

XTL BIOPHARMACEUTICALS LTD  
Form 20-F  
April 25, 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

OR

**TRANSITIONAL 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**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

Commission file number: **000-51310**

**XTL BIOPHARMACEUTICALS LTD.**

(Exact name of registrant as specified in its charter)

**Israel**

(Jurisdiction of incorporation or organization)

Herzliya Business Park

85 Medinat Hayehudim, Building G, PO Box 4033

Herzliya Pituach 46140, Israel

(Address of principal executive offices)

David Grossman

Chief Executive Officer

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Herzliya Pituach 46140, Israel

Tel: +972-9-955-7080

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(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:**

American Depositary Shares, each representing twenty Ordinary Shares, par value NIS 0.1 (Title of Class)	None (Name of each exchange on which registered)
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**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.**

1,898,685 American Depositary Shares      229,471,669 Ordinary Shares

**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 period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the**

past 90 days.

Yes  No

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

Yes  No

**Indicate by check mark 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  Other  
by the International Accounting Standards Board

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

Item 17  Item 18

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

Yes  No

**XTL BIOPHARMACEUTICALS LTD.**

**ANNUAL REPORT ON FORM 20-F**

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## **SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS**

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “estimate,” and similar expressions are intended to identify such forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under “Item 3. Key Information–Risk Factors,” “Item 4.- Information on the Company,” “Item 5. Operating and Financial Review and Prospects,” and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.



## **PART I**

*Unless the context requires otherwise, references in this report to “XTL,” “the Company,” “we,” “us” and “our” refer to XTL Biopharmaceuticals Ltd. and our consolidated subsidiaries, InterCure Ltd., InterCure Inc., InterCure UK, Xtepo Ltd, XTL Biopharmaceuticals, Inc. and XTL Development, Inc. We have prepared our consolidated financial statements in United States, or US, dollars and in accordance with International Financial Reporting Standards, or IFRS. All references herein to “dollars” or “\$” are to US dollars, and all references to “Shekels” or “NIS” are to New Israeli Shekels.*

### **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 Financial Data**

The tables below present selected financial data for the fiscal years ended as of December 31, 2012, 2011, 2010, 2009 and 2008. We have derived the selected financial data for the fiscal years ended December 31, 2012, 2011 and 2010, from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board (“IASB”). Until 2009, we have presented our financial statements using the accounting standards and principles as set forth under United States Generally Accepted Accounting Principles (“US GAAP”). Since 2009 and effective since January 1, 2007, we have prepared our consolidated financial statements in accordance with IFRS. The selected financial data for the fiscal years ended as of December 31, 2012, 2011, 2010, 2009 and 2008 are presented in accordance with IFRS. You should read the selected financial data in conjunction with “Item 5. Operating and Financial Review and Prospects,” “Item 8. Financial Information” and “Item 18. Financial Statements.”



## Consolidated Statements of Comprehensive income:

	Year ended December 31,				
	2012	2011	2010	2009	2008
	U.S Dollars in thousands				
Revenues	938	-	-	-	5,940
Cost of revenues	(380)	) -	-	-	(1,841 )
Gross profit	558	-	-	-	4,099
Research and development costs	(99	) (158	) (64	) -	(11,722 )
Selling and marketing expenses	(848	) -	-	-	-
General and administrative (expenses ) income	(2,769	) (1,078	) (1,222	) *)2,429	(3,937 )
Impairment loss of intangible asset	-	-	-	-	(7,500 )
Other gains, net	802	12	30	139	288
Operating income (loss)	(2,356	) (1,224	) (1,256	) 2,568	(18,772 )
Finance income	60	24	6	6	331
Finance costs	(15	) (7	) (7	) (10	) (17 )
Financial income (costs), net	45	17	(1	) (4	) 314
Earnings from investment in associate	569	-	-	-	-
Income (loss) before taxes on income tax benefit	(1,742	) (1,207	) (1,257	) 2,564	(18,458 )
	-	-	-	23	31
Net income (loss) for the year	(1,742	) (1,207	) (1,257	) 2,587	(18,427 )
Other comprehensive income:					
Foreign currency translation adjustments	114	-	-	-	-
Total other comprehensive income	114	-	-	-	-
Total comprehensive income (loss) for the year	(1,628	) (1,207	) (1,257	) 2,587	(18,427 )
Income (loss) for the year attributable to:					
Equity holders of the Company	(1,390	) (1,207	) (1,257	) 2,587	(18,427 )
Non-controlling interests	(352	) -	-	-	-
	(1,742	) (1,207	) (1,257	) 2,587	(18,427 )
Total comprehensive income (loss) for the year attributable to:					
Equity holders of the Company	(1,276	) (1,207	) (1,257	) 2,587	(18,427 )
Non-controlling interests	(352	) -	-	-	-

	(1,628 )	(1,207 )	(1,257 )	2,587	(18,427 )
Basic and diluted earnings (loss) per share (in U.S. dollars)	(0.006 )	(0.006 )	(0.011 )	0.044	(0.315 )

Weighted average number of issued ordinary shares	217,689,926	201,825,645	113,397,846	58,561,065	58,553,864
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\*) Including reduced expenses which result from forfeiture of shares that were contingent on the performance of the former chairman and former CEO.

## Consolidated Statements of Financial Position Data:

	Year ended December 31,				
	2012	2011	2010	2009	2008
	U.S Dollars in thousands				
Cash, cash equivalents and bank deposits	3,312	1,495	1,066	412	2,924
Working capital	2,143	955	259	(151)	1,433
Total assets	11,086	4,073	3,797	715	3,402
Long term liabilities	13	-	-	-	-
Total shareholders' equity	7,353	3,444	2,834	7	1,474
Non-controlling interests	2,071	-	-	-	-

**Investment in Proteologics Ltd**

On November 21, 2012, we acquired from Teva Pharmaceutical Industries Ltd. (Hereinafter: "Teva"), in a transaction outside of the Tel Aviv stock exchange ("TASE") market, 4,620,356 ordinary shares of NIS 1.0 par value each of Proteologics Ltd. (Hereinafter: "Proteologics"), which comprises Teva's full holdings in Proteologics and approximately 31.35% of the issued and outstanding share capital of Proteologics (as of the date of acquisition; approximately 31.24% as of December 31, 2012), in consideration of approximately NIS 6.5 million (approximately \$1.7 million).

Proteologics is a public company whose shares are listed on the TASE and that specializes in the discovery and development of drugs that operate on various components of the Ubiquitin system that was discovered by Dr. Avram Hershko and Dr. Aaron Ciechanover, 2004 Nobel Prize laureates in chemistry for this discovery. For further details on Proteologics' activity see item 4. "Information on the Company - Business Overview".

**Acquisition of control over InterCure Ltd.**

On June 13, 2012, we entered into an agreement with InterCure Ltd. (hereinafter "InterCure") according to which, subject to carrying out the debt settlement pursuant to Article 350 to the Israeli Companies Law, 1999 ("the Debt Settlement") before the transaction, InterCure will convert all of its debts into Ordinary shares of InterCure based on the distribution mechanism determined with all of its debtors (including its employees). The Company will acquire control over InterCure in consideration for investing in InterCure an aggregate amount of approximately \$ 2.7 million, subject to adjustments, as detailed below. Also, in addition to the Company's investment in InterCure, a third party ("Medica Fund") will invest approximately \$ 630,000 in InterCure (subject to adjustments).

InterCure is a public company whose shares are traded on the TASE and which develops a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension.

The transaction was consummated on July 25, 2012 (the "InterCure Closing"). The Company acquired 16,839,532 Ordinary shares of InterCure with no par value in consideration of a private placement of 7,165,662 Ordinary shares of the Company of NIS 0.1 par value each whose value on the date of signing the agreement, measured based on the quoted market price of the Company's shares on the TASE, approximated \$ 2.2 million (the market value of such shares on the InterCure Closing date was approximately \$2.47 million), which represented a pre-money valuation of InterCure of \$ 1.75 million, after all of InterCure's debts were converted as described above ("InterCure's adjusted value").

In addition, the Company provided InterCure an amount of approximately \$ 150,000 in cash on the basis of InterCure's adjusted value. After effecting the above allocation, the Company held about 50.79% of the issued and outstanding share capital of InterCure. The investment of Medica Fund on the date of closing on the basis of InterCure's adjusted value amounted to approximately \$ 460,000.

Further, the Company and Medica Fund provided InterCure a loan of \$ 500,000 (the Company's share is \$ 330,000) for a period of up to ten months at an overall interest rate of 15%. The Company and Medica Fund have the right to convert the loan into an additional 11,546,507 shares of InterCure (the Company's share is 7,620,695 shares) which will constitute, upon conversion and assuming full dilution on the date of closing, approximately 24.47% of the issued and outstanding share capital of InterCure (the Company's share in the convertible loan is 16.15% of the issued and outstanding share capital of InterCure). On August 6, 2012, Medica Fund converted the loan it provided InterCure into shares and its stake in InterCure rose to approximately 23.69% of the issued and outstanding share capital of InterCure (about 18.61% on a fully diluted basis, as of the date of the loan's conversion). On March 3, 2013, the Company notified InterCure that if the Company decides not to convert the loan granted to InterCure into shares, it will provide InterCure another six months to repay the loan ("the repayment date"), provided that if any funds are received from InterCure from any source, excluding receipts from operating income, by the repayment date, InterCure will be required to repay the outstanding loan amount, or any part thereof, in installments of at least \$ 50,000 each.

As of the date of the approval of the financial statements, our stake in InterCure is approximately 45.41% of the issued and outstanding share capital of InterCure. However, if we convert the loan extended to InterCure into shares, our stake in InterCure will be approximately 54.72%. Assuming that all of the options granted to employees and directors in InterCure are exercised, and assuming the above loan is converted, our stake in InterCure will be approximately 52.63%.

In October 2012, InterCure granted 20,185,184 performance contingent options (exercisable into 20,185,184 Ordinary shares with no par value) to Giboov (see "Item 10. Additional Information - Material Contracts"). If all of the performance contingent options granted to Giboov are exercised, and assuming the conversion of said loan and the exercise of all of the options granted to directors and employees, our stake in InterCure will be approximately 36.69% of the issued and outstanding share capital of InterCure.

#### **Exclusive License for the patent on SAM-101**

On March 24, 2011, we entered into a Memorandum of Understanding with MinoGuard, pursuant to which we shall acquire the exclusive rights to SAM-101 by obtaining an exclusive license to use MinoGuard's entire technology. SAM-101 is based on a combination of anti-psychotic drugs with minocycline, a recognized medicinal compound. On November 30, 2011, we completed our engagement with MinoGuard for the worldwide exclusive license, as follows: We have engaged in a worldwide exclusive license with MinoGuard by which we shall develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on Schizophrenia. We will conduct clinical

trials, develop, register, market, distribute and sell the drugs that will emerge from MinoGuard's technology, with no limitations for a specific disorder ("the License"). We shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of its net sales and/or percentage from the Company third-party out-license receipts in the range of 7.5%-20% according to the clinical phase of the drug at the time of an out-license transaction. It should be noted that the Company has the sole discretion to pay any of the above amounts in cash or by way of issuing of its shares to MinoGuard. In addition to the above payments, if we shall not commence a Phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of \$45,000 for the initial year, which will increase by \$90,000 per year and up to \$675,000 for the eighth year of license. According to the agreement receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter. As of the date of this report the Company is preparing and researching the regulatory and clinical path for this clinical trial. The Company estimates that the preparation for this clinical trial shall be completed by the end of 2013 and accordingly the Company anticipates paying MinoGuard the aforesaid license fee in an amount of \$45,000.



**Exclusive License for the use patent on Erythropoietin**

On March 18, 2009, we entered into an asset purchase agreement with Bio-Gal Ltd. (hereinafter "Bio-Gal"), a private company, for the rights to a use patent on Recombinant Human Erythropoietin, or rHuEPO, for the treatment of multiple myeloma, or "MM". On December 31, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL shall acquire all the issued and outstanding share capital of XTEPO Ltd. (a special purpose company that was established by Bio-Gal's shareholders who also transferred Bio-Gal's intellectual property rights on rHuEPO and will raise by way of a private placement approximately \$1.5 million) (hereinafter "XTEPO"). We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. The course of the disease is progressive, and various complications occur, until death. In the United States alone, there are approximately 74,800 people living with MM, with about 22,350 new cases that are expected to be diagnosed in 2013 (Cancer Facts & Figures 2013), making MM the second most prevalent blood cancer.

On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the closing conditions had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to Sections 104 and 103 to the Israeli Income Tax Ordinance (Revised), 1961.

