2002 for the year 2011, were begun later than appropriate. Therefore, we were not able to perform sufficient testing to conclude as to the operating effectiveness of those controls over financial reporting for the year ended December 31, 2011. Furthermore, inadequate resources were allocated for this matter during the year, and the examinations of the effectiveness of controls were made only after the end of the reported year.

Management implemented remedial measures to address these matters, including taking actions to further review the design and effectiveness of our internal controls over financial reporting and to perform sufficient testing to determine the operating effectiveness of those controls over financial reporting for the year ended December 31, 2012. Management has determined that, as of December 31, 2012, we have remediated this material weaknesses in internal control over financial reporting.

Except as set forth above with respect to remediating the previously reported material weakness, there were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the last fiscal year, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 16. RESERVED**

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our audit committee consists of Gerald Dogon (Chairman), Dr. David Sidransky and Tali Yaron-Eldar, all of whom are independent under the rules and regulations of NASDAQ. Our board of directors has determined that Mr. Dogon qualifies as an "audit committee financial expert" as defined in the instructions to Item 16A of Form 20-F.

**ITEM 16B. CODE OF ETHICS**

We have adopted a code of conduct and ethics that applies to all of our employees, officers and directors. The text of the code of conduct and ethics is posted on the "Corporate Governance" section of our website at [www.rosettagenomics.com](http://www.rosettagenomics.com). Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial and accounting officers will be included in a Form 6-K within four business days following the date of the amendment or waiver, unless website posting of such amendments or waivers is then permitted by the rules of The NASDAQ Stock Market.

**ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES****Accounting Fees and Services**

The following table presents fees for professional audit services rendered by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accountants, for the audit of our consolidated financial statements and services normally provided by the independent auditor in connection with statutory and regulatory filings or engagements for the years ended December 31, 2012 and December 31, 2011 and fees billed for other services rendered by Kost Forer Gabbay & Kasierer during those periods.

	2012	2011
Audit fees (1)	\$ 107,000	\$ 88,706
Audit-related fees	75,000	28,000
Tax fees (2)	13,600	15,257
All other fees (3)	-	-
Total	<u>\$ 195,600</u>	<u>\$ 131,963</u>

- (1) Audit services were comprised of services associated with the audit of our consolidated financial statements and services normally provided by the independent auditor in connection with statutory and regulatory filings or engagements and registration statements.
- (2) Tax services were comprised of tax compliance, tax advice and tax planning services.
- (3) All other services were comprised of business related consultation.

**Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Auditors**

Our audit committee was established effective upon the completion of our initial public offering in March 2007. Consistent with policies of the Securities and Exchange Commission regarding auditor independence, the audit committee has responsibility for appointing, setting compensation and overseeing the work of the independent auditor. The audit committee operates under a written charter which provides that the committee must approve in advance all audit services and all permitted non-audit services, except where such services are determined to be de minimis under the Exchange Act. The audit committee may delegate, to one or more designated members of the audit committee, the authority to grant such pre-approvals. The decision of any member to whom such authority is delegated is to be presented to the full audit committee at each of its scheduled meetings.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

Not applicable.

**ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

There are no significant differences between our corporate governance practices and those required of a U.S. domestic issuer under the rules of The NASDAQ Stock Market. However, pursuant to the rules and regulations of The NASDAQ Stock Market, a foreign private issuer may follow its home country practice in lieu of certain NASDAQ listing requirements. We have in the past elected to follow home country practice in lieu of

certain NASDAQ requirements as follows:

- NASDAQ rules require that the quorum for meetings of a company's shareholders be not less than 33 1/3% of the outstanding voting stock of the company. We have, however, chosen to follow home country practice with respect to shareholder meeting quorum and our Articles provide that the quorum required for any meeting of our shareholders shall consist of at least two shareholders present, in person or by proxy, who hold or represent between them more than 25% of the voting power of our issued share capital.
- Under NASDAQ's rules, (1) the private placement completed in December 2010, (2) the concurrent private placement and registered direct offering completed in February 2011, (3) the private placement completed in October 2011, (4) the convertible debt transaction completed in January 2012, and (5) the registered direct offerings completed in April 2012 and May 2012, would have required shareholder approval because these offerings represented the issuance (or potential issuance) of more than 20% of our outstanding ordinary shares at a price per share below the greater of book value per share or market value per share. However, we chose to follow our home country practice, which did not require shareholder approval of these offerings.

Because of these SEC and NASDAQ exemptions, investors are not afforded the same protections or information generally available to investors holding shares in public companies organized in the United States. See also "Item 3. Key Information — D. Risk Factors — Risks Related to Israeli Law and Our Operations in Israel — Being a foreign private issuer exempts us from certain SEC and NASDAQ requirements."

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**PART III**

**ITEM 17. FINANCIAL STATEMENTS**

See Item 18.

**ITEM 18. FINANCIAL STATEMENTS**

Our consolidated financial statements and related notes are included in this Annual Report beginning on page F-1.

## ITEM 19. EXHIBITS

The following is a list of exhibits filed as part of this Annual Report.

### Exhibit Number Description of Exhibit

1.1(12)	Amended and Restated Articles of Association.
2.1(1)	Form of Share Certificate for Ordinary Shares.
2.2(1)	Investor Rights Agreement dated April 4, 2006.
2.3(6)	Form of Ordinary Share Purchase Warrant issued by Rosetta Genomics Ltd. to the investors and the placement agent in the January 2010 registered direct offering.
2.4(7)	Form of Series A Warrant issued by Rosetta Genomics Ltd. to the investors and the placement agent in the December 2010 private placement.
2.5(7)	Form of Series B Warrant issued by Rosetta Genomics Ltd. to the investors in the December 2010 private placement.
2.6(7)	Registration Rights Agreement, dated November 29, 2010, by and between Rosetta Genomics Ltd. and the investors in the December 2010 private placement.
2.7(8)	Form of Ordinary Share Purchase Warrant issued by Rosetta Genomics Ltd. to the investors and the placement agent in the February 2011 private placement.
2.8(8)	Form of Ordinary Share Purchase Warrant issued by Rosetta Genomics Ltd. to the investors in the February 2011 registered direct offering.
2.09(8)	Form of Ordinary Share Purchase Warrant issued by Rosetta Genomics Ltd. to the placement agent in the February 2011 registered direct offering.
2.10(8)	Registration Rights Agreement, dated February 16, 2011, by and between Rosetta Genomics Ltd. and the investors in the February 2011 private placement.
2.11(9)	Form of Series A Warrant issued by Rosetta Genomics Ltd. to the investors and the placement agent in the October 2011 private placement.
2.12(9)	Registration Rights Agreement, dated October 13, 2011, by and between Rosetta Genomics Ltd. and the investors in the October 2011 private placement.
2.13(18)	Form of warrant issued to the placement agent in the January 2012 debt financing.
2.14(14)	Form of Purchase Option Agreement issued to Aegis Capital Corp as placement agent in the April 2012 Registered Direct Offering.
2.15(15)	Form of Purchase Option Agreement issued to Aegis Capital Corp as placement agent in the May 2012 Registered Direct Offering.
2.15(11)	Form of Purchase Option Agreement issued to Aegis Capital Corp as placement agent in the second May 2012 Registered Direct Offering.
2.16(18)	Form of warrant issued to consultants.
2.17(18)	Form of Purchase Option Agreement issued to the underwriter in the August 2012 underwritten public offering.
4.1(1)@	License Agreement, dated as of May 4, 2006, by and between Rosetta Genomics Ltd. and The Rockefeller University.
4.2(2)@	License Agreement, dated effective as of May 1, 2007, by and between Rosetta Genomics Ltd. and The Rockefeller University.
4.3(1)	Lease Agreement, dated August 4, 2003, by and between Rosetta Genomics Ltd., as tenant, and Rorberg Contracting and Investments (1963) Ltd. and Tazor Development Ltd., as landlords, as amended in April 2004 and as extended on April 9, 2006 (as translated from Hebrew).
4.4(3)	Lease, dated December 2, 2007, between 15 Exchange Place Corp. and Rosetta Genomics Inc.
4.5(4)	Lease Agreement from Wexford-UCSC II, L.P. to Rosetta Genomics Inc., dated July 7, 2008, and First Amendment thereto, dated August 11, 2008.
4.6(1)	2003 Israeli Share Option Plan.
4.7*	2006 Employee Incentive Plan (Global Share Incentive Plan).
4.8(1)	Form of Director and Officer Indemnification Agreement.
4.9(5)@	Amended and Restated License Agreement, dated as of March 3, 2009, by and between Rosetta Genomics Ltd. and Max Planck Innovation GmbH.
4.10(16)@	Amended and Restated License Agreement, dated August 14, 2011, by and between The Johns Hopkins University and Rosetta Genomics Ltd.
4.11(1)@	License Agreement, dated as of December 22, 2006, by and between Rosetta Genomics Ltd. and Max Planck Innovation GmbH.
4.12(1)@	Cooperation and Project Funding Agreement, dated effective as of May 1, 2006, by and among Rosetta Genomics Ltd., the Israel-United States Binational Industrial Research and Development Foundation and Isis Pharmaceuticals, Inc.
4.13(3)@	License Agreement, dated effective as of January 8, 2008, by and between Rosetta Genomics Ltd. and The Rockefeller University.
4.14(4)@	Exclusive Testing and Administrative Services Agreement between Rosetta Genomics Ltd. And Teva Pharmaceutical Industries Ltd.

4.14.1(16)	Letter Agreement, dated January 17, 2011, amending the Exclusive Testing and Administrative Services Agreement between Rosetta Genomics Ltd. And Teva Pharmaceutical Industries Ltd.
4.15(13)	Share Transfer Agreement, dated December 13, 2011, by and between Rosetta Genomics Ltd and the purchasers listed on Exhibit A thereto.
4.16(17)	Agreement and Release, dated June 21, 2012, by and between Rosetta Genomics Ltd. and the investor in the January 2012 debt financing.
4.17@*	Revised Co-Marketing Agreement, dated October 11, 2012, by and between Rosetta Genomics Ltd., Rosetta Genomics, Inc. and Precision Therapeutics, Inc.
8.1(16)	Subsidiaries.
12.1*	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
12.2*	Certification of Principal Accounting and Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b).
13.1*	Certification of the Principal Executive Officer and the Principal Accounting and Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
15.1*	Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global.
101*#	The following materials from Rosetta Genomics Ltd.'s Annual Report on Form 20-F for the year ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Income (Loss), (iv) the Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements

- 
- (1) Incorporated by reference from the Registrant's Registration Statement on Form F-1 (Reg. No. 333-137095), initially filed with the SEC on September 1, 2006.
  - (2) Incorporated by reference from the Registrant's Form 6-K dated August 2, 2007 (Reg. No. 001-33042), filed with the SEC on August 3, 2007.
  - (3) Incorporated by reference from the Registrant's Annual Report on Form 20-F for the year ended December 31, 2007 (Reg. No. 001-33042), filed with the SEC on June 26, 2008.
  - (4) Incorporated by reference from the Registrant's Annual Report on Form 20-F for the year ended December 31, 2008 (Reg. No. 001-33042), filed with the SEC on June 30, 2009.
  - (5) Incorporated by reference from the Registrant's Form 6-K dated August-September 2009 (Reg. No. 001-33042), filed with the SEC on September 9, 2009.
  - (6) Incorporated by reference from the Registrant's Form 6-K dated January 2010 (Reg. No. 001-33042), filed with the SEC on January 14, 2010.
  - (7) Incorporated by reference from the Registrant's Form 6-K dated November 2010 (Reg. No. 001-33042), filed with the SEC on November 30, 2010.
  - (8) Incorporated by reference from the Registrant's Form 6-K dated February 2011 (Reg. No. 001-33042), filed with the SEC on February 18, 2011.
  - (9) Incorporated by reference from the Registrant's Form 6-K dated October 2011 (Reg. No. 001-33042), filed with the SEC on October 14, 2011.
  - (10) Incorporated by reference from the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010 (Reg. No. 001-33042), filed with the SEC on March 31, 2011.
  - (11) Incorporated by reference from the Registrant's Form 6-K dated May 2012 (Reg. No. 001-33042), filed with the SEC on May 25, 2012.
  - (12) Incorporated by reference from the Registrant's Form 6-K dated May 2012 (Reg. No. 001-33042), filed with the SEC on May 14, 2012.
  - (13) Incorporated by reference from the Registrant's Form 6-K dated December 2011 (Reg. No. 001-33042), filed with the SEC on December 19, 2011.
  - (14) Incorporated by reference from the Registrant's Form 6-K dated April 2012 (Reg. No. 001-33042), filed with the SEC on April 16, 2012.
  - (15) Incorporated by reference from the Registrant's Form 6-K dated April 2012 (Reg. No. 001-33042), filed with the SEC on May 17, 2012.
  - (16) Incorporated by reference from the Registrant's Annual Report on Form 20-F for the year ended December 31, 2011 (Reg. No. 001-33042), filed with the SEC on April 2, 2012.
  - (17) Incorporated by reference from the Registrant's Form 6-K dated June 2012 (Reg. No. 001-33042), filed with the SEC on June 22, 2012.
  - (18) Incorporated by reference from the Registrant's Registration Statement on Form F-1 (Reg. No. 333-182329), filed with the SEC on June 25, 2012, as amended on July 26, 2012 and August 2, 2012..

\* Filed herewith.

@ Confidential portions of these documents have been filed separately with the SEC pursuant to a request for confidential treatment.

# Users of the XBRL data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

**SIGNATURE**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

ROSETTA GENOMICS LTD.

Dated: March 22, 2013

By: /s/ Kenneth A. Berlin

Kenneth A. Berlin, Chief Executive Officer and  
President

**ROSETTA GENOMICS LTD. AND SUBSIDIARY**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2012**

**U.S. DOLLARS IN THOUSANDS**

**INDEX**

	<u>Page</u>
<b>Report of Independent Registered Public Accounting Firm</b>	<b>F-2</b>
<b>Consolidated Balance Sheets</b>	<b>F-3 - F-4</b>
<b>Consolidated Statements of Comprehensive Loss</b>	<b>F-5</b>
<b>Consolidated Statements of Changes in Shareholders' Equity (Deficiency)</b>	<b>F-6</b>
<b>Consolidated Statements of Cash Flows</b>	<b>F-7 - F-8</b>
<b>Notes to Consolidated Financial Statements</b>	<b>F-9 - F- 35</b>

-----

□

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Board of Directors and Shareholders of Rosetta Genomics Ltd.**

We have audited the accompanying consolidated balance sheets of Rosetta Genomics Ltd. ("the Company") and its subsidiary as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 misstatements. We were not engaged to perform an audit of the Company's and its subsidiary 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 and its subsidiary internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, based on our audits, the consolidated financial statements referred to above, present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2011 and 2012, and the consolidated results of their comprehensive loss and cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

Tel-Aviv, Israel  
March 22, 2013

/s/ KOST FORER GABBAY & KASIERER  
A Member of Ernst & Young Global

## CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	Note	December 31,	
		2012	2011
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents		\$ 30,798	\$ 735
Restricted cash	9a	34	37
Short-term bank deposits	5	130	112
Trade receivables		88	11
Other accounts receivable and prepaid expenses	6	568	298
Current asset of discontinued operation	1e	135	17
<b>Total current assets</b>		<b>31,753</b>	<b>1,210</b>
<b>LONG TERM ASSETS:</b>			
Long-term receivables		7	-
Severance pay fund		-	133
Property and equipment, net	7	546	592
Long-term asset of discontinued operation	1e	224	109
<b>Total long term assets</b>		<b>777</b>	<b>834</b>
<b>Total assets</b>		<b>\$ 32,530</b>	<b>\$ 2,044</b>

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

**CONSOLIDATED BALANCE SHEETS**

U.S. dollars in thousands (except share and per share data)

	Note	December 31,	
		2012	2011
<b>LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIENCY)</b>			
<b>CURRENT LIABILITIES:</b>			
Trade payables		\$ 754	\$ 584
Other accounts payable and accruals	8	512	1,264
<b>Total current liabilities</b>		<b>1,266</b>	<b>1,848</b>
<b>LONG-TERM LIABILITIES:</b>			
Warrants related to share purchase agreements	10c	136	165
Deferred revenue		228	228
Accrued severance pay		-	159
<b>Total long-term liabilities</b>		<b>364</b>	<b>552</b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>	9		
<b>SHAREHOLDERS EQUITY (DEFICIENCY):</b>			
Share capital:	10		
Ordinary Shares of NIS 0.6 par value: 20,000,000 and 2,000,000 shares authorized at December 31, 2012 and 2011, respectively; 9,099,805 and 704,489 shares issued at December 31, 2012 and 2011, respectively; 9,096,547 and 702,436 shares outstanding at December 31, 2012 and 2011, respectively		1,379	108
Additional paid-in capital		125,023	84,581
Accumulated deficit		(95,502)	(85,045)
<b>Total shareholders' equity (deficiency)</b>		<b>30,900</b>	<b>(356)</b>
<b>Total liabilities and shareholders' equity (deficiency)</b>		<b>\$ 32,530</b>	<b>\$ 2,044</b>

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

**CONSOLIDATED STATEMENTS OF COMERHENSIVE LOSS**

U.S. dollars in thousands (except share and per share data)

	Note	Year ended December 31,		
		2012	2011	2010
Revenues		\$ 201	\$ 103	\$ 279
Cost of revenues		258	324	628
Gross loss		57	221	349
Operating expenses:				
Research and development, net		1,247	3,386	5,707
Marketing and business development		3,938	2,633	4,881
General and administrative		3,025	2,537	2,424
Other expenses related to the settlement arrangement, net		-	-	554
<b>Total operating expenses</b>		<b>8,210</b>	<b>8,556</b>	<b>13,566</b>
Operating loss		8,267	8,777	13,915
Financial expense (income), net	12	2,429	(1,384)	(942)
Loss from continuing operations		10,696	7,393	12,973
Other comprehensive income attributed to marketable securities		-	7	89
Net comprehensive (income) loss from discontinued operations	1c,1e	(239)	1,444	1,871
Net comprehensive loss after discontinued operations		\$ 10,457	\$ 8,830	\$ 14,755
Basic and diluted net loss per Ordinary Share from continuing operations		\$ 2.40	\$ 14.55	\$ 45.75
Basic and diluted net loss (income) per Ordinary Share from discontinuing operations		\$ (0.054)	\$ 2.85	\$ 6.60
Basic and diluted net loss per Ordinary Share		\$ 2.35	\$ 17.40	\$ 52.35
Weighted average number of Ordinary Shares used to compute basic and diluted net loss per Ordinary Share		4,448,449	507,622	281,801

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

ROSETTA GENOMICS LTD., AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY (DEFICIENCY)

U.S. dollars in thousands (except share data)