In accordance with the terms of the amended asset purchase agreement, we issued to XTEPO's shareholders approximately 133 million ordinary shares representing 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are also obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful completion of Phase 2. Such payment of \$350,000 mentioned above shall be made to Yeda Research and Development Company Ltd. ("Yeda") upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO of a minimum amount of \$2 million at any time after the completion of the Phase 2 (See notes 1 and 14(c) to the consolidated financial statements: General, Intangible Asset, and Item 4. "Business Overview - Development Status").

On June 1, 2012, the Company applied for the relisting of its ADRs on the NASDAQ (after the ADRs had been delisted from trade on the NASDAQ in July 2009), subject to compliance with all the criteria reviewed by the NASDAQ admissions committee, including minimum ADR price (according to the various listing criteria). On September 24, 2012, the Company's Board approved a change in the number of shares underlying the ADRs such that 20 Ordinary Company shares will constitute a single ADR, this in order to support the Company's compliance with the NASDAQ's ADR listing conditions. The record date of change in the ADR ratio is October 4, 2012. As of the date of the financial statements, the relisting proceeding is still underway and the Company is holding negotiations with the NASDAQ compliance committee for finalizing the proceeding. There is no certainty that the process of re-listing our ADRs in the NASDAQ will end successfully.

**B. Capitalization And Indebtedness**

Not applicable.

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**C. Reasons For Offer And Use Of Proceeds**

Not applicable.

**D. Risk Factors**

*Before you invest in our ordinary shares or American Depositary Receipts representing American Depositary Shares, which we refer to in this report as ADRs, you should understand the high degree of risk involved. You should carefully consider the risks described below and other information in this report, including our financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or ADRs. If any of the following risks actually occur, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our ordinary shares or ADRs could decline and you could lose part or all of your investment.*

**Risks Related to Our Business**

*We have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future in our drug development activity and may incur losses in our medical device activity and may never become profitable.*

You should consider our prospects in light of the risks and difficulties frequently encountered by development stage companies. We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. As of December 31, 2012, we had an accumulated accounting deficit of approximately \$143.6 million (our current carry forward tax losses are substantially lower - for our current carry forward tax losses, see “Item 5. Operating and Financial Review and Prospects - Governmental Economic, Fiscal, Monetary or Political Policies that Materially Affected or Could Materially Affect Our Operations”). We have not yet commercialized any of our drug candidates or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, consummate out-licensing agreements, obtain regulatory approval for our drug candidates and technologies and successfully commercialize them.

In addition, in July 2012 we acquired the control over InterCure, a public company whose shares are traded on the TASE and which develops a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension (see “Item 10. Additional Information - Material Contracts”). As of the date of this report, we are holding approximately 45.41% of the issued and outstanding shares of InterCure. Since the acquisition and until

December 31, 2012, InterCure's revenues amounted to approximately \$938,000 and the operating loss amounted to approximately \$617,000 (including the amortization of identifiable intangible assets and other Purchase Price Allocation ("PPA") adjustments in the amount of approximately \$176,000). Despite the fact that InterCure's management is acting to increase InterCure's revenues and operating profit, it is possible that InterCure will not be profitable within the next coming years, if at all.

**Risks Related to both of our Drug Development and Medical Device businesses:**

***If our competitors develop and market products that are less expensive, more effective or safer than our products, our revenues and results may be harmed and our commercial opportunities may be reduced or eliminated.***

The pharmaceutical industry is highly competitive. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. For a discussion of these competitors and their drug candidates, see “Item 4. Information on the Company - Business Overview – Competition,” below. Some of these potential competing drugs are already commercialized or are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing safe, effective drugs, our products may not compete successfully with products produced by our competitors, who may be able to market their drugs more effectively.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields present substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop products that could render our technologies or our drug candidates obsolete or noncompetitive.

Development of new drugs, medical technologies and competitive medical devices may damage the demand for our medical device products (through InterCure) without any certainty that InterCure will successfully and effectively contend with its competitors. In 2010, InterCure discovered a competitive product in the UK that claimed to be a non-medical treatment for hypertension which was cheaper than the product it developed. Tests executed by InterCure and its consultants showed that the competitive device does not interactively guide breathing during exercise (a method patented by InterCure and proven effective in reducing hypertension). We cannot, at this stage, assess whether and how sales of the competitive device will affect sales of InterCure in the UK. Should sales of the competitive device increase, this may damage InterCure and the Group's financial results.

***If we lose our key personnel or are unable to attract and retain additional personnel, our business could be harmed.***

As of April 24, 2013, XTL had four full-time employees (one of whom is an officer, who is engaged with the Company as a service provider) and three part-time service providers (one of whom is an officer). As of the same date InterCure had 12 full-time employees and service providers and one part-time service provider.

To successfully develop our drug candidates and technologies, we must be able to attract and retain highly skilled personnel, including consultants and employees. The retention of their services cannot be guaranteed.

The success of InterCure greatly depends on its ability to retain, recruit and develop professional staffs and specifically key management personnel and professional teams. InterCure's failure to retain and/or recruit such professionals, particularly given the significant downsizing made by it in 2011 and during the reported period, might impair its performance and materially affect its technological and product development capabilities and its product marketing ability. In addition, upon completion of the Debt Settlement (see above), InterCure will be required to act to recruit additional scientific and patent skilled professionals as well as online sales and marketing teams, given that this market is characterized by competitiveness in the field of skilled manpower.

*Any acquisitions or in-licensing transactions we make may dilute your equity or require a significant amount of our available cash and may not be scientifically or commercially successful.*

As part of our business strategy, we may effect acquisitions or in-licensing transactions to obtain additional businesses, products, technologies, capabilities and personnel. If we complete one or more such transactions in which the consideration includes our ordinary shares or other securities, your equity in us may be significantly diluted. If we complete one or more such transactions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Specifically, as per the terms of our amended agreement with Bio-Gal and XTEPO, we issued approximately 133 million ordinary shares par value NIS 0.10 representing 69.44% of our then issued and outstanding ordinary share capital. Also, on November 30, 2011 we entered into a license agreement with MinoGuard by which we received an exclusive license to use SAM-101 in return for royalties on sales and milestones that may be paid in cash or our ordinary shares. In July 25, 2012 we issued 7,165,662 ordinary shares par value NIS 0.10 to InterCure, representing 3.14% of our then issued and outstanding ordinary share capital. In addition, on November 21, 2012 we acquired 4,620,356 shares, of NIS 1.00 par value each, of Proteologics from Teva, which represents approximately 31.35% of Proteologics' issued and outstanding share capital, in consideration for an amount of approximately NIS 6.5 million (approximately \$1.66 million). (see "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents" and "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below). Acquisitions and in-licensing transactions also involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology or personnel of the business;
  - our inability to attract and retain management, key personnel and other employees necessary to conduct the business;
  - our inability to maintain relationships with key third parties, such as alliance partners, associated with the business;
  - exposure to legal claims for activities of the business prior to the acquisition;
  - the diversion of our management's attention from our core business; and
- the potential impairment of substantial goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

In addition, the basis for completing the acquisition or in-licensing could prove to be unsuccessful as the drugs or processes involved could fail to be scientifically or commercially viable. In addition, we may be required to pay third parties substantial transaction fees, in the form of cash or ordinary shares, in connection with such transactions.

If any of these risks occur, it could have an adverse effect on both the business we acquire or in-license and our existing operations.

***We face product liability risks and may not be able to obtain adequate insurance.***

The use of our drug candidates and technologies in clinical trials, and the sale of any approved products (drugs or medical devices), exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates and technologies or limit commercialization of any approved products.



We believe that we will be able to obtain sufficient product liability insurance coverage for our planned clinical trials and sales of medical devices. We intend to expand our insurance coverage to include the commercial sale of any approved products, other than RESPeRATE, if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

injury to our reputation;

inability to continue to develop a drug candidate or technology;

withdrawal of clinical trial volunteers; and

loss of revenues.

Consequently, a product liability claim or product recall may result in material losses.

***The Company's holding in InterCure may be diluted to the extent that it will not be consolidated into our consolidated financial statements, should options already allocated or that shall be allocated to InterCure employees and service providers be exercised or should InterCure raise capital by means of issuing shares.***

As at the date of approval of this report the Company holds approx. 45.41% of InterCure shares capital. Additionally, the Company granted InterCure a loan of \$330,000 convertible into 7,620,695 ordinary shares of InterCure. Should the Company convert the loan granted to InterCure into shares, its holdings in InterCure shall be 54.72% of the issued and outstanding share capital of InterCure. As part of the course of its business InterCure allocated warrants that are contingent on performance to a certain service provider and share options to employees and other service providers. Furthermore, InterCure may allocate additional share options to any of its employees or service providers or raise capital by issuing securities. Should share options or warrants be exercised or shares issued, the Company's holdings in InterCure might be diluted to such an extent that the Company will not be able to consolidate InterCure's financial statements.

***Our financial results may fluctuate from quarter to quarter.***

Demand for our products varies from quarter to quarter, and these variations may cause our revenue to fluctuate significantly. As a result, it is difficult for us to accurately predict sales for subsequent periods. In addition, we base our production, inventory and operating expenditure levels on anticipated orders. If orders are not received when expected in any given quarter, expenditure levels could be disproportionately high in relation to revenue for that quarter. A number of additional factors over which we have limited control may contribute to fluctuations in our financial results, including:

- the willingness of individuals to pay directly for medical procedures, due to the general lack of reimbursement by third-parties;

- availability of attractive equipment financing terms for our customers, which may be negatively influenced by the current economic climate;

- changes in our ability to obtain and maintain regulatory approvals;

- increases in the length of our sales cycle;

performance of our direct sales force and independent distributors; and

delays in, or failures of, product and component deliveries by our subcontractors and suppliers.

**Risks related to our drug development business**

***If we are unable to successfully complete our clinical trial programs for our drug candidates, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.***

Whether or not and how quickly we complete clinical trials depends in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we are able to collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases and stages as we are studying. In addition, the multi-national nature of our studies adds another level of complexity and risk as the successful completion of those studies is subject to events affecting countries outside the United States. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis.

***If third parties on which we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our products.***

We depend on independent clinical investigators, and other third-party service providers to conduct the clinical trials of our drug candidates and technologies, and we expect to continue to do so. We also may, from time to time, engage a clinical research organization for the execution of our clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but we do not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the US Food and Drug Administration, or the FDA, and/or other foreign regulatory agencies/authorities relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trial's plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products, or could result in enforcement action against us.

*Our international clinical trials may be delayed or otherwise adversely impacted by social, political and economic factors affecting the particular foreign country.*

We may conduct clinical trials in different geographical locations. Our ability to successfully initiate, enroll and complete a clinical trial in any of these countries, or in any future foreign country in which we may initiate a clinical trial, are subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with clinical research organizations and physicians;
- different standards for the conduct of clinical trials and/or health care reimbursement;

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our inability to locate qualified local consultants, physicians, and partners;

the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and

general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.

Any disruption to our international clinical trial program could significantly delay our product development efforts.

***If the clinical data related to our drug candidates and technologies do not confirm positive early clinical data or preclinical data, our corporate strategy and financial results will be adversely impacted.***

Our drug candidates and technologies are either in preclinical or clinical stages. Specifically, our lead product candidates, Recombinant Human Erythropoietin (rHuEPO) and SAM-101 are planned for a Phase 2 clinical program. As for the Diversity Oriented Synthesis, or DOS program, which has not yet been tested in humans, it is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of the reverted DOS technology from Presidio Pharmaceuticals Inc. (Hereinafter: "Presidio") (see "Item 10. Additional Information - Material Contracts"). In order for our candidates to proceed to later stage clinical testing or marketing approval, they must show positive clinical and/or preclinical data.

While rHuEPO has shown promising preclinical data and has also shown promising clinical observation data for the extension and improvement of the quality of life of Multiple Myeloma terminal patients prior to it being licensed to us, preliminary results of pre-clinical, clinical observations or clinical tests do not necessarily predict the final results, and promising results in pre-clinical, clinical observations or early clinical testing might not be obtained in later clinical trials. While SAM-101 has shown improvement in the positive symptoms of schizophrenia as well as the patients' cognitive state, minimizes the negative symptoms (social parameters and patient cognition) and reduces weight gain side effects among patients, preliminary results of pre-clinical, clinical observations or clinical tests do not necessarily predict the final results, and promising results in pre-clinical, clinical observations or early clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Any negative results from future tests may prevent us from proceeding to later stage clinical testing or marketing approval, which would materially impact our corporate strategy and our financial results may be adversely impacted.