	Number of Ordinary Shares	Share capital	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Non- controlling interests	Total equity (deficiency)
Balance as of January 1, 2010	238,532	\$ 32	\$ 68,174	\$ 96	\$ (61,460)	\$ -	\$ 6,842
Employee options exercised	2,108	(*)	-	-	-	-	(*)
Issuance of restricted shares	150	(*)	-	-	-	-	(*)
Issuance of shares in January 2010, net of \$301 issuance cost	42,167	7	3,400	-	-	-	3,407
Issuance of shares in December 2010, net of \$145 issuance cost	41,667	7	1,149	-	-	-	1,156
Conversion of convertible note related to Rosetta Green establishment	-	-	1,252	-	-	248	1,500
Stock-based compensation relating to options issued to non-employees	-	-	19	-	-	-	19
Stock-based compensation relating to options issued to employees	-	-	738	-	-	939	1,677
Unrealized loss from marketable securities, net of realized gain	-	-	-	(89)	-	-	(89)
Net loss	-	-	-	-	(14,755)	(387)	(15,142)
Balance as of December 31, 2010	324,624	46	74,732	7	(76,215)	800	(630)
Issuance of restricted shares	84	(*)	-	-	-	-	-
Issuance of shares in February and October 2011, net of \$541 and \$70 issuance cost, respectively	301,672	50	5,803	-	-	-	5,853
Conversion of Warrants in February and November 2011	76,056	12	716	-	-	-	728
Stock-based compensation relating to options issued to non-employees	-	-	1	-	-	-	1
Stock-based compensation relating to options issued to employees	-	-	603	-	-	568	1,171
Decrease in holdings in Rosetta Green as a result of its IPO	-	-	2,726	-	-	2,352	5,078
Unrealized loss from marketable securities, net of realized gain	-	-	-	(7)	-	-	(7)
Loss of control in Rosetta Green shares in December 2011	-	-	-	-	-	(2,447)	(2,447)
Net loss	-	-	-	-	(8,830)	(1,273)	(10,103)
Balance as of December 31, 2011	702,436	108	84,581	-	(85,045)	-	(356)
Expenses related to the January 27, 2012 convertible debenture	-	-	(96)	-	-	-	(96)
Issuance of shares on April 17, 2012, at \$2.55 per share, net of \$149 issuance expenses	540,000	81	1,147	-	-	-	1,228
Issuance of shares on May 16, 2012, at \$3.5 per share, net of \$278 issuance expenses	632,057	101	1,833	-	-	-	1,934
Issuance of shares on May 24, 2012, at \$11.5 per share, net of \$643 issuance expenses	570,755	90	5,831	-	-	-	5,921
Issuance of shares on August 8, 2012, at \$5 per share, net of \$2,514 issuance expenses	5,500,000	826	24,160	-	-	-	24,986
Issuance of shares on August 29, 2012, at \$5 per share, net of \$289 issuance expenses	825,000	123	3,713	-	-	-	3,836
Conversion of October 2011 series A' Warrants in May and June, 2012	113,341	18	1,490	-	-	-	1,508
Employee options exercised	1,093	(*)	-	-	-	-	-
Stock-based compensation relating to options and RSUs issued to employees and directors	-	-	549	-	-	-	549
Conversion of debenture	211,865	32	268	-	-	-	300
Amortization of embedded conversion feature	-	-	1,547	-	-	-	1,547
Net loss	-	-	-	-	(10,457)	-	(10,457)
Balance as of December 31, 2012	9,096,547	1,379	125,023	-	(95,502)	-	30,900

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

U.S. dollars in thousands

	Year ended December 31,		
	2012	2011	2010
<b>Cash flows from operating activities:</b>			
Net loss	\$ (10,457)	\$ (10,103)	\$ (15,142)
Loss (income) from discontinued operations	(239)	2,676	926
Loss from continuing operations	(10,696)	(7,427)	(14,216)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	274	454	415
Foreign currency adjustments	(26)	8	16
Amortization of discount and change in fair value of embedded conversion feature in the convertible debenture	1,547	-	-
Capital loss from sale of property and equipment	(18)	15	(3)
Increase (decrease) in accrued severance pay, net	(26)	(8)	11
Stock-based compensation to employees	549	603	737
Compensation related to shares and warrants granted to non-employees	-	1	19
Gain from marketable securities, net	-	(7)	(125)
Decrease (increase) in trade receivables	(77)	9	51
Decrease (increase) in other accounts receivable and prepaid expenses	(277)	(68)	57
Increase (decrease) in trade payables	170	(516)	498
Increase (decrease) in other accounts payable and accruals	(722)	(1,502)	1,229
Loss from Rosetta Green's sale	-	41	-
Adjustment for settlement arrangement	-	-	94
Increase in deferred revenue	-	-	(1,700)
Revaluation of warrants related to share purchase agreements	635	(1,640)	(1,072)
Net cash used in operating activities from continuing operations	(8,667)	(10,037)	(13,989)
Net cash provided by (used in) operating activities from discontinued operations	30	(1,224)	268
Net cash used in operating activities	(8,637)	(11,261)	(13,721)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(270)	(11)	(425)
Proceeds from sale of property and equipment	60	168	7
Decrease (increase) in bank deposits	(18)	78	2,952
Purchase of marketable securities	-	-	(1,489)
Proceeds and redemption from sale of marketable securities	-	148	3,889
Decrease (increase) in restricted cash	3	(37)	1,076
Proceeds from sale of Parkway	-	-	148
Proceeds from sale of Rosetta Green	-	814	-
Net cash provided by (used in) investing activities from continuing operations	(225)	1,160	6,158
Net cash used in investing activities from discontinued operations	-	(3,687)	(15)
Net cash provided by (used in) in investing activities	(225)	(2,527)	6,143

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

U.S. dollars in thousands

	Year ended December 31,		
	2012	2011	2010
<b>Cash flows from financing activities:</b>			
Repayment of capital lease	(28)	(70)	(142)
Receipt of long-term bank loan and capital lease	-	-	5
Issuance of convertible loan	1,750	-	-
Repayment of convertible loan	(1,450)	-	-
Issuance of shares and warrants, net	38,653	9,634	7,113
Net cash provided by financing activities from continuing operations	38,925	9,564	6,976
Net cash provided by financing activities from discontinued operations	-	2,232	-
Net cash provided by financing activities	38,925	11,796	6,976
Increase (decrease) in cash and cash equivalents	30,063	(1,992)	(602)
Cash and cash equivalents at beginning of year	735	2,727(*)	3,329
Cash and cash equivalents at end of year	\$ 30,798	\$ 735	\$ 2,727(*)
<b>Supplemental disclosure:</b>			
<b>Cash paid during the year for:</b>			
Interest	\$ 288	\$ 380	\$ -
<b>Non-cash activities:</b>			
Conversion of convertible notes into RG Ordinary Shares	\$ -	\$ -	\$ 1,500
Conversion of Warrants	\$ -	\$ 729	\$ -
Amortization of embedded conversion feature	\$ 1,547	\$ -	\$ -

(\*) Includes cash and cash equivalents of discontinued operations of \$84 at December 31, 2011

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)****NOTE 1:- GENERAL**

- a. Rosetta Genomics Ltd. ("the Company") commenced operations on March 9, 2000. The Company's integrative research platform combining bioinformatics and state-of-the-art laboratory processes has led to the discovery of hundreds of biologically validated novel human microRNAs. Building on its strong patent position and proprietary platform technologies, Rosetta Genomics is working on the application of these technologies in the development of a full range of microRNA-based diagnostic tools. The Company's microRNA-based tests, miRview<sup>®</sup>™ mets2, miRview<sup>®</sup>™ Lung, miRview<sup>®</sup>™ meso, and miRview<sup>®</sup>™ kidney are commercially available worldwide and all samples are processed in its Philadelphia-based CAP-accredited, CLIA-certified lab.
- b. The Company has a wholly-owned subsidiary in the U.S., Rosetta Genomics Inc. The principal business activity of the subsidiary is to commercialize the Company's products, perform and develop tests in its CLIA-approved laboratory and expand the business development of the Company in the U.S.

- c. Rosetta Green Ltd. ("RG"):

During 2011, Rosetta Green Ltd. was an Israeli subsidiary which the Company established to leverage its capabilities in the areas of cleantech and plant biotech by using its proprietary microRNA technologies to develop plants and algae which are more suitable for various applications such as improved feedstocks for biofuels and advanced agriculture.

On December 16, 2011, the Company closed a transaction pursuant to which the Company sold all of the Ordinary Shares of RG held by the Company (50.03% of the outstanding Ordinary Shares) to certain purchasers. The transaction was effected pursuant to a share transfer agreement, dated December 13, 2011.

Since RG was consolidated prior to the disposal it met the criteria for reporting as discontinued operations and, therefore, the results of operations of the business and the loss on the sale have been classified as discontinued operations loss in the Statement of Comprehensive Loss and prior periods results have been classified accordingly.

In addition, the Company may receive in the future, an additional payment of \$2,000 if RG is acquired within three years from the date of signing of the share transfer agreement at a price per share reflecting RG valuation of at least \$90,000. As of December 31, 2012, the Company estimates that such contingent payment is remote.

- d. The Company incurred an accumulated deficit of approximately \$95,502 since inception, and incurred recurring operating losses and negative cash flows from operating activities in each of the three years in the period ended December 31, 2012. As of December 31, 2012 the Company's total shareholders' equity amounted to \$30,900.

The total aggregate amount of debt and equity capital that has been raised from January 1, 2012 through December 31, 2012 was \$43,528, of which \$1,450 has been used to prepay the January 2012 convertible debenture outlined in Note 3. As a result of the various financing rounds occurred during 2012, the Company believes that it has sufficient liquidity resources to support its operations for approximately the next twenty four months.

- e. Parkway Clinical Laboratories, Inc. ("Parkway"):

Parkway was a national, full-service Clinical Laboratories Improvement Amendments ("CLIA") certified clinical laboratory service that was owned by the Company. Parkway specializes in oral drug screening in the workplace environment and genetics testing services.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

On May 18, 2009, the Company sold Parkway, in a management buy-out for up to a maximum amount of \$2,500, to be paid as a fixed percentage of revenues (15%) over six years and minimum price of \$750. According to ASC 810, "Consolidation", the Company calculated the fair value of future consideration by using discounted estimate of future cash receipt. As a result of the transaction, the controlling interests in Parkway were transferred to the buyer, as well as all the risks. Accordingly, the Company has no future liabilities or obligation related to Parkway. As of the transaction date, the fair value of the estimated future consideration was \$759. During the years ended December 31, 2012, 2011 and 2010, the Company received an amount of \$30, \$0 and \$148, respectively, in respect of this consideration.

As of December 31, 2012 and 2011, the Company revalued the fair value of the estimated future consideration to \$359 and \$126, respectively, out of which \$135 and \$17 is recorded as current asset of discontinued operation as of December 31, 2012 and 2011, respectively, and \$224 and \$109 is recorded as long-term asset of discontinued operation as of December 31, 2012 and 2011, respectively.

The sale of Parkway met the criteria for reporting as discontinued operations and, therefore, the results of operations of the business and the gain on the sale have been classified as discontinued operations in the Consolidated Statement of Comprehensive Loss and prior period's results have been reclassified accordingly. In addition, the comparative data of the asset has been reclassified as asset attributed to discontinued operations in the Consolidated Balance Sheets.

As a result of the fair value update of the estimated future consideration, the Company recorded a gain of \$239, which was attributed to discontinued operations, and an amount of \$24 was attributed to financial income in the year ended December 31, 2012.

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES**

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

a. Use of estimates:

The preparation of financial statements, in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

b. Financial statements in U.S. dollars:

The Company's financing activities are incurred in U.S. dollars. A portion of the Company's costs is incurred in U.S. dollars. The Company's management believes that the U.S. dollar is the primary currency of the economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the U.S. dollar.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**U.S. dollars in thousands (except share and per share data)**

Accordingly, monetary accounts maintained in currencies other than the dollar are remeasured into U.S. dollars in accordance with ASC 830, "Foreign Currency Matters". All transaction gains and losses from the remeasurement of monetary balance sheet items are reflected in the Statements of Comprehensive Loss as financial income or expenses, as appropriate.

c. Basis of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Rosetta Genomics Inc. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash equivalents:

Cash equivalents include short-term, highly liquid investments that are readily convertible to cash with original maturities of three months or less.

e. Restricted cash:

Restricted cash is an interest bearing savings account which is used as a security for the Company's Israeli facilities leasehold bank guarantee.

f. Short-term bank deposits:

Short-term bank deposits are deposits with maturities of more than three months but less than one year. The short-term deposits are presented at their cost.

g. Property and equipment:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets.

The annual depreciation rates are as follows:

	%
Computer equipment	33
Office furniture and laboratory equipment	7 - 15 (mainly 15)
Leasehold improvement	Over the shorter of the lease term or useful economic life

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

## h. Impairment of long-lived assets:

The long-lived assets of the Company and its subsidiary and all identifiable intangible assets that are subject to amortization are reviewed for impairment in accordance with ASC 360-10-35, "Property, Plant and Equipment - Subsequent Measurement"/ ASC 250, "Presentation of Financial Statements", 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 assets. 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 assets exceeds the fair value of the assets. As of December 31, 2012 and 2011, no impairment losses have been identified.

## i. Discontinued operation:

According to ASC 360, "Property, Plant, and Equipment" and ASC 205, "Presentation of Financial Statements" when a component of an entity, as defined in ASC 360, has been disposed of, the results of its operations, including the gain or loss on its disposal should be classified as discontinued operations when the operations and cash flows of the component have been eliminated from the Company's consolidated operations and the Company will no longer have any significant continuing involvement in the operations of the component.

## j. Revenue recognition:

The Company generates revenues from diagnosing patient tissue received from private patients or third-party distributors. The Company performs the diagnostic testing in its lab in the U.S.

Revenues from sales of the Company's diagnostic services are recognized in accordance with "Revenue Recognition in Financial Statements" ("ASC 605") when (1) persuasive evidence of an agreement exists, (2) delivery of tests result has occurred or services have been rendered, (3) the vendor's fee is fixed or determinable, and (4) no further obligation exists and collectability is probable. In arrangements with private patients, in which prior to delivery the patient's third-party insurance provider has not contractually set the sale prices, the Company does not recognize revenue until the fees are fixed and determinable and collectability assured.

Criterion (1) is satisfied when the Company has an arrangement to pay or a contract with the payor in place addressing reimbursement for the test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes the patient report available to the patient. Determinations of criteria (3) and (4) are based on management's judgments regarding whether the fee charged for products or services delivered is fixed or determinable, and the collectability of those fees under any contract or arrangement. When evaluating collectability, the Company considers whether it has sufficient history to reliably estimate a payor's individual payment patterns. To the extent all criteria set forth above are not met when test results are delivered, service revenues are recognized when cash is received from the payor. Under the arrangements with distributors, once delivery of a test result has occurred, the distributor is obligated to pay the Company the fixed price for such test pursuant to the relevant distribution agreement.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

Royalties from licensing the right to use the Company's products are recognized when earned and when written sales confirmation from the licensee is received and no future obligation exists. Non-refundable, up front advancements of royalties from licensing the right to use the Company's products which are fully chargeable against royalties, are recorded as deferred revenue until the above mentioned criteria for recognizing revenue are met. As of December 31, 2012, the Company has deferred revenue in an amount of \$228.

k. Research and development expenses, net:

Research and development expenses include costs of salaries and related expenses, various activities related to intellectual property, research materials and supplies, and equipment depreciation. All research and development costs are expensed as incurred. The Company has entered into several license agreements for rights to utilize certain technologies. The terms of the licenses may provide for upfront payments, annual maintenance payments and royalties on product sales. Costs to acquire and maintain licensed technology are charged to research and development and expensed as incurred. During the years ended December 31, 2012, 2011 and 2010, the Company charged to research and development expense \$245, \$ 277 and \$ 123 of costs associated with license fees, respectively (See also Note 9e-9k).

Royalty bearing grants from the Bi-national Industrial Research and Development Foundation ("BIRD") and from the Chief Scientist of Israel's Ministry of Industry, Trade and Labor ("the OCS") for funding approved research and development projects, are presented as a reduction from the research and development expenses (see also Note 9.l). The Company received grants in an amount of \$165, \$206 and \$0, in the years 2012, 2011 and 2010, respectively. Such grants are presented as a reduction from research and development expenses.

l. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation-Stock Compensation". ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated income statements.

The Company recognizes compensation expenses for the value of its awards granted based on the straight line method over the requisite service period of each of the awards, net of estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Estimated forfeitures are based on actual historical pre-vesting forfeitures.

The Company selected the Black-Scholes option pricing model as the most appropriate fair value method for its stock-options awards and values restricted stock units based on the market value of the underlying shares at the date of grant. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

The weighted-average estimated fair value of employee stock options granted during the 12 months ended December 31, 2012, 2011 and 2010 was \$4.62, \$7.35 and \$56.4, respectively per share using the Black-Scholes option pricing model with the following weighted-average assumptions (annualized percentages):

	Year ended December 31,		
	2012	2011	2010
Dividend yield	0%	0%	0%
Expected volatility	122%	88%	61%-67%
Risk-free interest	1.12%	1.2%	1.8%
Expected life	6.25 years	5-6 years	5.5-6.25 years

The Company is required to assume a dividend yield as an input in the Black-Scholes model. The dividend yield assumption is based on the Company's historical experience and expectation of future dividend payouts. The Company has historically not paid dividends and has no foreseeable plans to pay dividends. The dividend yield used for the twelve months ended December 31, 2012 and 2011 was 0%.

The computation of expected volatility is based on realized historical stock price volatility of the Company's stock starting from the IPO date.

The risk-free interest rate assumption is the implied yield currently available on United States treasury zero-coupon issues with a remaining term equal to the expected life term of the Company's options.

The Company determined the expected life of the options according to the simplified method, average of vesting and the contractual term of the Company's stock options.

The Company applies ASC 718 and ASC 505-50, "Equity-Based Payments to Non-Employees" with respect to options and warrants issued to non-employees. ASC 718 requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

m. Net loss per share:

Basic earnings per share are computed based on the weighted average number of Ordinary Shares outstanding during each year. Diluted earnings per share are computed based on the weighted average number of Ordinary Shares outstanding during each year, plus dilutive potential Ordinary Shares considered outstanding during the year, in accordance with ASC 260, "Earnings per Share".

Basic and diluted net loss per share is computed using the weighted average number of Ordinary Shares outstanding during the period.

For the years ended December 31, 2012, 2011 and 2010, all outstanding options, RSUs, and warrants, if any, have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

## n. Income taxes:

The Company and its subsidiary account for income taxes and uncertain tax positions in accordance with ASC 740, "Income Taxes". ASC 740 prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on the differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company and its subsidiary provide a valuation allowance, if necessary, to reduce deferred tax assets to the amounts that are more likely-than-not to be realized.

The Company adopted ASC 740-10. ASC 740-10 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with ASC 740. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement.

## o. Severance pay:

The Israeli Company's employees are included under section 14 of the Israeli Severance Compensation Law ("Section 14"). Under Section 14, the company's monthly deposits, at a rate of 8.33% of such employees' monthly salary, are made on their behalf with insurance companies on account of severance pay. Payments in accordance with Section 14 release the Israeli companies from any future severance payments in respect of those employees. Deposits under Section 14 are not recorded as an asset in the Company's balance sheet.

Severance expenses for the years ended December 31, 2012, 2011 and 2010 were \$38, \$173 and \$225, respectively.

The U.S. subsidiary has a 401(k) defined contribution plan covering certain employees in the U.S. All eligible employees may elect to contribute to the plan. The subsidiary provides a 3% safe-harbor contribution to the plan up to the employee's eligible compensation. In the years 2012, 2011 and 2010, the subsidiary recorded an expense for matching contributions in the amount of \$25, \$30 and \$48, respectively.

## p. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term bank deposits, trade receivables and other accounts receivable.

Cash and cash equivalents are deposited with major banks in Israel and in the United States. Such deposits in the United States may be in excess of insured limits and are not insured in other jurisdictions. Management believes that the financial institutions that hold the Company's investments are institutions with high credit standing, and accordingly, minimal credit risk exists with respect to these investments.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

## q. Fair value of financial instruments:

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, short-term bank deposits, accounts receivable, accounts payable and accrued liabilities, approximate fair value because of their generally short-term maturities.