***We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals. If our drug candidates and technologies do not receive the necessary regulatory approvals, we will be unable to commercialize our products.***

We have not received, and may never receive, regulatory approval for commercial sale for any of our drug products. We currently do not have any drug candidates or technologies pending approval with the FDA or with regulatory authorities of other countries. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. In order to obtain FDA approval to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we and/or our potential partners will have to conduct extensive pre-clinical testing and “adequate and well-controlled” clinical trials.

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Pre-clinical testing and clinical development are long, expensive and uncertain processes. Clinical trials are very difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

- obtaining regulatory approvals to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment due to narrow screening requirements;
- the inability of patients to meet protocol requirements imposed by the FDA or other regulatory authorities;
- the need or desire to modify our manufacturing process;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Following the completion of a clinical trial, regulators may not interpret data obtained from pre-clinical and clinical tests of our drug candidates and technologies the same way that we do, which could delay, limit or prevent our receipt of regulatory approval. In addition, the designs of our ongoing clinical trials were not, and the designs of future clinical trials may not be, reviewed or approved by the FDA prior to their commencement, and consequently the FDA could determine that the parameters of any existing or future studies are insufficient to demonstrate proof of safety and efficacy in humans. Failure to approve a completed study could also result from several other factors, including unforeseen safety issues, the determination of dosing, low rates of patient recruitment, the inability to monitor patients adequately during or after treatment, the inability or unwillingness of medical investigators to follow our clinical protocols, and the lack of effectiveness of the trials.

Specifically, in 2008, Amgen Inc. announced that US regulators added black box, or black label, warnings to its erythropoietin drugs, Epogen and Aranesp. Similar warnings were also added to Johnson and Johnson’s Procrit which is also licensed from Amgen. In the United States, a black box warning is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects. A black box warning means that medical

studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. The warnings warn that the erythropoietin drugs increased death and accelerated tumor growth in patients with several types of cancer, including breast and cervical. Prior labeling warned of similar risks in other types of cancers.

If the clinical trials fail to satisfy the criteria required, the FDA and/or other regulatory agencies/authorities may request additional information, including additional clinical data, before approval of marketing a product. Negative or inconclusive results or medical events during a clinical trial could also cause us to delay or terminate our development efforts. If we experience delays in the testing or approval process, or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates and technologies may be materially impaired.



Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after achieving promising results in earlier trials. It may take us many years to complete the testing of our drug candidates and technologies, and failure can occur at any stage of this process.

Even if regulatory approval is obtained, our products and their manufacture will be subject to continual review, and there can be no assurance that such approval will not be subsequently withdrawn or restricted. Changes in applicable legislation or regulatory policies, or discovery of problems with the products or their manufacture, may result in the imposition of regulatory restrictions, including withdrawal of the product from the market, or result in increased costs to us.

***Because all of our proprietary drug candidates and technologies are licensed to us by third parties, termination of these license agreements could prevent us from developing our drug candidates.***

We do not own all of our drug candidates and technologies. We have licensed the rights, patent or otherwise, to our drug candidates from third parties. Specifically, we have licensed a patent on SAM-101 for the treatment of psychotic disorders, focusing on Schizophrenia from MinoGuard, who in turn licensed it from Mor. Furthermore, we licensed a use patent for the use patent on Recombinant Human Erythropoietin (rHuEPO) for the prolongation of multiple myeloma patients' survival and improvement of their quality of life from Bio-Gal, who in turn licensed it from Mor and Yeda, and we have licensed DOS from VivoQuest, Inc. (see "Item 10. Additional Information-Material Contracts"). These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed drugs and technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates and technologies. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development, collaboration and commercialization of our drug candidates or could require or result in litigation or arbitration, which could be time-consuming and expensive. For a further discussion on our license agreements, the patent rights related to those licenses, and the expiration dates of those patent rights, see "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents" and "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below.

***If we do not establish or maintain drug development and marketing arrangements with third parties, we may be unable to commercialize our drug candidates and technologies into products.***

We are an emerging company and do not possess all of the capabilities to fully commercialize our drug candidates and technologies on our own. From time to time, we may need to contract with third parties to:

- assist us in developing, testing and obtaining regulatory approval for some of our compounds and technologies;
- manufacture our drug candidates; and
- market and distribute our products.

We can provide no assurance that we will be able to successfully enter into agreements with such third-parties on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our drug candidates and technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our drug candidates and technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products will be scientifically or commercially successful.

***Even if we or our collaborative/strategic partners or potential collaborative/strategic partners receive approval to market our drug candidates, if our products fail to achieve market acceptance, we will never record meaningful revenues.***

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

- perceptions by members of the health care community, including physicians, of the safety and efficacy of our products;
- the rates of adoption of our products by medical practitioners and the target populations for our products;
- the potential advantages that our products offer over existing treatment methods or other products that may be developed;
- the cost-effectiveness of our products relative to competing products including potential generic competition;
- the level of off-label use of our drug candidates;
- the availability of government or third-party pay or reimbursement for our products;
- the side effects or unfavorable publicity concerning our products or similar products; and
- the effectiveness of our and/or partners' sales, marketing and distribution efforts.

Specifically, Recombinant Human Erythropoietin or SAM-101, if successfully developed and commercially launched for the treatment of multiple myeloma or schizophrenia, respectively, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe our products unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. Because we expect sales of our products to generate substantially all of our revenues in the long-term, the failure of our products to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

***If the third parties upon whom we rely to manufacture our products do not successfully manufacture our products, our business will be harmed.***

We do not currently have the ability to manufacture the compounds that we need to conduct our clinical trials and, therefore, rely upon, and intend to continue to rely upon, certain manufacturers to produce and supply our drug candidates for use in clinical trials and for future sales. See “Item 4. Information on the Company – Business Overview - Supply and Manufacturing,” below. In order to commercialize our products, such products will need to be manufactured in commercial quantities while adhering to all regulatory and other local requirements, all at an acceptable cost. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

We believe that we will either be able to purchase rHuEPO and the components of the SAM-101 combination from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our planned development programs for the treatment of multiple myeloma and schizophrenia, respectively. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or sources, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates.

Our contract manufacturers will be required to produce our clinical drug candidates under strict compliance with current Good Manufacturing Practices, or cGMP, in order to meet acceptable regulatory standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our drug candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our drug candidates. Any difficulties or delays in our contractors’ manufacturing and supply of drug candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign or local governmental agencies to ensure strict compliance with, among other things, cGMP, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers’ compliance with these regulations and standards. No assurance can be given that our third-party manufacturers will comply with these regulations or other regulatory requirements now or in the future.

In the event that we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products as planned. If third-party manufacturers fail to deliver the required quantities of our products on a timely basis and at commercially reasonable prices, our ability to develop and deliver products on a timely and competitive

basis may be adversely impacted and our business, financial condition or results of operations will be materially harmed.

**Risks related to our Medical Device business:**

***InterCure's products are manufactured by a single manufacturer, which has limited production capacity. In the case of a sharp increase in demand for InterCure's products, it may take a few months to adjust the production capacity to demands. Shift of production to another manufacturer may take few months.***

As of the date of this report, InterCure meets all its production needs through subcontractors and particularly a major subcontractor in China which has been manufacturing the RESPeRATE Ultra versions since November 2008. In 2012, InterCure manufactured an average of less than 1,000 product units a month. The Chinese production line's monthly manufacturing capacity is about 10,000. In the event of increased demand, the manufacturing capacity can be enhanced within several weeks given that the product's assembly line and testing process is not complicated. The time needed to prepare for increased production mainly depends on the ability of the component suppliers to respond to increased order volumes and the availability of components with variable manufacturing technology. InterCure estimates that in the event of a major increase in product demand, the subcontractor will be able to add another production line within three months without material costs. InterCure is dependent on the manufacturer. However, due to the fact that there are several manufacturers who are able to manufacture such products, InterCure has the ability to transfer the manufacturing of its products to another manufacturer. In order to overcome such dependency, InterCure owns a significant inventory in its warehouse, which is sufficient for more than 6 months of sales, in accordance to InterCure's estimated sales expectancy.

***There is no certainty as to whether we will be capable of developing additional medical device applications based on InterCure's intellectual property.***

Based on its IP and the technologies it developed InterCure aims to develop additional applications in the future in order to broaden its product offering. It is uncertain whether InterCure will be capable of fulfilling the technological, clinical and regulatory or other requirements applicable during the process of developing new products. Additionally, there is no certainty that InterCure will have the required financing resources available to enable the aforesaid development.

***Our medical device activity, through InterCure, is dependent on a unique technology which the medical community may reject and should it happen may significantly affect its results as well as the results of the Group.***

All of InterCure's products and revenues, marketed or developed by the Company, are based on its unique technological development. All of these products focus on interactive guided respiration using a sensor that monitors the patient's breathing and composes music. Should the market and the medical community reject this technology (although to date it has been warmly accepted), then InterCure may face difficulties marketing its products.

Additionally, developments in the market, science and medicine which may not acknowledge this technology (regardless of its proven effectiveness), may materially affect the results of InterCure and the Group's activity.

***Failure or delay in submission or revoking the approvals, permits and licenses required for marketing our medical devices products may significantly damage the results of our consolidated subsidiary, InterCure, and the Group's activity.***

Marketing InterCure products worldwide is subject to receiving and maintaining the validity of the permits and regulatory accreditation from a variety of international bodies such as the FDA in the USA. InterCure has already received regulatory approvals for marketing its products in the USA, Europe, Canada, South Korea and Israel. Processes for receiving certification and permits, as mentioned, for marketing in additional territories, specifically in Japan, and the receipt of approvals and permits for marketing future InterCure products, to the extent required, is an intensive and costly process that stretches over a period of between 3 months to several years. Changes in legislation and/or the policies of the regulatory bodies or new legislation may delay the process of receiving the required permits, a delay that may cause the Company additional expenses or result in revoking the existing ones. Additionally, there is no certainty that InterCure will receive the permits required for marketing its future products. Should InterCure fail to receive the aforementioned certificates and permits or existing certificates or permits be revoked, there may be a detrimental impact on the results of its activities.



Additionally, our medical device activity (through InterCure) is affected by policies of volunteer, non-statutory organizations in the field of advertising such as the NAD in the US and ASA in the UK. Non-compliance with regulations set by these organizations may damage InterCure's ability to advertise its products and consequently, be detrimental to the sales of its products. Furthermore, changes in legislation, and/or the policies of the voluntary organizations may delay the process of approvals, a delay that may cause InterCure additional expenses or result in adding new remarks to existing publications.

***Non-recognition and acceptance of our medical device products by the international medical community may damage our medical device business.***

InterCure's success is dependent to an extent on the medical community's recognition of the technology and the product it developed. The medical community's recognition of InterCure's products depends on InterCure's ability to substantiate that its products are efficient, cost-effective and that they provide a good solution for reducing, in the long-term, hypertension in patients for whom the existing medications are insufficient. There is no certainty that InterCure will succeed in retaining and/or increasing the market or medical community's recognition of its products and bringing such recognition to the markets in which it is active.

***There is no certainty regarding the level of demand for our medical device products and there is no certainty regarding the effectiveness of advertising with regard to its cost.***

There is no certainty regarding the level of demand for InterCure products, which depends on how the target audience received these products, increasing awareness to the product and how it is perceived as an added value device compared to other possible treatments, including changing lifestyle, nutrition and medication. The general economic situation in the main target markets (United States and United Kingdom) influences the demand for the product directly. As a result of InterCure's financial situation over the past years, prior to the Company's investment therein, InterCure encountered increasing difficulties finding and using printed media advertisement and as a result was obliged to reduce the scope of advertisement in both the USA and UK – which in turn caused a drop in sales.

Furthermore, on-line advertisements have a significant share in InterCure's marketing activity. The growing costs of on-line advertisements used by InterCure may affect the profitability of using this advertising channel and consequently InterCure and the Group's financial results.

***Uncertainty regarding global economy in general, and particularly in the US and UK, may damage the Group's revenues and results.***

The significant part of the Group's revenues is derived from sales of InterCure in the United States and United Kingdom. The financial crisis in the US and UK had a decisive effect on InterCure. General market developments and fluctuations in markets, and specifically a drop in consumer spending, and in the consumer confidence index may have negative implications on InterCure's business results, its cash flow, the value of its assets, its business situation and financial norms, its ability to distribute dividend and raise capital for its activities to the extent required, as well as the conditions for providing the aforesaid funding.