The Company adopted ASC 820, "Fair Value Measurements and Disclosures". ASC 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1- Observable input that reflects quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2- Include other inputs that are directly or indirectly observable in the marketplace.

Level 3- Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

**NOTE 3: - CONVERTIBLE DEBENTURE**

On January 26, 2012, the Company entered into a Secured Loan Agreement, pursuant to which on January 27, 2012, the Company sold and issued a \$1,750 senior secured debenture (the "Debenture") with a maturity date of January 26, 2013 and accrued interest at a rate between 10% and 18%. On March 15, 2012, an aggregate of \$300 in principal amount of the Debenture became convertible, into the Company's Ordinary Shares at a conversion price of \$1.416 per share. The Debenture was secured by a security interest in all of the Company's current and future assets and any current or future subsidiary.

On June 21, 2012, the Company entered into an agreement and release with the Debenture holders, pursuant to which the Company prepaid an aggregate of \$1,450 in principal and \$288 in interest and the Debenture holders agreed to convert the remaining \$300 in principal into Ordinary Shares no later than July 31, 2012 according to the original conversion terms. Such conversion occurred on July 27, 2012. Following the prepayment of the \$1,450 in principal and \$288 in interest, all of the Company's obligations (other than the obligation to convert the remaining \$300 in principal into Ordinary Shares) were satisfied and terminated and the security interest in all of the Company's assets terminated. The agreement also contained a mutual release and discharge of future claims.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

The Company accounts for convertible debenture with ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20"). ASC 470-20 requires companies first allocate the proceeds to freestanding liability instrument, with its embedded conversion feature that are measured at fair value at each reporting date, based on their fair value (valued as level 3 in accordance with ASC 820). The remaining proceeds then will be allocated to the convertible debt.

Embedded derivatives are separated from the loan and are bifurcated based on their fair value and re-measured on each reporting date.

The embedded conversion feature was calculated on the commitment date and amortized using the effective rate method. The Company computed the fair value of the conversion feature using the Black-Scholes model. The following are the key assumptions used in connection with this computation:

	<u>Issuance date</u>
Risk-free interest rate (1)	0.9%
Expected volatility (2)	136%
Expected life (in years) (3)	1.0
Expected dividend yield (4)	0%

- 1) Risk-free interest rate - based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.
- 2) Expected volatility - was calculated based on actual historical stock price movements of the Company over a term that is equivalent to the expected term of the conversion option.
- 3) Expected life - the expected life was based on the maturity date of the conversion option.
- 4) Expected dividend yield - was based on the fact that the Company has not paid dividends to its shareholders in the past and does not expect to pay dividends to its shareholders in the future.

On July 27, 2012, the Company issued 211,865 Ordinary Shares, following the conversion of the remaining \$300, in principal amount of the Debenture in amount of \$1,547. As a result of the amortization of the discount and the changes of the fair value of the embedded conversion feature in the convertible debenture described above, the Company recorded expense of \$1,547 and an interest expense of \$288, which were attributed to financial expenses.

**NOTE 4: - FAIR VALUE MEASUREMENTS**

In accordance with ASC 820, "Fair Value Measurements and Disclosures" (originally issued as SFAS 157), The Company valued the level 3 other accounts receivable, which resulted from the fair value of Parkway's estimated future consideration based on a valuation using the discounted cash flow model. Unobservable inputs used in this model are significant to the fair value of the asset. The fair value of the liability for warrants related to share purchase agreement was calculated using the Black-Scholes Model and the Company classified this liability within Level 3.

The Company's financial assets (liabilities) measured at fair value on a recurring basis, excluding accrued interest components, consisted of the following types of instruments as of December 31, 2012:

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

<u>Assets</u>	<u>Fair value measurements using input type</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Asset of discontinued operation resulting from Parkway's estimated future consideration	-	-	359	359
<b>Total assets</b>	<b>-</b>	<b>-</b>	<b>359</b>	<b>359</b>

For more details, refer to note 1e.

<u>Liabilities</u>	<u>Fair value measurements using input type</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Warrants related to share purchase agreements	-	-	136	136
<b>Total liabilities</b>	<b>-</b>	<b>-</b>	<b>136</b>	<b>136</b>

For more details, refer to note 10c.

**NOTE 5:- SHORT-TERM BANK DEPOSITS**

As of December 31, 2012 and 2011, the Company's bank deposits are as follows:

<u>December 31, 2012</u>		
<u>Amount</u>	<u>Maturity date</u>	<u>Annual interest</u>
\$ 18	January 27, 2013	1.73%
112	December 2, 2013	0.2%
<b>\$ 130</b>		
<u>December 31, 2011</u>		
<u>Amount</u>	<u>Maturity date</u>	<u>Annual interest</u>
\$ 112	December 5, 2012	0.6%

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

**NOTE 6:- OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES**

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Prepaid expenses	\$ 327	\$ 57
Employees	58	136
Government authorities	108	20
Other accounts receivable	75	85
	<u>\$ 568</u>	<u>\$ 298</u>

**NOTE 7:- PROPERTY AND EQUIPMENT**

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cost:</b>		
Computer equipment	\$ 598	\$ 584
Office furniture and laboratory equipment	1,049	1,336
Leasehold improvements	617	384
	<u>2,264</u>	<u>2,304</u>
<b>Accumulated depreciation:</b>		
Computer equipment	537	497
Office furniture and laboratory equipment	790	920
Leasehold improvements	391	295
	<u>1,718</u>	<u>1,712</u>
Depreciated cost	<u>\$ 546</u>	<u>\$ 592</u>

Depreciation expenses for the years ended December 31, 2012, 2011 and 2010 were \$274, \$458 and \$415, respectively.

**NOTE 8:- OTHER ACCOUNTS PAYABLE AND ACCRUALS**

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Employees' salaries and payroll accruals	\$ 328	\$ 333
Accrued expenses and other	184	110
Settlement arrangement	-	791
Current maturity of capital lease	-	30
	<u>\$ 512</u>	<u>\$ 1,264</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

**NOTE 9: - COMMITMENTS AND CONTINGENT LIABILITIES**

- a. Restricted cash:

As of December 31, 2012 and December 31, 2011, restricted cash was primarily attributed to a bank guarantee to the landlord of the Israeli property.

- b. The facilities of the Company are rented under operating leases. Aggregate minimum rental commitments under the non-cancelable rent agreements as of December 31, 2012, are as follows:

2013	\$ 375
2014	343
2015	343
2016	342
2017 and thereafter	<u>560</u>
<b>Total</b>	<b>\$ 1,963</b>

Total rent expenses for the years ended December 31, 2012, 2011 and 2010 were \$531, \$630 and \$565, respectively.

- c. The Company leases its motor vehicles under cancelable operating lease agreements. The minimum payment under these operating leases, upon cancellation of these lease agreements was \$7 as of December 31, 2012.

Lease expenses for motor vehicles for the years ended December 31, 2012, 2011 and 2010, were \$53, \$152 and \$139, respectively.

- d. As of December 31, 2012 and 2011, the Company provided a bank guarantee for the fulfillment of its lease commitments in the amount of approximately \$163 and \$140, respectively.

- e. In May 2006, the Company signed a royalty-bearing, co-exclusive, worldwide license agreement with a third party. Under this agreement, the Company was granted the right to make, use and sell the third party's proprietary microRNAs for diagnostic purposes including a limited right to sublicense. In consideration for this license the Company paid an initiation fee and will pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of the Company's revenues from any sublicense. The Company estimates that until 2029 the minimum aggregate license maintenance fees over the term of this agreement will be approximately \$960, of which \$680 will be paid after December 31, 2012. During the years ended December, 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$47, \$47 and \$47, respectively, to the third party. The Company recorded the payments as research and development expenses.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

- f. In June 2006, the Company signed a royalty-bearing, co-exclusive, worldwide license agreement with a third party. Under this agreement, the Company licensed from this third party the rights to its proprietary microRNAs for diagnostic purposes. In consideration for this license the Company paid an initiation fee and will pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of the Company's revenue from any sublicense. The Company estimates that until 2022 the minimum aggregate license maintenance fees over the term of this agreement should be approximately \$514, of which \$395 will be paid after December 31, 2012. During the years ended December 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$34, \$39 and \$27, respectively, to the third party. The Company recorded the payments as research and development expenses.
- g. In August 2006, the Company signed a royalty-bearing, exclusive, worldwide license agreement with a third party. Under this agreement, the Company has exclusively licensed from this third party the rights to its proprietary microRNAs for all fields and applications including a limited right to sublicense. In consideration for this license the Company paid an initiation fee and will pay minimum annual royalties, royalties based on net sales and a percentage of the Company's revenues from any sublicense. This agreement was amended and restated in August 2011 and is now on a non-exclusive basis. For the amendment, the Company paid an amendment fee. The Company estimates that until 2032 the aggregate minimum royalties over the term of this agreement should be approximately \$320, of which \$200 will be paid after December 31, 2012. During the years ended December 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$5, \$12 and \$59, respectively to the third party. The Company recorded the payments as research and development expenses.
- h. In December 2006, the Company signed a royalty-bearing, non-exclusive, worldwide license agreement with a third party. Under this agreement the Company licensed from the third party its proprietary microRNAs for research purposes. In consideration for this license the Company will pay an initiation fee and will be required to pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of the Company's revenues from any sublicenses. The Company estimates that until 2022 the minimum aggregate license maintenance fees over the term of this agreement should be approximately \$316, of which \$198 will be paid after December 31, 2012. During the years ended December 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$17, \$21 and \$22, respectively under this agreement. The Company recorded the payments as research and development expenses.
- i. In May 2007, the Company signed a royalty-bearing, co-exclusive, worldwide license agreement with a third party. Under this agreement, the Company has licensed from this third party the rights to its proprietary microRNAs for therapeutic purposes including a limited right to sublicense. In consideration for this license the Company paid an initiation fee and will pay a fixed annual license maintenance fee, payments based on milestones and royalties based on net sales and a percentage of the Company's revenues from any sublicense. The Company estimates that until 2029 the minimum aggregate maintenance fees over the term of this agreement should be approximately \$690, of which \$510 will be paid after December 31, 2012. During the years ended December 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$35, \$35 and \$35, respectively, to the third party. The Company recorded the payments as research and development expenses.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

- j. In January 2008, the Company signed a royalty-bearing, co-exclusive, worldwide license agreement with a third party. Under this agreement, the Company was granted the right to make, use and sell the third party's proprietary microRNAs for research purposes including a limited right to sublicense. In consideration for this license the Company paid an initiation fee and will pay a fixed annual license maintenance fee, royalties based on net sales and a percentage of the Company's revenues from any sublicense. The Company estimates that until 2029 the minimum aggregate license maintenance fees over the term of this agreement should be approximately \$440, of which \$340 will be paid after December 31, 2012. During the years ended December, 31, 2012, 2011 and 2010, the Company paid fees in the amount of \$24, \$24 and \$24, respectively, to the third party. During the year ended December, 31, 2008, the Company paid initiation fees in the amount of \$40, to the third party. The Company recorded the payments as research and development expenses.
- k. In June 2011 the Company entered into an agreement with PACE claims services, LLC, a wholly owned subsidiary of Navigant Inc. ("PACE"), according to which, PACE will provide the Company exclusive educational and marketing services to defendants involved in lawsuits relating to malignant pleural mesothelioma and asbestos exposure, provided the exclusivity does not apply to the Company's marketing efforts and to any marketing efforts of the Company's distributors offering the Company's tests outside of the United States of America. According to this agreement, PACE will be entitled to certain remuneration derived from actual sales to defendants in these lawsuits.
- l. Rimonim Consortium:

In January 2011, the Company joined the Rimonim Consortium, which is supported by the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor, of the State of Israel (the "OCS"). The purpose of the consortium is to develop RNA interference-based therapeutics. As a member of this consortium, the Company is entitled to certain grants to support its research and development activities. Under the terms applicable to members of the consortium, so long as the Company continues to meet the criteria for receiving these grants, which criteria include the payment by the Company of part of the expenses for the activities funded by the grants and the timely delivery to OCS of written reports regarding those activities, then the Company is not required to repay the grants. If the Company ceases to meet these and other criteria, then the grant amounts for the year in which the Company ceased to meet the criteria become immediately due and payable to OCS. As of December 31, 2012 the Company received total grants of \$165 from the OCS for its development within the consortium and continued to meet the criteria to receive grants such that the Company was not then obligated to repay those funds.

**NOTE 10:- SHARE CAPITAL**

- a. Ordinary Shares:

Ordinary Shares confer upon the holders the right to receive notice to participate and vote in the general meetings of the Company, the right to receive dividends, if declared.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**U.S. dollars in thousands (except share and per share data)**

---

b. Reverse stock split and increase in share capital:

On May 14, 2012, the Company held an Extraordinary General Meeting of Shareholders on which the following actions were approved and taken:

a) To consolidate the registered (authorized) share capital of the Company as follows: every fifteen (15) Ordinary Shares with a nominal (par) value of NIS 0.04 each will be consolidated into one (1) Ordinary Share with a nominal (par) value of NIS 0.6 each. All Ordinary Shares, options and per share amounts have been adjusted to give retroactive effect to this reverse split for all periods presented.

b) To increase the registered (authorized) share capital of the Company to 20,000,000 Ordinary Shares with a nominal (par) value NIS 0.6 each.

All Ordinary Shares, warrants and options and per share amounts have been adjusted to give retroactive effect to these reverse splits for all periods presented.

c. Investment agreements:

1. In January 2010, the Company completed a registered direct offering with several institutional investors. The Company received proceeds of approximately \$4,650 net of placement agent fees and other offering expenses. Under the terms of the financing, the Company sold 168,667 units, consisting of an aggregate of 42,167 Ordinary Shares and warrants to purchase 21,084 additional Ordinary Shares. Each unit, consisting of one 1/15 Ordinary Share and a 0.033 warrant to purchase an Ordinary Share, was sold for a purchase price of \$8.00. In addition, the Company granted additional warrants as finders' fee to purchase up to 1,582 Ordinary Shares ("January 2010 Warrants").

The exercise price of the warrants is \$150 per Ordinary Share. The warrants are exercisable for a period of five years.

The Company accounted for these warrants according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity" and based on certain terms of the warrants classified them as liabilities, measured at fair value each reporting period until they will be exercised or expired, with changes in the fair values being recognized in the Company's statement of comprehensive loss as financial income or expense.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

The fair value was measured using the Black-Scholes model. In estimating the warrants' fair value, the Company used the following assumptions:

	<u>December 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Risk-free interest rate (1)	0.25%	0.41%
Expected volatility (2)	161%	92.7%
Expected life (in years) (3)	2	3
Expected dividend yield (4)	0%	0%
Fair value:		
Warrants	\$ 25	\$ 1

- (1) Risk-free interest rate - based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.
  - (2) Expected volatility - was calculated based on actual historical stock price movements of the Company over a term that is equivalent to the expected term of the option
  - (3) Expected life - the expected life was based on the maturity date of the warrants.
  - (4) Expected dividend yield - was based on the fact that the Company has not paid dividends to its shareholders in the past and does not expect to pay dividends to its shareholders in the future.
2. On December 1, 2010, the Company completed a private placement ("PIPE") offering with several investors. The Company received proceeds of approximately \$2,240, net of placement agent fees and other offering expenses. Under the terms of the financing, the Company sold 166,667 units, consisting of an aggregate of 41,667 Ordinary Shares, warrants to purchase up to an aggregate of 20,841 Ordinary Shares at an exercise price of \$78 per share ("Series A Warrants") and warrants to purchase up to an aggregate of 10,417 Ordinary Shares at an exercise price of \$0.6 per share ("Series B Warrants"). Each unit was sold for a purchase price of \$60. In addition, the Company granted additional warrants as finders' fee to purchase up to 1,042 Ordinary Shares.

The Series A Warrants are exercisable immediately upon issuance, expire on December 1, 2015 and the exercise price is subject to potential future adjustment upon occurrence of various events, such as stock splits or dilutive issuances. On February 23, 2011, in connection with the financing transactions closed by the Company, the exercise price of the Series A Warrants was automatically adjusted thereof from \$78 per share to \$60 per share.

Each Series B Warrant were automatically exercised on a cashless basis on the 33rd trading day following December 23, 2010, to a number of Ordinary Shares that was subject to adjustment as defined in the agreement.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

On February 9, 2011, the Series B Warrants were automatically exercised on a cashless basis to 10,417 Ordinary Shares. Upon the conversion of Series B Warrants, the fair value of Series B Warrants was classified as equity.

The Company accounted for the Series A Warrants according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity", and based on certain terms of the warrants, classified them as liabilities, measured at fair value in each reporting period until they are exercised or expired, with changes in the fair values being recognized in the Company's Statement of Comprehensive Loss as financial income or expense.

The fair value of the Series A Warrants was measured using the Black-Scholes model. The fair value was estimated taking into consideration (a) the possibility of the Company becoming privately owned and/or a possibility in which there is an all-cash transaction in the Company's shares, (b) the possibility that the Company will issue additional shares for a share price of under \$60. In estimating the warrants' fair value, the Company used the following assumptions:

	<b>December 31,</b>	<b>December 31,</b>
	<b>2012</b>	<b>2011</b>
	<u>          </u>	<u>          </u>
Risk-free interest rate	0.365	0.69%
Expected volatility	138%	86.3%
Expected life (in years)	3	4
Expected dividend yield	0	0
Fair value:		
Warrants	\$ 39	\$ 5

3. On February 23, 2011, the Company completed a concurrent private placement and registered direct offering. The Company received proceeds of approximately \$5,500 net of placement agent fees and other offering expenses of \$542.

Under the terms of the private placement, the Company has issued 75,695 Ordinary Shares at a price of \$36 per share. The purchasers in the private placement also received warrants to purchase up to an aggregate of 56,776 Ordinary Shares at an exercise price of \$48 per share ("the Private Placement Warrants"). The Private Placement Warrants are exercisable immediately upon issuance and have a term of five years. In addition, the Company granted additional warrants as finders' fee to purchase up to 1,893 Ordinary Shares.

Under the terms of the registered direct offering, the Company has issued 90,978 Ordinary Shares at a price of \$36 per share. The purchasers in the registered direct offering also received warrants to purchase up to an aggregate of 45,509 Ordinary Shares at an exercise price of \$48 per share ("the Registered Direct Warrants"). The Registered Direct Warrants are exercisable immediately upon issuance and have a term of five years. In addition, the Company granted additional warrants as finders' fee to purchase up to 2,275 Ordinary Shares.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

The Company accounted for the Private Placement Warrants and the registered direct offering according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity", and based on certain terms of the warrants, classified them as equity.

4. On October 19, 2011, the Company completed a private placement offering from investors. The Company received proceeds of approximately \$1,300, net of placement agent fees and other offering expenses of \$236. Under the terms of the financing, the Company sold 135,010 units, consisting of an aggregate of 135,010 Ordinary Shares, warrants to purchase up to an aggregate of 135,010 Ordinary Shares at an exercise price of \$7.50 per share ("Series A' Warrants") and warrants to purchase up to an aggregate of 67,501 Ordinary Shares at an exercise price of \$0.15 or NIS 0.6 per share ("Series B' Warrants"). Each unit was sold for a purchase price of \$11.25. In addition, the Company granted additional warrants as finders' fee to purchase up to 3,375 Ordinary Shares. The Series A' Warrants expire on October 19, 2016.