**Risks Related to Our Related Company (Proteologics)**

*As of the date of this report we hold approximately 30.88% of Proteologics issued and outstanding share capital. Our investment in Proteologics is accounted for using the Equity method of accounting in accordance with International accounting standard IAS 28 "investment in associates". In addition to the risk factor sections mentioned above related to our drug development activity, the risk factor sections below describe unique risks to Proteologics.*

***If Proteologics fails to show positive results on its pre-clinical and clinical trials, our investment in Proteologics will be adversely impacted and we may record impairment losses over our investment in it.***

Proteologics has certain technologies based on the Ubiquitin system, which are currently in pre-clinical development stages. The development continuance of most of Proteologics' potential drugs depends on the success of pre-clinical and clinical trials. The commencement and the completion of such pre-clinical and clinical trials may be delayed or ceased for a variety of reasons, such as the appearance of toxic signs in animals, failure to receive regulatory approvals, difficulties in patient enrollment, appearance of side effects in patients, inefficacy and/or death of patients. Proteologics dependence on clinical trials for drug development may make it difficult for Proteologics to reach advanced levels of development and may result in loss of all and/or part of its business operations and consequently, may result in impairment losses over our investment in it.

***If Proteologics is unable to successfully complete its development plans for its drug candidates, or if such developments will take longer to complete than Proteologics projects, its ability to execute its current business strategy will be adversely affected and we may record impairment losses over our investment in it.***

There is uncertainty about Proteologics' ability to complete the research and development of its drug candidates due to difficulties and/or scientific and/or technological problems. Even if the drugs are developed, there is no certainty that the drugs will be efficacious and safe. Proteologics R&D plan is for developing novel drugs in innovative fields and technologies. There is no certainty that the R&D in this field will yield a marketable drug. In addition, there is no certainty that Proteologics will successfully complete product development according to schedules and costs anticipated. Failure to meet deadlines may result in additional costs in connection with the development and may even prevent the completion of the product development, and thus will cause losses on our investment in it.

***Proteologics is at an early stage of development and has a limited source of income. There is no certainty that Proteologics will be able to develop additional sources of income, or that its activities will become profitable in the future.***

Proteologics is at an early stage of development. Proteologics has a limited source of income derived from the collaboration agreement with GlaxoSmithKline LLC (hereinafter: "GSK") and has no income from sale of products. Proteologics expects to incur operating losses in the upcoming years. There is no certainty that Proteologics will be able to develop additional sources of income, or that its activities will become profitable in the future, if at all. As a result, we may record losses over our investment in it.

*Proteologics may fail to raise additional funds in the future for its activities.*

Proteologics financial needs may vary due to trial results, competitiveness, technological development in the field of activity and additional costs that cannot be estimated at the time of this report. There is no way to guarantee that Proteologics will successfully raise additional funds, if and when they require that. Lack of appropriate funding measures may result in loss of part and/or all of Proteologics' business operations.

*There is no certainty about Proteologics' ability to continue to finance the joint projects with GSK and its self-financed projects and there is no certainty for its ability to raise alternative financing resources*

Proteologics has a collaboration agreement with GSK on certain projects. GSK has the right to terminate the agreement at its sole discretion. If GSK chooses to terminate the agreement with Proteologics, there is no certainty regarding Proteologics' ability to continue to finance the joint projects and for its ability to raise alternative financing resources. Also, Proteologics has self-financed projects and there is uncertainty regarding the success of these projects and there is no assurance that it will be able to finance them. Absence of appropriate funding could stop all and / or part of Proteologics' research and development activities. Moreover, there is no way to guarantee that GSK will continue to develop the molecules, in whole or in part, and there is no assurance regarding the rate of continued development and / or its success.

*If Proteologics lose their key personnel or are unable to attract and retain additional personnel, their business could be harmed*

As per our associate, Proteologics has certain dependency on principal researchers employed by it, when replacing some or one of them may significantly delay the progress of the relevant development plan. Proteologics' management believes that there are three key employees whose departure may substantially harm Proteologics.

### **Risks Related to Our Financial Condition**

*The Company's revenues from operations derive from InterCure's business, and are not sufficient at this stage to support the financing of our entire operations. We fund our operations from our own capital and from external sources by way of issuing equity instruments. If we need to raise additional capital and are unable to do so on terms favorable to us, or at all, we may not be able to continue our operations.*

The Company has incurred continuing losses and its entire income at this stage originates from InterCure, a subsidiary which was consolidated for the first time in these financial statements (following the completion of the transaction of July 2012. see also “Item 10. Additional Information -Material Contracts.”). The Company depends on external financing resources to continue its activities. From March 2012 to the date of the approval of the financial statements the Company raised through a private placement and exercise of tradable and non-tradable warrants total net proceeds of approximately \$4.3 million. In the opinion of the Company's management and based on its business plans, the balances of cash and cash equivalents with the balances of short-term deposits, will enable the Company to fund its activities through at least into the third quarter of 2014. However, the actual amount of cash that the Company will need to fund its operations is subject to many factors, including, but not limited to, the timing, design and conduct of the clinical trials of our existing drug candidates, any future projects which may be in-licensed or any other business development activities. For example, changing circumstances and/or in-licenses of new technologies may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

The Company will incur additional losses in 2013 from research and development activities and from current operation which will be reflected in negative cash flows from operating activities. Accordingly, in order to complete the clinical trials to bring a product to market, the Company will be required to raise additional cash through the issuance of equity securities. However, if the Company is not able to raise additional capital at acceptable terms, the Company may be required to exercise tradable securities held by it or reduce operations or sell or out-license to third parties some or all of its technologies.

Our drug development business depends on a number of factors, some of which are beyond our control. These factors include, among others:

- the progress of our planned research activities;
- the accuracy of our financial forecasts;
- the number and scope of our planned development programs;
- our ability to establish and maintain current and new licensing or acquisition arrangements;
- our ability to achieve our milestones under our licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs and timing of the clinical trials according to regulatory requirements;
- rHuEPO patent expiration in 2019 and failure to obtain orphan drug designation in Europe; and
- SAM-101 patent expiration in 2027.

Our medical device business depends on a number of factors, some of which are beyond our control. These factors include, among others:

- Maintaining InterCure's patents;

Technological exclusivity - since the hypertension market is very large and plays host to numerous multinational pharmaceutical companies, any new entity interested in entering and operating in the market will need, among others, a proven technological advantage that separates it from competitors;

- Recognition among the medical community

- Obtaining regulatory approvals from the FDA in the U.S. or the CE Mark in Europe by our competitors;

Branding - An important parameter in deciding whether to acquire a therapeutic device is consumer confidence that the product is efficient and safe;

- Our ability to setting up a marketing, advertising and sale system for effectively increasing activity;

The grant of a reimbursement code by an insurer or healthcare authority that offer participation in the cost of purchase of our products



The global capital markets have been experiencing extreme volatility and disruption for the last five years. In recent year, the volatility and disruption has increased mainly due to the financial instability and debt of some European countries, the uprisings against the regime in some Middle Eastern and North African countries, and the tension with Iran. Given recent particularly adverse market conditions for small biotechnology companies, additional financing may not be available to us when we need it. In order to complete the clinical trials to bring a product to market we will need to raise additional capital. However we may be unable to do so on terms favorable to us, or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our technologies. If we raise additional funds by selling ordinary shares, ADRs, or other securities, the ownership interests of our shareholders will be diluted. If we need to raise additional funds through the sale or license of our drug candidates or technology, we may be unable to do so on terms favorable to us or at all.

***We may not be able to utilize our accumulated net losses owned by the Company in Israel and/or offsetting the tax liability of the Subsidiaries***

We have had a “permanent establishment” in the United States, or US, which began in 2005 and ended in 2009. As a result, any income attributable to such US permanent establishment for the years 2005-2009 was subject to US corporate income tax in the same manner as if we were a US corporation. If this is the case, we may not be able to utilize any of the accumulated Israeli loss carry forwards mentioned in our notes to the 2012 financial statements since these losses were not attributable to the US permanent establishment. However, we would be able to utilize losses attributable to the US permanent establishment to offset such US taxable income. As of December 31, 2012, US net operating loss carry forwards are approximately \$23 million. These losses are limited in use and may be significantly reduced due to "change of control" limitations as a result of the Bio-Gal transaction (see “Item 8. Financial Information-Material Contracts”) and subject to further limitations in case of a future offering or capital raise, resulting in more than 50 percentage point change over a three year look back period, and expiring through 2029. US corporate tax rates are higher than those to which we are subject in the State of Israel, and if we are subject to US corporate tax, it would have a material adverse effect on our results of operations. Currently we do not have any activity in the US subsidiaries XTL Biopharmaceuticals Inc and XTL Development Inc. However, if these subsidiaries commence operations in the future, they will be subject to the tax rules mentioned above.

***We may not be able to utilize our accumulated net losses owned by our Subsidiaries in the US or offsetting any tax liabilities we may incur in the next years***

As of December 31, 2012, the net operating tax losses (“NOL”) of the US subsidiaries amounted to approximately \$20 million. The utilization of these NOLs is subject to significant limitations and/or reductions to offset income in the future, if any, due to, among other, the shifts in ownership of XTL resulting from the Bio-Gal transaction (see “Item 10. Financial Information-Material Contracts”) and subject to further limitations pursuant to a US tax rule, in case of a future offering or capital raise, resulting in more than 50 percentage point change over a three year look back period, and expiring through 2029.

InterCure Inc. has carryforward business losses and capital losses which total approximately \$ 24 million as of December 31, 2012. It should be noted that following the composition of creditors agreed upon in July 2012 (See “Item 10. Additional Information -Material Contracts.”) in which the control over InterCure was changed, the utilization of said losses is limited and they are expected to be significantly reduced according to internal U.S. laws.

## Risks Related to Our Intellectual Property

*If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.*

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. As part of our business strategy, our policy is to actively file patent applications in the US and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and composition and improvements in each of these. See “Item 4. Information on the Company - Business Overview - Intellectual Property and Patents,” below regarding our patent position with regard to our product candidates. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Generally, patent applications in the US are maintained in secrecy for a period of at least 18 months. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. We cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the US that claim compounds or technology also claimed by us, we may be required to challenge competing patent rights, which could result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to the licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

We also rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to protect our trade secrets or other proprietary information adequately. In addition, we share ownership and publication rights to data relating to some of our drug candidates and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this

information, our ability to receive patent protection or protect our proprietary information will be at risk.

We pursue patent protection in the US and in certain foreign countries relating to our development and commercialization of rHuEPO for the prolongation of multiple myeloma patients' survival and improvement of their quality of life. A main use patent (United States Patent 6,579,525 "Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer") was submitted by Mor Research Applications Ltd., an Israeli corporation and Yeda Research and Development Company Ltd., an Israeli corporation, in Israel on April 8, 1998 and a PCT was filed on March 30, 1999. The patent was granted in the United States, certain countries in Europe (major countries), Israel, Japan, Hong Kong and Canada and will expire in 2019. Notably, we were granted an Orphan Drug Designation from the FDA in May 2011 in the US, (see "Item 4. Information on the Company - Government and Industry Regulation"). Currently, under the license agreement which is held by XTEPO, we have the exclusive worldwide rights to the above patent for the use of rHuEPO in multiple myeloma. See "Item 4. Information on the Company – Business Overview - Intellectual Property and Patents." However, we cannot guarantee the scope of protection of any issued patents, or that such patents will survive a validity or enforceability challenge.

A PCT application (PCT/IL2007/001251) relating to our development and commercialization of SAM-101 for the treatment of schizophrenia was filed in October 2007. National stage applications derived from this PCT are pending in Canada, Europe, India, Israel and the US. The resulting patents will expire in 2027. Currently, under the license agreement with MinoGuard, we have the exclusive worldwide rights to the above patent family for the use of SAM-101 in schizophrenia. See “Item 4. Information on the Company – Business Overview - Intellectual Property and Patents.” However, we cannot guarantee the scope of protection of any issued patents, or that such patents will survive a validity or enforceability challenge.

In addition, InterCure pursues patent protection in the US and certain countries in Europe, Hong Kong, Japan, Singapore, India, Canada and Israel relating to its development and commercialization of its device RESPeRATE® for the treatment of hypertension as well as additional applications, such as treatment of stress, insomnia, PTSD, etc. The patents will expire between 2014 and 2028.

InterCure is dependent on its ability to protect its patented rights, to obtain patents on further developments and to protect trade secrets and trademarks. There is no certainty that InterCure will be able to obtain additional patents on each of its various developments or that challenges are not filed by third parties against existing or future patents. In addition, in certain countries, InterCure's IP rights are not protected by local laws.

***Litigation or third-party claims of intellectual property infringement could require us to spend substantial time, money and other resources defending such claims and adversely affect our ability to develop and commercialize our products.***

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our products infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected products could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all. In addition, any legal action against us that seeks damages or an injunction relating to the affected activities could subject us to monetary liability and/or require us to discontinue the affected technologies or obtain a license to continue use thereof.

In addition, there can be no assurance that our patents or patent applications or those licensed to us will not become involved in opposition or revocation proceedings instituted by third parties. If such proceedings were initiated against one or more of our patents, or those licensed to us, the defense of such rights could involve substantial costs and the outcome could not be predicted.

Competitors or potential competitors may have filed applications for, may have been granted patents for, or may obtain additional patents and proprietary rights that may relate to compounds or technologies competitive with ours. If patents are granted to other parties that contain claims having a scope that is interpreted to cover any of our products (including the manufacture thereof), there can be no assurance that we will be able to obtain licenses to such patents at reasonable cost, if at all, or be able to develop or obtain alternative technology.

## **Risks Related to Our Ordinary Shares and ADRs**

*Our ADRs are traded in small volumes, limiting your ability to sell your ADRs that represent ordinary shares at a desirable price, if at all.*

The trading volume of our ADRs has historically been low. Even if the trading volume of our ADRs increases, we can give no assurance that it will be maintained or will result in a desirable stock price. As a result of this low trading volume, it may be difficult to identify buyers to whom you can sell your ADRs in desirable volume and you may be unable to sell your ADRs at an established market price, at a price that is favorable to you, or at all. A low volume market also limits your ability to sell large blocks of our ADRs at a desirable or stable price at any one time. You should be prepared to own our ordinary shares and ADRs indefinitely.

*Our stock price can be volatile, which increases the risk of litigation and may result in a significant decline in the value of your investment.*

The trading price of the ADRs representing our ordinary shares is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- developments concerning our drug candidates or medical devices;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- developments in the markets of the field of activities and changes in customer attributes;
- announcements by us of significant acquisitions, in/out license transactions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;

actual or anticipated variations in interim operating results and near-term working capital as well as failure to raise required funds for the continued development and operations of the company;

- expiration or termination of licenses, patents, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- failure to obtain orphan drug designation status for the relevant drug candidates in the relevant regions;
- increase in costs and lengthy timing of the clinical trials according to regulatory requirements;

failure to increase awareness to our non-medicinal non-invasive therapy and its benefits; changes in reimbursement policy by governments or insurers in markets we operate or may operate in the future;



any changes in the regulatory environment relating to the Company's products may impact our ability to market and sell our products;

failure to obtain renewal of the required licenses for marketing and sells of the Company's products in the main markets in which the Company's products are sold;

changes in the market valuations of similar companies; and

additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our ordinary shares or ADRs, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources even if we prevail in the litigation, all of which could seriously harm our business.

***Future issuances or sales of our ordinary shares could depress the market for our ordinary shares and ADRs.***

Future issuances of a substantial number of our ordinary shares, or the perception by the market that those issuances could occur, could cause the market price of our ordinary shares or ADRs to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

The Company has incurred continuing losses and its entire revenues at this stage originate from InterCure, a subsidiary which was consolidated for the first time in these financial statements (following the completion of the transaction on July 2012. see also "Item 10. Additional Information -Material Contracts."). The Company depends on additional external financing resources to continue its activities. During the period the Company raised through a private placement and exercise of tradable and non-tradable warrants from March 2012 to the date of the approval of the financial statements total net proceeds of approximately \$ 4.3 million. In the opinion of the Company's management and based on its business plans, the balances of cash and cash equivalents with the balances of short-term deposits, will enable the Company to fund its activities through at least into the third quarter of 2014. However, the actual amount of cash that the Company will need to fund its operations is subject to many factors, including, but not limited to, the timing, design and conduct of the clinical trials of our existing drug candidates, any future projects which may be in-licensed or any other business development activities. For example, changing circumstances and/or in-licenses of new technologies may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

The Company will incur additional losses in 2013 from research and development activities and from current operation which will be reflected in negative cash flows from operating activities. Accordingly, in order to complete the clinical trials to bring a product to market, the Company will be required to raise additional cash in the future through the issuance of securities. However, if the Company is not able to raise additional capital at acceptable terms, the Company may be required to exercise tradable securities held by it or reduce operations or sell or out-license to third parties some or all of its technologies.

Also, if we make one or more significant acquisitions in which the consideration includes ordinary shares or other securities, your portion of shareholders' equity in us may be significantly diluted. In addition, pursuant to a license agreement with MinoGuard, we may elect to execute any payment under the agreement resulting from milestone achievements, royalties, and sublicensing by way of issuing ordinary shares in lieu of cash payments. In the future, we may also enter into additional arrangements with other third-parties permitting us to issue ordinary shares in lieu of certain cash payments. Also, in connection with our agreement with DOV Pharmaceutical Inc., or DOV, which was terminated in March, 2010 (see "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below), XTL Development committed to pay a transaction advisory fee to certain third party intermediaries. The advisory fees can be paid in cash or by issuance of shares, at our sole discretion. Pursuant to the agreement with the certain third party intermediaries, and after we examined the settlement issue, in furtherance to our financial condition, it is possible that the advisory fees will be paid by way of issuing 1,659,945 shares (equity-settled).

***Concentration of ownership of our ordinary shares among our principal stockholders may prevent new investors from influencing significant corporate decisions.***

There are 3 shareholders (Messrs. Alexander Rabinovitch, David Bassa and Shalom Manova) who hold more than 5% each of our outstanding ordinary shares (approximately 35.72% cumulative, as of April 24, 2013). As a result, these persons, either acting alone or together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting alone or together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our ADRs or ordinary shares.

Notwithstanding the aforesaid, in connection with Section 239 of the Israeli Companies Law that focuses on the number of votes required to appoint external directors, and in connection with Section 121(c) of the Israeli Companies Law that focuses on the number of votes required to authorize the Chairman of the Board in a company to act also as the Chief Executive Officer of such company, the Company will deem these 3 shareholders as controlling shareholders in the Company, for as long as such individuals are interested parties in the Company. In addition, any contractual arrangement as detailed in Section 270 (4) of the Israeli Companies Law with any of these 3 shareholders and/or their relatives will be presented for approval in accordance with the provisions of Section 275 of the Israeli Companies Law. In all of the aforementioned situations, the Company will consider any of the aforesaid parties, who are not part of the transaction presented for approval as individual interested parties in such transaction so that their vote will not be included in the quorum comprising of majority (50%) of the votes who are not interested parties in such transaction.

***Our ordinary shares and ADRs trade on more than one market, and this may result in price variations and regulatory compliance issues.***

ADRs representing our ordinary shares are quoted on the Pink Sheets Market and our ordinary shares are traded on the TASE. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the US and Israel. Consequently, the effective trading prices of our shares on these two markets may differ. Any decrease in the trading price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

***Our ADRs are quoted on the Pink Sheets market, which may result in them being classified as “Penny Stock.”***

Our ADRs may become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our securities. If our ADRs become considered penny stock, the ability of broker-dealers to sell our ADRs and the ability of our shareholders to sell their ADRs in the secondary market would be limited and, as a result, the market liquidity for our ADRs would be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

***Holders of our ordinary shares or ADRs who are US citizens or residents may be required to pay additional income taxes***

There is a risk that we will be classified as a passive foreign investment company, or PFIC, for certain tax years. If we are classified as a PFIC, a US holder of our ordinary shares or ADRs representing our ordinary shares will be subject to special federal income tax rules that determine the amount of federal income tax imposed on income derived with respect to the PFIC shares. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The risk that we will be classified as a PFIC arises because cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income and the relative values of passive and non-passive assets, including goodwill. A determination as to a corporation's status as a PFIC must be made annually. We believe that we were likely not a PFIC for the taxable years ended December 31, 2008, 2009, 2010 and 2011. Although such a determination is fundamentally factual in nature and generally cannot be made until the close of the applicable taxable year, based on our current operations, we believe that we were likely not a PFIC for the taxable year ended December 31, 2012 but we may be a PFIC in subsequent years. Although we may not be a PFIC in any one year, the PFIC taint remains with respect to those years in which we were or are a PFIC and the special PFIC taxation regime will continue to apply.

In view of the complexity of the issues regarding our treatment as a PFIC, US shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC. For further discussion of tax consequences of being a PFIC, see "US Federal Income Tax Considerations - Tax Consequences If We Are A Passive Foreign Investment Company," below.

***Provisions of Israeli corporate law may delay, prevent or affect a potential acquisition of all or a significant portion of our shares or assets and thereby depressing the price of our ordinary shares.***

We are incorporated in the State of Israel. Israeli corporate law regulates acquisitions of shares through tender offers. It requires special approvals for transactions involving significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay or prevent an acquisition, or make it less desirable to a potential acquirer and therefore depress the price of our shares. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders.

Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of such acquisition, the purchaser would become a 25% or greater shareholder of the company. This rule does not apply if there is already another 25% or greater shareholder of the company. Similarly, Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of the acquisition, the purchaser's shareholdings would entitle the purchaser to over 45% of the shares in the

company, unless there is a shareholder with 45% or more of the shares in the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received the approval of the company's shareholders, (2) was from a 25% or greater shareholder of the company which resulted in the purchaser becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. These rules do not apply if the acquisition is made by way of a merger.

Finally, in general, Israeli tax law treats specified acquisitions less favorably than does US tax law. See "Item 10. Additional Information - Taxation - Israeli Tax Considerations," below.

***Our ADR holders are not shareholders and do not have shareholder rights.***

The Bank of New York Mellon, as depositary, executes and delivers our ADRs on our behalf. Each ADR is a certificate evidencing a specific number of ADRs. Our ADR holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADRs. Holders of our ADRs will have ADR holder rights. A deposit agreement among us, the depositary and our ADR holders, and the beneficial owners of ADRs, sets out ADR holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs. Our shareholders have shareholder rights. Israeli law and our Articles of Association, or Articles, govern shareholder rights. Our ADR holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. Our ADR holders may instruct the depositary to vote the ordinary shares underlying their ADRs, but only if we ask the depositary to ask for their instructions. If we do not ask the depositary to ask for the instructions, our ADR holders are not entitled to receive our notices of general meeting or instruct the depositary how to vote. Our ADR holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depositary. However, our ADR holders may not know about the meeting enough in advance to withdraw the ordinary shares. If we ask for our ADR holders' instructions, the depositary will notify our ADR holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as is practical, subject to the provisions of the deposit agreement, to vote the shares as our ADR holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADR holders. We cannot assure our ADR holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, there may be other circumstances in which our ADR holders may not be able to exercise voting rights.

Our ADR holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary stock and we do not anticipate paying any cash dividends in the foreseeable future). Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to our ADR holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Our ADR holders will receive these distributions in proportion to the number of shares their ADRs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADR holders amounts distributed by us as a dividend or distribution. See the risk factor "There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADRs," below.

***There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADRs.***

The deposit agreement with the depositary allows the depositary to distribute foreign currency only to those ADR holders to whom it is possible to do so. If a distribution is payable by us in New Israeli Shekels, the depositary will hold the foreign currency it cannot convert for the account of the ADR holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, our ADR holders may lose some of the value of the distribution.



The depository is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders. This means that our ADR holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for the depository to make such distributions available to them.

## **Risks Relating to Operations in Israel**

### *Conditions in the Middle East and in Israel may harm our operations.*

Our headquarters and most of our planned clinical sites and suppliers are located in Israel. Political, economic and military conditions in Israel directly affect our operations. 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, military conflicts and terrorist actions. There has been a significant increase in violence since September 2000, which has continued with varying levels of severity through to the present. This state of hostility has caused security and economic problems for Israel. To date, Israel is facing political tension in its relationships with Iran and other Arab neighbor countries. Specifically, the hostilities along Israel's border with the Gaza Strip have increased, escalating to a wide scale attack by Israel and continuous rocket attacks into southern and center of Israel in December 2008 and in November 2012. In addition, recently in some Arab countries in the Middle East and North Africa there were violent uprisings against the regimes in these countries. Consequently, there is a concern for the stability in the region which may affect the political and security situation in Israel. We cannot insure that the political and security situation will not impact our business. Any 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.

Our commercial 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, we cannot assure you 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.

Further, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Also, sales of InterCure's products in countries besides Israel may be affected by the international status of the State of Israel as shaped by the global public opinion.