According to Series B' Warrants agreement, each Series B' Warrant will be automatically exercised on a cashless basis on the 11th trading day following November 10, 2011, to a number of Ordinary Shares equal to the difference between (a) the quotient obtained by dividing (1) 200% of the maximum number of warrant Shares issuable under the Series B' warrant multiplied by the \$11.25 by (2) the greater of \$7.50 and 80% of the average of the 10 Volume-weighted average price immediately following the November 10, 2011 and (b) the maximum number of Warrant Shares issuable under the Series B' warrant multiplied by 2.

On November 28, 2011, the Series B' Warrants were automatically exercised on a cashless basis to 65,749 Ordinary Shares. Upon the conversion of Series B' Warrants, the fair value of Series B' Warrants was classified as equity.

During 2012, of the 135,010 Series A' warrants, 113,341 were exercised for aggregate gross proceeds of \$850,065. As of December 31, 2012, 21,668 Series A' warrants remain outstanding.

The Company accounted for the Series A' according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity", and based on certain terms of the warrants, classified them as liabilities, measured at fair value in each reporting period until they are exercised or expired with changes in the fair values being recognized in the Company's Consolidated Statement of Comprehensive Loss as financial income or expense.

The fair value of the Series A' Warrants was measured using Black & Scholes model. In estimating the warrants' fair value, the Company used the following assumptions:

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

	December 31, 2012	December 31, 2011
Risk-free interest rate	0.54%	0.9%
Expected volatility	127%	81.2%
Expected life (in years)	4	4.8
Expected dividend yield	0	0
Fair value:		
Warrants	\$ 72	\$ 159

5. On April 17, 2012, the Company completed a registered direct offering with several institutional investors. The Company received proceeds of approximately \$1,228, net of placement agent fees and other offering expenses in amount of \$149. Under the terms of the financing, the Company sold 540,000 Ordinary Shares at a price of \$2.55 per Share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 13,500 Ordinary Shares at an exercise price of \$3.1875 per share. The Option Agreement expires on April 12, 2017.
6. On May 22, 2012, the Company completed a registered direct offering with several institutional investors. The Company received proceeds of approximately \$1,934, net of placement agent fees and other offering expenses in amount of \$278. Under the terms of the financing, the Company sold 632,057 Ordinary Shares at a price of \$3.50 per Share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 15,802 Ordinary Shares at an exercise price of \$4.375 per share. The Option Agreement expires on May 16, 2017.
7. On May 31, 2012, the Company completed a registered direct offering with several institutional investors. The Company received proceeds of approximately \$5,921, net of placement agent fees and other offering expenses in amount of \$643. Under the terms of the financing, the Company sold 570,755 Ordinary Shares at a price of \$11.50 per Share. For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 14,269 Ordinary Shares at an exercise price of \$14.375 per share. The Option Agreement expires on May 24, 2017.
8. On August 8, 2012, the Company closed a public offering of 5,500,000 Ordinary Shares at a public offering price of \$5.00 per share for aggregate proceeds of \$24,986, net of placement agent fees and other offering expenses in amount of \$2,514. Under the terms of the underwriting agreement, the Company granted the underwriter an option, exercisable for 45 days, to purchase up to an additional 825,000 of the Company's Ordinary Shares at the same price, solely to cover over-allotments.

On August 28, 2012, the underwriter exercised its over-allotment option in full, and on August 29, 2012, the Company closed the sale of an additional 825,000 Ordinary Shares at a price to the public of \$5.00 per share for proceeds approximately \$3,836, net of placement agent fees and other offering expenses in amount of \$289.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

For its services in the offering, the placement agent received a Purchase Option Agreement to purchase 148,937 Ordinary Shares at an exercise price of \$6.25 per share. The Option Agreement expires on August 2, 2017.

In addition, the Company's former placement agent received a warrant certificate to purchase up to 26,481 Ordinary Shares at an exercise price of \$5.5769 per share, under its fee-tail agreement. The Option Agreement expires on November 24, 2014.

The fair value of the Series A' Warrants was measured using Black & Scholes model. In estimating the warrants' fair value, the Company used the following assumptions:

The following table summarizes information about the fair value of the above warrants related to share purchase agreements:

	Year ended December 31,		Note
	2012	2011	
January Warrants	\$ 25	\$ 1	10.b.1
A Warrants	39	5	10.b.2
A' Warrants	72	159	10.b.4
<b>Total</b>	<b>\$ 136</b>	<b>\$ 165</b>	

d. Stock option plans:

1. In March 2003, the Company adopted the 2003 Israeli Share Option Plan ("the 2003 Plan"), pursuant to which options may be granted to the Company's officers, directors, employees and consultants. Pursuant to the 2003 Plan, the Company has reserved an additional 3,139 shares for the 2003 Plan and for any other share option plans that have previously been, or in the future may be, adopted by the Company.

In July 2006, the Company adopted the 2006 Global Share Incentive Plan ("the 2006 Plan"), pursuant to which options may be granted to the Company's directors, employees, consultants and service providers. Pursuant to the 2006 Plan, the Company has reserved an additional 7,534 shares for the 2006 Plan and for any other share option plans that have previously been, or in the future may be, adopted by the Company. In November 2007, the Company approved an additional 8,334 shares for the 2006 Plan.

In December 2009, the Company approved an additional 25,000 Ordinary Shares for the 2006 Plan.

In October 2012, the Company approved an additional 853,770 Ordinary Shares for the 2006 Plan.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

During 2012, the Company's Board of Directors approved the granting of 50,000 Restricted Share Units ("RSUs") to certain employees. Furthermore, during 2012, the Company's shareholders approved the granting of 25,000 RSUs to certain members of the Company's Board of Directors. The total amount of 75,000 RSUs were granted during 2012.

The total number of options authorized for grant under the plans amounted to 910,751. As of December 31, 2012, an aggregate of 594,395 options of the Company are available for future grants.

Options granted under the 2001 and 2003 Plans typically vest, as set forth in each optionee's option agreement, over three years. Options granted under the 2006 Plan typically vest, as set forth in each optionee's option agreement, over four years. All options are exercisable for ten years from the grant of the option. Any options which are forfeited or unexercised become available for future grants. The exercise price equals the fair market value of the Company's shares on the date of the grant.

2. The following is a summary of the Company's stock options granted among the various plans:

	<u>Number of options</u>	<u>Weighted- average exercise price</u>	<u>Weighted- average remaining contractual term (in years)</u>	<u>Aggregate intrinsic value</u>
Outstanding at January 1, 2012	41,963	\$ 97.65		
Granted	283,500	\$ 5.27		
Exercised	(1,093)	\$ 1.48		
Forfeited	(19,218)	\$ 1,150		
Outstanding at the end of the year	<u>305,152</u>	<u>\$ 13.19</u>	<u>\$ 9.47</u>	<u>\$ 11.87</u>
Vested or expected to vest	<u>186,346</u>	<u>\$ 18.31</u>	<u>\$ 9.35</u>	<u>\$ 7.23</u>
Options exercisable at the end of the year	<u>25,761</u>	<u>\$ 98.12</u>	<u>\$ 6.85</u>	<u>\$ 1.12</u>

The weighted-average grant-date fair value of options granted during the twelve months ended December 31, 2012, 2011 and 2010 was \$4.62, \$7.35 and \$56.4, respectively. The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the fair market value of the Company's Ordinary Shares on December 31, 2012 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2012. This amount changes based on the fair market value of the Company's shares.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

During the year ended December 31, 2012, 1,093 options were exercised. As of December 31, 2012, there was \$719 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Company's stock option plans. The cost is expected to be recognized over a weighted average period of 3.74 years.

In February 2011, the board of directors of the Company approved the grant of 1,250 restricted shares. During 2012 no restricted shares were issued.

The following table summarizes information about options to employees and non-employees outstanding at December 31, 2012 under the Plans:

<u>Exercise price</u>	<u>Options outstanding at December 31, 2012</u>	<u>Weighted average remaining contractual life (years)</u>	<u>Weighted average exercise price</u>	<u>Options exercisable at December 31, 2012</u>	<u>Average exercise price of options exercisable</u>
\$ 0	141	1.27	\$ 0	141	\$ 0
\$ 0.6 -123	301,412	9.62	\$ 9.78	22,054	\$ 64
\$ 128-282	1,968	2.74	\$ 224	1,935	\$ 225
\$ 327-396	943	4.54	\$ 358	943	\$ 358
\$ 411-528	688	3.93	\$ 485	688	\$ 485
	<u>305,152</u>			<u>25,761</u>	

The following table sets forth the total stock-based compensation expense resulting from stock options and RSUs granted to employees and directors included in the Company's Consolidated Statement of Comprehensive Loss:

	<u>Year ended December 31,</u>	
	<u>2012</u>	<u>2011</u>
Cost of goods sold	\$ 15	\$ 19
Marketing and business development expenses	326	266
General and administrative expenses	182	138
Research and development costs, net	26	180
<u>Total</u> stock-based compensation expense	<u>\$ 549</u>	<u>\$ 603</u>

## e. Options and warrants issued to non-employees:

- As of December 31, 2012 there were no unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the Company's stock option plans.
- The Company had accounted for its options to non-employees under the fair value method of ASC 718 and ASC 505-50. The fair value of options granted with an exercise price of \$0, was equal to the share price at the date of grant.
- On April 11, 2011, the Company granted 1,167 warrants to purchase 1,167 Ordinary Shares of the Company, nominal value NIS 0.6 per share to its non-employee. The warrants are exercisable for a period of four years. During the year 2012, an expense of \$1 was recognized.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

**NOTE 11:- INCOME TAXES**

- a. Measurement of taxable income under the Income Tax (Inflationary Adjustments) Law, 1985:

Results for tax purposes in Israel are measured and reflected in real terms in accordance with the change in the Consumer Price Index (CPI) until the end of 2007. As explained in Note 2b, the consolidated financial statements are presented in dollars. The differences between the change in the Israeli CPI and in the NIS/dollar exchange rate causes a difference between taxable income or loss and the income or loss before taxes reflected in the consolidated financial statements. In accordance with paragraph 9(f) of ASC 740, the Company has not provided deferred income taxes on this difference between the reporting currency and the tax bases of assets and liabilities.