*Our results of operations may be adversely affected by inflation and foreign currency fluctuations.*

We have generated most of our revenues and hold most of our cash, cash equivalents, bank deposits and marketable securities in US dollars. Until 2008, a substantial amount of our operating expenses were in US dollars (approximately 96% in 2008). Commencing from 2009 the Company's head office moved back to Israel, and thus the portion of our expenses in New Israeli Shekels ("NIS") and our cash held in NIS has increased, mainly due to payment to Israeli employees and suppliers. As a result, we could be exposed to the risk that the US dollar will be devalued against the NIS or other currencies, and consequentially our financial results could be harmed. To protect against currency fluctuations we may decide to hold a significant portion of our cash, cash equivalents, bank deposits and marketable securities in NIS, as well as to enter into currency hedging transactions. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the US dollar or that the timing of any devaluation may lag behind inflation in Israel.

***Our results of operations may be adversely affected by changes in tax policy by the Israeli government***

The income of the Company is subject to corporate tax at the regular rate; the guidance of the amendment to the Income Tax Ordinance, 2005 from August 2008 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2008 are as follows: 2008 - 27%, 2009 - 26% and 2010 and thereafter - 25%.

On July 14, 2009, the “Knesset” (Israeli Parliament) passed the Law for Economic Efficiency (Amended Legislation for Implementing the Economic Plan for 2009 and 2010), 2009, which prescribes, among others, an additional gradual reduction in the corporate tax rates starting 2011 to the following tax rates: 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 - 20%, 2016 and thereafter - 18%.

On December 6, 2011 the reduction in the corporate tax rates outline abovementioned was revoked by the "Knesset" and it was also resolved that the corporate tax rate will be 25% for the tax year 2012 and thereafter. We cannot ensure that the "Knesset" will re-implement its plan for reducing the corporate tax rate in the future and therefore it may adversely affect our results if we will be profitable. Moreover, we cannot guarantee that there will be no additional changes in the corporate tax rate in the future that may harm the Company's results.

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

Service of process upon us, since we are incorporated in Israel, and upon our directors and officers and our Israeli auditors, most of whom reside outside the US, may be difficult to obtain within the US. In addition, because substantially most of our assets and most of our directors and officers are located outside the US, any judgment obtained in the US against us or any of our directors and officers may not be collectible within the US. There is a doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act pursuant to original actions instituted in Israel. Subject to particular time limitations and provided certain conditions are met, executory judgments of a US court for monetary damages in civil matters may be enforced by an Israeli court. For more information regarding the enforceability of civil liabilities against us, our directors and our executive officers, see “Item 10. Additional Information - Memorandum and Articles of Association - Enforceability of Civil Liabilities,” below.

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

##### **A. History and Development of XTL**

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, currently for the treatment of MM, schizophrenia and Hepatitis C. Also, through InterCure, we research, develop, market and sell home therapeutic devices for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress. Our lead compound is Recombinant Human Erythropoietin, or rHuEPO, a known compound that we are planning to develop for the prolongation of MM patients' survival and improvement of their quality of life. SAM-101 is a combination of anti-psychotic drugs with minocycline, a recognized medicinal compound, for the treatment of schizophrenia.

## Recent Developments

### **Investment in Proteologics**

On November 21, 2012, in an off-market transaction, we purchased from Teva 4,620,356 Ordinary shares of NIS 1.0 par value each of Proteologics, representing Teva's entire stake in Proteologics and approximately 31.35% of Proteologics' issued and outstanding share capital, in consideration of approximately NIS 6.5 million (approximately \$ 1.7 million), which were paid in cash. Proteologics is a public company whose shares are traded on the TASE and is engaged in the discovery and development of drugs comprised of various components of the UBIQUITIN system, which was discovered by Dr. Avram Hershko and Dr. Aaron Ciechanover, both 2004 Nobel Prize laureates in Chemistry for the discovery of the UBIQUITIN system.

### **Termination of the DOS program by Presidio**

On August 22, 2012, Presidio requested to terminate its engagement with the Company effective as of August 24, 2012. Following such notice, Presidio's entire DOS technology (including all the patents maintained by Presidio) reverted to the Company within 90 days from the date of said notice in accordance with the provisions of the agreement. Presidio is a U.S. biotechnological company, which received an exclusive global sublicense for the development, regulation and commercialization of the Company's DOS technology from March 2008 (updated in August 2008) (which includes products for the treatment of Hepatitis C virus) according to which the Company has had certain milestone rights in the development of the DOS program (see also Note 18(a) to the consolidated financial statements for 2012).

It is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology.

### **Acquisition of control over InterCure Ltd.**

On June 13, 2012, we entered into an agreement with InterCure according to which, subject to carrying out the Debt Settlement before the transaction, InterCure will convert all of its debts into Ordinary shares of InterCure based on the distribution mechanism determined with all of its debtors (including its employees). The Company will acquire control over InterCure in consideration for investing in InterCure an aggregate amount of approximately \$ 2.7 million, subject to adjustments, as detailed below. Also, in addition to the Company's investment in InterCure, Medica Fund

will invest approximately \$ 630,000 in InterCure (subject to adjustments).

InterCure is a public company whose shares are traded on the TASE and which develops a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension.

The transaction was consummated on July 25, 2012. The Company acquired 16,839,532 Ordinary shares of InterCure with no par value in consideration of a private placement of 7,165,662 Ordinary shares of the Company of NIS 0.1 par value each whose value on the date of signing the agreement, measured based on the quoted market price of the Company's shares on the TASE, approximated \$2.2 million (the market value of such shares on the InterCure Closing date was approximately \$2.47 million), which represented a pre-money valuation of InterCure of \$1.75 million, after all of InterCure's debts were converted as described above ("InterCure's adjusted value").

In addition, the Company provided InterCure an amount of approximately \$150,000 in cash on the basis of InterCure's adjusted value. After effecting the above allocation, the Company held about 50.79% of the issued and outstanding share capital of InterCure. The investment of Medica Fund on the date of closing on the basis of InterCure's adjusted value amounted to approximately \$ 460,000.

Further, the Company and Medica Fund provided InterCure a loan of \$ 500,000 (the Company's share is \$ 330,000) for a period of up to ten months at an overall interest rate of 15%. The Company and Medica Fund have the right to convert the loan into an additional 11,546,507 shares of InterCure (the Company's share is 7,620,695 shares) which will constitute, upon conversion and assuming full dilution on the date of closing, approximately 24.47% of the issued and outstanding share capital of InterCure (the Company's share in the convertible loan is 16.15% of the issued and outstanding share capital of InterCure). On August 6, 2012, Medica Fund converted the loan it provided InterCure into shares and its stake in InterCure rose to approximately 23.69% of the issued and outstanding share capital of InterCure (about 18.61% on a fully diluted basis, as of the date of the loan's conversion). On March 3, 2013, the Company notified InterCure that if the Company decides not to convert the loan granted to InterCure into shares, it will provide InterCure another six months to repay the loan ("the repayment date"), provided that if any funds are received from InterCure from any source, excluding receipts from operating income, by the repayment date, InterCure will be required to repay the outstanding loan amount, or any part thereof, in installments of at least \$ 50,000 each.

As of the date of this report, the Company's stake in InterCure is approximately 45.41% of the issued and outstanding share capital of InterCure (36.69% on a fully diluted basis, including the exercise of performance options granted to Giboov (as detailed below) and 52.63% excluding the exercise of Giboov performance options).

#### **Agreement with Giboov Ltd., a Provider of Online Marketing and Sales Services**

On September 24, 2012, InterCure announced the signing of a three-year non-exclusive strategic service agreement with Giboov, a private company wholly-owned by Messrs. Shay Ben-Yitzhak and Avner Yassur, for the provision of online marketing and sales services of InterCure's products.

According to the strategic agreement, which is territorially unlimited, Giboov will provide InterCure online sales services in return for a monthly fee of \$ 40,000 plus VAT in return for the services ("the consideration") whereby in the first four months of the strategic agreement period, no consideration will be paid and will later be paid provided that revenues are derived from online sales in an amount of at least \$50,000. In addition, InterCure will provide monthly online advertising budgets for the online sale activity performed by Giboov, which will not be less than \$130,000, and all under the mechanism as described in the agreement.

In the context of the strategic agreement, Giboov will be allocated up to 20,185,184 unlisted stock options that are exercisable into shares of InterCure for an exercise price (dividend adjusted) of NIS 0.54 per stock option which will vest according to Giboov's compliance with annual sales targets. In the context of the strategic agreement, Giboov's shareholders were given a put option to sell to InterCure Giboov's entire share capital for a period of 18 months from the effective date of the strategic agreement. On the date of signing the strategic agreement, InterCure was granted a call option to purchase Giboov's entire share capital for a period of one year from the effective date of the strategic agreement. The agreement's allocation items were approved by the general meeting of InterCure's shareholders on October 28, 2012. InterCure will be able to cancel the agreement if Giboov fails to meet the sales targets prescribed in

the strategic agreement effective from March 2014 or in the event of material breach of the agreement, fraud, damage etc. For further details regarding the agreement with Giboov, see note 18(a) to the consolidated financial statements.



### **Relisting our ADRs on the NASDAQ**

On June 1, 2012, the Company has filed an application for relisting its ADRs on the NASDAQ Stock Exchange, which is subject to complying with all the required criteria that is examined by the NASDAQ Listing Qualifications Committee, including the criteria of minimum ADR price (according to the different listing criteria). On September 24, 2012, the Company's Board approved to change the ratio of its ordinary shares to ADR, such that every 20 Ordinary shares of the Company will automatically be combined into one ADR of the Company (1:20 ratio), this in order to support the Company's compliance with the NASDAQ's listing requirements. The record date of the change in the ADR ratio is October 4, 2012. As of the date of the financial statements, the relisting proceeding is still underway and the Company is holding negotiations with the NASDAQ compliance committee for finalizing the proceeding. There is no assurance that such activity shall result in the Company's ADRs being accepted for re-listing on NASDAQ.

### **Issuance of Shares and Warrants under a Private Placement**

On March 18, 2012, the Company's Board approved a private placement to institutional and private investors (foreign as well as Israeli) for the total of approximately \$ 2.4 million (approximately NIS 9.1 million), net of issuance expenses of approximately \$ 19,000. According to the private placement, the Company allocated 11,560,362 Ordinary shares of the Company of NIS 0.1 par value each, 3,853,454 warrants (series A) and 1,926,727 warrants (series B).

Warrants (series A) are exercisable into one Ordinary share of NIS 0.1 par value from the date of allocation (March 18, 2012) to September 17, 2012 at an exercise price equal to NIS 1.046 per share, linked to the U.S. dollar. During the period, 560,000 warrants (series A) were exercised into 560,000 Ordinary shares of the Company of NIS 0.1 par value each for the total consideration of approximately \$155,000. On September 17, 2012, the outstanding 3,293,454 warrants (series A) expired.

Warrants (series B) are exercisable into one Ordinary share of NIS 0.1 par value from the date of allocation (March 18, 2012) to March 17, 2015 at an exercise price equal to NIS 1.124 per share, linked to the U.S. dollar.

### **Strategic collaboration framework agreement with Clalit Health Services - Clalit Research Institute Ltd.**

On March 14, 2012, we signed a strategic collaboration framework agreement with Clalit Health Services - Clalit Research Institute Ltd. ("the Institute") and Mor Research Applications Ltd. according to which the Institute provides the Company with the right to receive contents which are based on the Institute's database in connection with

technologies that stem from inventions and patents of Clalit Health Services' physicians, in projects whose content shall be agreed upon by us, the Institute and Mor in advance and in writing. In consideration for the above, we shall pay the Institute the cost basis related to the Institute's activity in the framework of any project plus an additional 10% of the total royalties Mor is entitled pursuant to its agreements with the Company in connection with each technology where rights were granted to the Company. This agreement may be terminated by giving a written and advance notice of 180 days by any of the parties on condition that all joint active projects have reached their end.

#### Company Information and History

Our legal and commercial name is XTL Biopharmaceuticals Ltd. We were established as a private company limited by shares under the laws of the State of Israel on March 9, 1993, under the name Xenograft Technologies Ltd. We re-registered as a public company on June 7, 1993, in Israel, and changed our name to XTL Biopharmaceuticals Ltd. on July 3, 1995. We commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Until 1999, our therapeutic focus was on the development of human monoclonal antibodies to treat viral, autoimmune and oncological diseases. Our first therapeutic programs focused on antibodies against the hepatitis B virus, interferon – and the Hepatitis C virus.