According to the law, until 2007 the results for tax purposes were adjusted for changes in the Israeli CPI.

In February 2008, the "Knesset" (Israeli parliament) passed an amendment to the Income Tax (Inflationary Adjustments) Law, 1985, which limits the scope of the law starting 2008 and thereafter. Starting 2008, the results for tax purposes are measured in nominal values, excluding certain adjustments for changes in the Israeli CPI carried out in the period up to December 31, 2007. The amendment to the law includes, inter alia, the elimination of the inflationary additions and deductions and the additional deduction for depreciation starting 2008.

- b. Tax benefits under Israel's Law for the Encouragement of Industry (Taxes), 1969 ("the Tax Law"):

The Company is currently qualified as an "industrial company", as defined by the Tax Law, and as such, is entitled to certain tax benefits, mainly amortization of costs relating to know-how and patents over eight years, the right to claim public issuance expenses over three years, and accelerated depreciation.

- c. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 ("the Law"):

The Company's production facilities in Israel have been granted "Approved Enterprise" status under the Law currently under separate investment programs. Pursuant to the Law, the Company elected the "Alternative Benefits Track" and has waived Government grants in return for tax exemption.

The main benefit arising from such status is the reduction in tax rates on income derived from "Approved Enterprises". Consequently, the Company is entitled to a two-year tax exemption and five years of tax at a reduced rate (25%).

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

Additionally, if the Company becomes a "foreign investors company", as defined by the Law, as such it will be entitled to a reduced tax rate of 10%-25% (based on the percentage of foreign ownership in each tax year) and an extension of three years for the benefit period. Since the Company has had no taxable income, the benefits have not yet commenced for any of the programs.

The period of tax benefits, detailed above, is subject to a limit of 12 years from the commencement of production, or 14 years from the approval date, whichever is earlier. The year's limitation does not apply to the exemption period.

The entitlement to the above benefits is conditional upon the Company's fulfilling the conditions stipulated by the Law, regulations published thereunder and the letters of approval for the specific investments in "Approved Enterprises". In the event of failure to comply with these conditions, the benefits may be canceled and the Company would be required to refund the amount of tax benefits, plus a consumer price index linkage adjustment and interest.

As of December 31, 2012, management believes that the Company will be able to meet all of the aforementioned conditions.

If these retained tax-exempt profits attributable to the "Approved Enterprise" are distributed in a manner other than in the complete liquidation of the Company, they would be taxed at the corporate tax rate at the applicable rate (10%-25%) in respect of the gross amount of the amount that the Company distributed. The Company is required to withhold tax at the source at a rate of 15% from any dividends distributed from income derived from the Approved Enterprise.

Income from sources other than the "Approved Enterprise" during the benefit period will be subject to tax at the regular corporate tax rate.

On April 1, 2005, an amendment to the Law came into effect ("the Amendment") and has significantly changed the provisions of the Law. The Amendment limits the scope of enterprises, which may be approved by the Investment Center by setting criteria for the approval of a facility as a Beneficiary Enterprise such as provision generally requiring that at least 25% of the Beneficiary Enterprise's income will be derived from export. Additionally, the Amendment enacted major changes in the manner in which tax benefits are awarded under the Law so that companies no longer require Investment Center approval in order to qualify for tax benefits.

If the Company pays a dividend out of income derived from the Beneficiary Enterprise during the tax exemption period, such income will be subject to corporate tax at the applicable rate (10%-25%) in respect of the gross amount of the dividend that the Company may be distributed. The Company is required to withhold tax at the source at a rate of 15% from any dividends distributed from income derived from the Beneficiary Enterprise. Under the Amendment, the benefit period for the Company will be extended until the earlier of (1) seven years from the commencement year or (2) twelve years from the first day of the year of election. This period may be extended for a Beneficiary Enterprise owned by a "foreign investor's company" during all or part of the benefit period.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****U.S. dollars in thousands (except share and per share data)**

---

However, the Amendment provides that terms and benefits included in any letter of approval already granted will remain subject to the provisions of the Law as they were on the date of such approval.

As of December 31, 2012, the Company did not generate income under the Law prior to and after the Amendment.

Amendments to the Law:

In December 2010, the "Knesset" (Israeli Parliament) passed the Law for Economic Policy for 2011 and 2012 (Amended Legislation), 2011, which prescribes, among others, amendments to the Law. The amendment became effective as of January 1, 2011. According to the amendment, the benefit tracks in the Law were modified and a flat tax rate applies to the Company's entire preferred income. The Company will be able to opt to apply (the waiver is non-recourse) the amendment and from then on it will be subject to the amended tax rates that are: 2011 and 2012 - 15% (in development area A - 10%), 2013 and 2014 - 12.5% (in development area A - 7%) and in 2015 and thereafter - 12% (in development area A - 6%).

The Company examined the possible effect of the amendment on the financial statements, if at all, and at this time do not believe it will opt to apply the amendment.

On November 5, 2012, the "Knesset" (Israeli Parliament) passed amendment No. 68 to the Law which prescribed reduction of the corporate tax rate applied to undistributed retained earnings. Under the new structure, companies can elect to account for tax on undistributed earnings prior to distribution. Depending on their election, companies will pay a corporate income tax ranging from 6% to 17.5%, with no change to the dividend withholding tax rate. The change is temporary and will expire one year from the date of enactment.

At this time the Company does not believe the amendment has any possible effect on the financial statements.

d. Tax rates applicable to the income of the Company:

On December 5, 2011, the Israeli Parliament (the Knesset) passed the Law for Tax Burden Reform (Legislative Amendments), 2011 ("the Law") which, among others, cancels effective from 2012, the scheduled progressive reduction in the corporate tax rate. The Law also increases the corporate tax rate to 25% in 2012. In view of this increase in the corporate tax rate to 25% in 2012, the real capital gains tax rate and the real betterment tax rate were also increased accordingly.

e. Deferred income taxes:

Deferred taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company and its subsidiary's deferred tax assets are comprised of operating loss carryforward and other temporary differences. Significant components of the Company and its subsidiary deferred tax assets are as follows:

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Tax asset in respect of:		
Operating loss carryforward and deductions	\$ 27,658	\$ 22,642
Reserves, allowances and other	10	15
Net deferred tax asset before valuation allowance	27,668	22,657
Valuation allowance	(27,668)	(22,657)
<b>Net deferred tax asset</b>	<b>\$ -</b>	<b>\$ -</b>

The Company and its subsidiary have provided full valuation allowances in respect of deferred tax assets resulting from operating loss carryforward and other temporary differences. Management currently believes that since the Company and its subsidiary have a history of losses it is more likely than not that the deferred tax regarding the loss carryforward and other temporary differences will not be realized in the foreseeable future.

f. Reconciliation of the theoretical tax expense (benefit) to the actual tax expense (benefit):

The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowances in respect of deferred taxes relating to accumulated net operating losses carried forward among the various subsidiary worldwide due to the uncertainty of the realization of such deferred taxes and the effect of the "Approved Enterprise" and few non deductible expense.

g. Net operating losses carryforward:

The Company has estimated accumulated losses for tax purposes as of December 31, 2012, in the amount of approximately \$86,253, which may be carried forward and offset against taxable income in the future for an indefinite period.

Rosetta Genomics Inc. is subject to U.S. income taxes. As of December 31, 2012, Inc. has estimated total available carryforward tax losses as of December 31, 2012 of approximately \$14,477 to offset against future tax profits which expires in the years 2013 to 2032.

h. Income taxes for the twelve months ended December 31, 2012 and 2011:

The Company and its subsidiary have not recorded any tax expenses during the 12 months ended December 31, 2012 and 2011, as the Company has losses. The Company believes that it is more likely than not that the deferred tax assets in respect of these carryforward losses will not be utilized, and therefore the Company recorded a valuation allowance for the entire balance of the deferred tax asset relating to the carryforward losses.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

U.S. dollars in thousands (except share and per share data)

- i. The Company adopted the provisions of ASC 740 for uncertain tax positions on January 1, 2007, and there was no effect on the financial statements. As a result, the Company did not record any cumulative effect related to adopting ASC 740 for uncertain tax positions. The Company did not record a liability deriving from the implementation of ASC 740 for uncertain tax positions.

**NOTE 12:- FINANCIAL EXPENSE (INCOME), NET**

	Year ended December 31,		
	2012	2011	2010
<b>Financial income:</b>			
Interest income on short-term deposits	\$ (39)	\$ (3)	\$ (32)
Interest and realized gain on marketable securities	-	(2)	(208)
Foreign currency adjustments gains and other	(33)	(15)	(462)
Revaluation of warrants related to share purchase agreement	-	(1,637)	(1,072)
	<u>(72)</u>	<u>(1,657)</u>	<u>(1,774)</u>
<b>Financial expenses:</b>			
Bank and interest expenses	31	19	36
Foreign currency adjustments losses	-	3	473
Revaluation of warrants related to share purchase agreement	635	-	-
Issuance cost derived from warrants related to share purchase agreement	-	-	244
Interest on convertible debenture	288		
Amortization of discount and change in fair value of embedded conversion feature in the convertible debenture	1,547	-	-
Others	-	251	79
	<u>2,501</u>	<u>273</u>	<u>832</u>
	<u>\$ 2,429</u>	<u>\$ (1,384)</u>	<u>\$ (942)</u>

**NOTE 13:- SUBSEQUENT EVENTS**

On February 18, 2013, the Company's board of directors approved a grant to employees of options to purchase a total of 12,500 Ordinary Shares, at an exercise price of \$ 4.69 per share. Such options to employees shall vest over a period of 4 years commencing on the above date.

-----