In January 2007, XTL Development, Inc., our wholly owned subsidiary (“XTL Development”), had signed an agreement with DOV Pharmaceutical, Inc. (“DOV”), to in-license the worldwide rights for Bicifadine, a serotonin and norepinephrine reuptake inhibitor (SNRI) (“the Bicifadine transaction”). XTL Development was developing Bicifadine for the treatment of diabetic neuropathic pain - a chronic condition resulting from damage to peripheral nerves. In November 2008, we announced that the Phase 2b clinical trial failed to meet its primary and secondary endpoints, and as a result we ceased development of Bicifadine for diabetic neuropathic pain, and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, XTL Development has ceased the prosecution and maintenance of those patents relating to Bicifadine, in coordination with DOV. In March 2010, the agreement was formally terminated.

In 2008, we signed an agreement to out-license the DOS program to Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio becomes responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a \$5.94 million, non-refundable, upfront payment in cash from Presidio and will receive up to an additional \$59 million upon reaching certain development and commercialization milestones. In addition, we will receive royalties on direct product sales by Presidio, and a percentage of Presidio’s income if the DOS program is sublicensed by Presidio to a third party. On August 22, 2012, Presidio requested to terminate its engagement with us effective as of August 24, 2012. Following a notice of the termination of the agreement, Presidio's entire DOS technology (including all the patents maintained by Presidio) has been reverted back to the Company (within the lapse of 90 days from the date of said notice in accordance with the provisions of the agreement). It is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology.

In March 2009, we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal, a private biotechnology company based in Gibraltar. In December 2009, we amended the asset purchase agreement with Bio-Gal so that XTL could acquire from the shareholders of XTEPO, a special purpose company that was established by Bio-Gal's shareholders who shall receive from Bio-Gal all of Bio-Gal’s right on rHuEPO and raised approximately \$1.5 million, all of their shares in XTEPO in exchange for the issuance to XTEPO’s shareholders of ordinary shares of XTL representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are also obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the success of Phase 2. Such payment of \$350,000 mentioned above shall be made to Yeda upon the earlier of (i) six months from the Successful Completion of Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO at any time after the completion of Phase 2 of an amount of minimum \$2 million. On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the closing conditions had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to Section 104 and 103 to the Israeli Tax Ordinance (Revised), 1961 (See note 14(c) to the consolidated financial statements: Intangible Asset).

On September 1, 2010, the Company and Yeda Research and Development Co. Ltd. (“Yeda”) entered into an option agreement granting an exclusive right to examine a medical technology in the field of the immune system, comprising of two proteins through which target molecules are examined and may serve as a basis for the development of therapeutics for diseases relating to the immune system, such as acute hepatitis, rheumatoid arthritis, Chron’s disease and psoriasis. Under the agreement, the Company purchased this exclusive option right to examine the medical technology for a 15-month period in consideration for \$120,000 payable by the Company in the following manner and at the earlier of:

(i) In the event of raising funds by a prospectus to the public for more than \$2 million, the Company is obligated to settle the payment in cash; or (ii) if 12 months after the date of closing of the agreement an amount of more than \$2 million was not raised, the liability to Yeda can be satisfied, at the Company’s sole discretion and after obtaining Yeda’s approval to the timing, in cash or by issuance of options with equivalent value in lieu of that payment. In December 2011 we notified Yeda that we do not intend to exercise the right given to us under this option agreement.

In March 2011, we raised by public issuance of 12,305,000 Ordinary shares of NIS 0.1 par value each, 6,152,500 warrants (series 1) and 18,457,500 warrants (series 2) on the TASE an immediate net amount of approximately \$ 1.75 million (approximately NIS 6.3 million) (See "Item 5. Operating and Financial Review and Prospects-Liquidity and Capital Resources").

On March 24, 2011, we entered into a Memorandum of Understanding with MinoGuard, pursuant to which we shall acquire the exclusive rights to SAM-101 by obtaining an exclusive license to use MinoGuard's entire technology. SAM-101 is based on a combination of anti-psychotic drugs with minocycline, a recognized medicinal compound. On November 30, 2011, we completed our engagement in a worldwide exclusive license with MinoGuard under which we shall develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on Schizophrenia. We will conduct clinical trials, develop, register, market, distribute and sell the drugs that will emerge from MinoGuard's technology, with no limitations for a specific disorder ("the License"). We shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of its net sales and/or percentage from the Company third-party out-license receipts in the range of 7.5%-20% according to the clinical phase of the drug at the time of an out-license transaction. It should be noted that the Company has the sole discretion to pay any of the above amounts in cash or by way of issuing of its shares to MinoGuard. In addition to the above payments, if we shall not commence a Phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of \$45,000 for the initial year, which will increase by \$90,000 per year and up to \$675,000 for the eighth year of license. According to the agreement receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter.

On November 2, 2011, the Company entered into a term sheet by which it will acquire a technology ("NiCure") from Mor, the Technology Transfer Office (TTO) of Clalit Health Services, by obtaining an exclusive license to use the entire technology and intellectual property in return for royalties on sales and milestone payments throughout the clinical development process. The agreement that will be signed by the parties is subject to, among others, the completion of due diligence, examination of the regulatory environment for the continued development of the drug, and the approval of the Company's board. NiCure's technology is based on the local administration of renin-angiotensin inhibitors (known drugs for the treatment of hypertension, i.e "Enalaprilat"), as novel treatment for the symptoms of cartilage-related diseases, such as Osteoarthritis. Osteoarthritis is one of the most frequent causes of physical disability in adults. The disease involves progressive deterioration of articular cartilage; being loss of the major polysaccharides glycosaminoglycan (GAGS) a main cause of the disease. The current invention offers a novel therapy focused on increasing or replenishing the level of GAGs in the synovial fluid and cartilage, thereby relieving or even reversing symptoms of such diseases. Moreover, as GAGs are an important component of the dermis, the same technology can be used in order to treat skin wrinkles. As of the date of approval of the financial statements, the transaction has not been completed and the Company is considering this project fit to its business plan.

Our ADRs are quoted on the Pink Sheets, an inter-dealer electronic quotation and trading system in the over-the-counter (OTC) securities market, under the symbol "XTLBY.PK." Our ordinary shares are traded on the TASE under the symbol "XTL." We operate under the laws of the State of Israel, under the Israeli Companies Act, and in the US, the Securities Act and the Exchange Act.

Our principal offices are located at Herzliya Business Park, 85 Medinat Hayehudim Street, Building G, PO Box 4033, Herzliya 46140, Israel, and our telephone number is +972-9-955-7080. XTL Biopharmaceuticals, Inc., our wholly-owned US subsidiary and agent for service of process in the US, can be reached at XTL Biopharmaceuticals, Inc c/o Corporation Trust Company, Corporation Trust Center, 1209 N. Orange Street, Wilmington, Delaware 19801, or by telephone at (800) 677-3394. Our primary internet address is [www.xtlbio.com](http://www.xtlbio.com). None of the information on our website is incorporated by reference into this annual report.

In March 2011, we raised by public issuance of 12,305,000 Ordinary shares of NIS 0.1 par value each, 6,152,500 warrants (series 1) and 18,457,500 warrants (series 2) on the TASE an immediate net amount of approximately \$ 1.75 million (approximately NIS 6.3 million). On March 18, 2012, the Company's Board approved a private placement to institutional and private investors (foreign as well as Israeli) for the total of approximately \$ 2.4 million (approximately NIS 9.1 million), net of issuance expenses of approximately \$ 19,000. According to the private placement, the Company allocated 11,560,362 Ordinary shares of the Company of NIS 0.1 par value each, 3,853,454 warrants (series A) and 1,926,727 warrants (series B). Concurrently, one of the investors in the Company exercised warrants (Series 2) in amount of approximately \$1.1 million. Since inception and until the date of the statement of financial position, we have raised net proceeds of approximately \$142.7 million to fund our activities, including the net proceeds from the public issuance and private placement (including proceeds from the exercise of warrants (Series 2)) abovementioned.

For the years ended December 31, 2012, 2011, and 2010 our capital expenditures were \$6,000, \$12,000 and \$16,000 respectively. During 2012 and 2011, proceeds from disposition of certain unused assets were immaterial (less than \$1,000). In 2010 we did not dispose any of our assets.

## **B. Business Overview**

### ***Introduction***

We operate in two major business fields:

**Drug Development** - we are a biopharmaceutical company engaged in the acquisition and development of  
1. pharmaceutical drugs for the treatment of unmet medical needs, currently for the treatment of MM, schizophrenia and Hepatitis C.

**Medical Device** - we develop a home therapeutic device for non-medicinal and non-invasive treatment of various  
2. diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension.

In addition, we invest in the development of the Ubiquitin system through our investment in our related company - Proteologics.

The description below presents details regarding each of our business lines:

**Drug development**

Our lead compound is rHuEPO, which we intend to develop for the survival extension of MM terminal patients' lives.

Erythropoietin (EPO) is a glycoprotein hormone produced mainly by the kidney. It is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis, the production of red blood cells, by binding to its receptor (EPO-R) on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. Over the last decade, several reports have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic properties, broadly beyond erythropoiesis. Erythropoietin is available as a therapeutic agent produced by recombinant DNA technology in mammalian cell culture. rHuEPO is used in clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia.



Currently incurable, MM is a severe plasma cell malignancy characterized by the accumulation and proliferation of clonal plasma cells in the marrow, leading to the gradual replacement of normal hematopoiesis. The course of the disease is progressive, and various complications occur, until death. This devastating disease affects the bone marrow, bones, kidneys, heart and other vital organs. It is characterized by pain, recurrent infections, anemia and pathological fractures. In the course of the disease, many patients become gradually disabled and bed-ridden.

The median overall survival duration today with chemotherapy and other novel treatments is about five years. These treatments have severe side effects, including the suppression of the immune system, susceptibility to infections, nausea, vomiting and bleeding disorders.

Our second program, SAM-101, is based on the technology we in-licensed from MinoGuard - the development of combination drugs for psychotic diseases, with focus on schizophrenia. MinoGuard completed a phase 2a study in accordance with the Helsinki guidelines under the Shalvata Medical Center in Israel on SAM-101, a unique proprietary combination of antipsychotic drugs and a known medicinal compound (minocycline). Schizophrenia is a chronic disorder that requires lifelong medication. While most of the available drugs are effective in remitting schizophrenia's "positive symptoms" (hallucinations, delusions, agitation), even the best available drug is only partially effective in remitting several of the most disturbing features of the disease, referred to as "negative symptoms" (apathy, poverty of speech, emotional withdrawal, depression) and severe cognitive impairment. This deficiency results in schizophrenic patients' poor quality of life. In addition, noncompliance results in aggravation in symptoms, which frequently causes lengthy hospitalization periods.

Following in-vivo studies demonstrating the efficacy of minocycline treatment in a schizophrenia murine model<sup>1</sup>, MinoGuard demonstrated in a successful phase 2a clinical study that the combination of atypical antipsychotic drugs and minocycline improves treatment efficacy and reduces side effects associated with current therapy as compared to antipsychotic treatment alone<sup>2</sup>. Three independent clinical research groups in Manchester, UK, Maryland USA and Japan<sup>3</sup> have replicated these results, further supporting MinoGuard's hypothesis.

Our third program is the Diversity Oriented Synthesis, or DOS, program, which is focused on the development of novel pre-clinical Hepatitis C small molecule inhibitors. Compounds developed to date inhibit HCV replication in a pre-clinical cell-based assay with potencies comparable to clinical stage drugs. On March 20, 2008, we announced that we had out-licensed the DOS program to Presidio. On August 22, 2012, Presidio requested to terminate its engagement with us effective as of August 24, 2012. Following a notice of the termination of the agreement, Presidio's entire DOS technology (including all the patents maintained by Presidio) will revert back to the Company within 90 days from the date of said notice in accordance with the provisions of the agreement. It is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology.

## **Medical device**

Our activity on the medical device field is performed through our consolidated subsidiary named InterCure, which operates as a medical device company and manufactures and sells personal therapeutic devices. The Company's products include RESPeRATE, a non-drug and non-invasive hypertension treatment device.

<sup>1</sup> Levkovitz Y., Levi U., Braw Y., and Cohen H., (2007) Brain Research, 1154: 154-162

<sup>2</sup> Levkovitz Y, Mendlovic S, et al. J Clin Psychiatry. 2010 Feb;71(2):138-49

<sup>3</sup> Miyaoka T et al. Clinical Neuropharmacology 31, October 2008 Sep-Oct;31(5):287-92

The cardiovascular and neurological effects of breathing exercises have been known for centuries. In fact, unaided slow breathing is a key element of relaxation techniques such as meditation and yoga but is generally considered unproven and impractical for treating chronic diseases such as hypertension and/or heart failure. InterCure's broadly patented Device Guided Breathing technology ingeniously takes advantage of the human body's natural tendency to follow external rhythms and has broadly patented an interactive "feed forward" concept. The technology composes rhythmic guiding tones, in real time, while measuring the user's individual respiration pattern. By dynamically manipulating and recalculating these personalized tones it guides users into a Therapeutic Zone, subliminally, with almost no conscious effort on the user's part leading to unprecedented efficacy, ease of use and compliance. InterCure has designated sleeplessness and heart failure as its next two target disease states. InterCure's heart failure product successfully met or exceeded primary endpoints in three phase 2a clinical studies and the results elicited great excitement in the heart failure community. The RESPeRATE harness the natural power of breathing to lower blood pressure. High blood pressure is generally caused by your blood vessels tightening up and narrowing, this then causes your heart to pump harder. RESPeRATE's unique breathing exercise relaxes constricted blood vessels to reduce high blood pressure.

InterCure's main field of activity since its establishment is the research and development of technologies and devices for the non-medicinal non-invasive treatment of chronic diseases, including hypertension, congestive cardiac failure, insomnia and stress. Below is a description of the hypertension market and the need for an effective non-medicinal therapy.

Hypertension as defined today is blood pressure which is over 140 mmHg (systolic) and/or 90 mmHg (diastolic) and represents one of the most serious risks of stroke, heart diseases, renal failure and death<sup>4</sup>. Hypertension, also known as the "silent killer", is one of the most common diseases in the population in general and specifically in the adult population. In the U.S., about 76 million people over the age of 20<sup>5</sup> have been diagnosed with high blood pressure and more than one billion in the entire world<sup>6</sup>. It is estimated that in 2025, their number will reach 1.5 billion<sup>7</sup>. In Israel, for example, about one million have hypertension, which are about 20% of the adult population.

The table below demonstrates how the percentage of people diagnosed with hypertension in the U.S. rises with age in both women and men<sup>8</sup>:

<b>Age</b>	<b>Men</b>	<b>Women</b>
20-34	11%	6.8%
35-44	25%	19%
45-54	37%	35%
55-64	54%	53.3%
65-74	64%	69%
75+	66.7%	78.5%

<sup>4</sup> The JNC 7 Report. Prevention, Detection, Evaluation, and treatment of High Blood Pressure, JAMA. 2003;289:2560-2572.

<sup>5</sup> [Www.americanheart.org/downloadable/heart/1265665152970DS-3241%20, HeartStrokeUpdate\\_2010](http://www.americanheart.org/downloadable/heart/1265665152970DS-3241%20,HeartStrokeUpdate_2010) American Heart Association: High Blood Pressure. Statistical Fact Sheet, 2012 update. [http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm\\_319587.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm_319587.pdf).

<sup>6</sup> Kearney PM et al, Global Burden of Hypertension: analysis of worldwide data, Lancet Jan 2005, 15-21;365(9455):217-23.

<sup>7</sup> Global burden of hypertension may reach 1.5 billion by 2025

<http://www.theheart.org/article/380077.do>, 2005

<sup>8</sup> [Www.americanheart.org/downloadable/heart/1265665152970DS-3241%20, HeartStrokeUpdate\\_2010](http://www.americanheart.org/downloadable/heart/1265665152970DS-3241%20,HeartStrokeUpdate_2010) American Heart Association: High Blood Pressure. Statistical Fact Sheet, 2012 update. [http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm\\_319587.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm_319587.pdf).

The overall annual cost of treating hypertension in InterCure's main market in the U.S. is estimated at approximately US\$ 56 billion<sup>9</sup>, of which US\$ 36 billion expensed on various hypertension medications<sup>10</sup>. The average annual individual cost is US\$ 1,131<sup>11</sup>. Even before the definitions of hypertension were changed, the disease and its complications in the U.S. led to more doctor visits than any other disease. Moreover, hypertension is on average the most expensive disease for the American patients themselves who pay an average of US\$ 550 a year on medications (not including additional prescriptions covered by the insurance companies)<sup>12</sup>.

The orthodox solutions for non-medicinal treatment of hypertension are changing one's lifestyle such as getting involved in physical activity, losing excess weight, reducing the consumption of salt and limiting the consumption of alcohol. If these measures are insufficient, the GP will generally recommend medication. Oftentimes, one drug is not enough and the patient is required to take more than one drug. The use of each of the existing hypertension drugs has side effects such as fatigue, depression, impotence, coughing, dizziness etc. Moreover, for an extremely large number of patients, the drugs are highly ineffective in stabilizing the patient's condition although about half of the patients in the U.S. who have been prescribed medications are treated with more than one drug simultaneously<sup>13</sup>. In addition, some of the patients are not interested in taking medications at all and more than 50% of the patients discontinue the use of the drugs in less than a year<sup>14</sup>, generally due to the side effects, which exposes them to the risks of hypertension.

Despite the apparent benefits of treating the disease and the enormous investments in increasing awareness and in medications in the U.S., less than 25% of hypertension patients (including undiagnosed patients and/or non-medicated patients) manage to stabilize their blood pressure to below 140/90 mmHg. About 45 million Americans who are aware of their condition are not properly stabilized or are stabilized but suffer from side effects and need a supplementary solution as described in the sketch below.

To the best of the Group's knowledge, through InterCure, the device's potential target audience can be categorized into several groups as follows:

- a) Subjects who form part of the pre-hypertension group for which developing hypertension is a matter of time. These subjects can prevent/defer the development of hypertension by changing their lifestyles, using methods of relaxation (such as the RESPeRATE) and it has been reported that medication can significantly defer the onset of hypertension.
- b) Subjects with borderline hypertension - many times, in these subjects both the caregiver and the patient are skeptical about introducing medication. This group has the potential of benefiting from relaxation therapy.
- c) The group of patients with hypertension who receive medication - relaxation therapy and the RESPeRATE are likely to improve their blood pressure balance and minimize the number/dosage of drugs they take.

d) All patient groups who suffer from stress can benefit from the RESPeRATE, including people with hypertension, diabetes, heart failure etc.

<sup>9</sup> Balu S, Thomas J 3rd. Incremental expenditure of treating hypertension in the United States. Am J Hypertens. 2006 Aug; 19(8):810-6.

<sup>10</sup> The World Hypertension Market 2007-2023. Reportlinker.com.

<sup>11</sup> Rui T. Economic Cost of Hypertension, 2011. Power Point Presentation.

<sup>12</sup> W.J Cohn, N.A Krause; Spending and Service Use among People With the Fifteen Most Costly Medical Condition, 1997. Gu Q, et.Gu Q, et. al, Trends in Antihypertensive Medication Use and Blood Pressure Control.

<sup>13</sup> Among United States Adults with Hypertension, Circulation. 2012; 126: 2105-2114.

<sup>14</sup> Osterberg L, Blaschke T. Drug therapy: Adherence to medication. N Engl J Med. 2005;353:487-497

In the UK, Germany, Italy and Canada, less than 10% of people with hypertension are stabilized<sup>15</sup>. In the UK, where the device was recently added to the British NHS Drug Tariff, the condition of eight out of ten patients diagnosed with hypertension is not stabilized.

In view of the size of the hypertension market and in the absence of an adequate non-medicinal non-invasive solution (as of the date of this report), as specified above, InterCure has developed the RESPeRATE for non-medicinal non-invasive treatment of hypertension.

The information presented above is based on various publications, including medical publications, which include data from the American Heart Organization, the National Center for Health Statistics and the Center for Disease Control and Prevention. InterCure estimates that the information and data herein are reliable and there is no linkage between InterCure and the entities which issued said publications.

As of the date hereof, and following proof of the clinical efficacy and after having obtained FDA approval, InterCure sold approximately 200,000 devices under the brand RESPeRATE®, in its various versions, to the first target market that it defined –non-medicinal and non-invasive treatment of hypertension in chronic patients who are unable to stabilize with drugs and/or who suffer from adverse events from drug therapy and/or who have not yet begun drug therapy. Most of the devices to treat hypertension were sold to the end-users (patients) at a price of \$300-400 per unit.

In addition, InterCure has several initial clinical trials and professional medical publications that indicate the efficacy of the technology it developed in non-medicinal and non-invasive treatment in heart failure patients. In addition, InterCure has evidence of the efficacy of the device in alleviating stress and in facilitating sleep.

Below are details of InterCure's products:

RESPeRATE - the basic version of the device

RESPeRATE Duo - a basic version of the device which enables two users to record their progress data in separate computer memory functions

<sup>15</sup> K Wolf-Maier, Hypertension Treatment and Control in Five European Countries, Canada, and the United States. Hypertension. 2004;43:10.



RESPeRATE Ultra<sup>16</sup> - a version of the device which guides new users on how to effectively use the device, offering a smaller device and larger user screen

RESPeRATE Ultra Duo<sup>8</sup> - a version of the device which enables two users to record their progress data on the RESPeRATE Ultra model in separate computer memory functions

RESPeRATE Ultra Deluxe - a version of the device with a screen light that makes it easy to read the screen in the dark (designed for the bedroom)

RESPeRATE Rx - a version of the device that is sold through a doctor's prescription in the UK

Device accessories such as a carry case and speakers

Extended warranty for the devices which provides a 36-month warranty instead of the initial 12-month warranty worldwide, excluding Europe where the initial warranty period is legally set at 24 months

Support and personal training program in the U.S. available via email and phone for a fee which improves the effectiveness of InterCure's products and ongoing support for customers

InterCure also offers its customers occasional supplementary aides (from which the revenues are immaterial as of the date of this report) such as blood pressure monitors and books in the subject of hypertension which it purchases from third parties as well as online added value services to the community of users and to anyone interested in non-medicinal therapy for hypertension (a users' forum, eNewsletters etc.). At this stage, InterCure does not charge for these online services.

InterCure also provides technical support services for its customers, including through call centers in the U.S., the UK and Israel. These services are given free of charge and are also offered to non-customers and prospective customers.

The RESPeRATE (and its various versions) developed and marketed by InterCure uses a unique and patented interactive breathing technology to reduce sympathetic nerve traffic, reduce peripheral resistance<sup>17</sup> and lower blood pressure in the home environment without using a guide. The use of the device for 15 minutes a day several times a week will significantly lower blood pressure throughout the day beyond the effects achieved through the use of medications and/or dietary changes and/or physical activity.

<sup>16</sup> Consecutive instructions that guide the user through a controlled breathing pattern but based on the user's own breathing pattern and consecutively monitored by a breathing sensor in order to allow users to relax their breathing (to less than 10 breaths a minute) in an effortless manner and by relatively extending the duration of exhaling compared to inhaling.

<sup>17</sup> Relaxing the small blood vessels reduces their resistance to blood flow and consequently the heart's need to develop high blood pressure to assure regular blood supply.

The device is made of three major parts: a respiration sensor placed on a flexible belt, a battery-operated portable computerized unit and earplugs. The user puts on the sensor belt around the chest or diaphragm, puts on the earplugs and turns the machine on. The machine picks up the breathing signal, analyzes breathing patterns - the breathing rate and the duration of inhalation and exhalation. Based on these features, using a synthesizer, the machine composes and sounds a musical note that is comprised of a high pitch sound which instructs the user to exhale while the sound is being made and a low pitch sound which instructs to inhale air. The respiration sensor and the guiding sounds are consecutive and simultaneous. By matching the duration of the sounds to the user's breathing pattern and changes therein according to unique algorithms, the device creates personal guided breathing exercises using people's natural tendency to adapt their movements to the sound pattern (as in dancing to the sounds of an orchestra and/or marching to a drum beat). The device guides the user to alter their natural breathing pattern from a typical rate of 14-18 times per minute to therapeutic breathing which is basically slower (less than 10 times a minute) and which is done effortlessly by relatively extending the duration of exhalation compared to inhalation. The device stops the guided slowing down of the breathing rate once it identifies that the user is not in sync with the device. This interactive therapeutic breathing technique, which combines the fruits of a decade's research of analyzing breathing signals and respiratory effort, allows practicing guided therapeutic breathing with no concentration or physical exertion, which enhances the efficacy of treatment by preventing increased sympathetic nervous system activity in times of exertion. In addition, InterCure has developed a technology designed to assure that the music played by the device is pleasant to the patient and facilitates the use of the device over time.

In order to obtain regulatory labeling for the device's commercialization as an efficient and safe therapy for hypertension and to increase the medical community's support of this new therapy, InterCure has been conducting a variety of clinical trials.

The device's ability to lower blood pressure has been demonstrated in ten<sup>18</sup> separate clinical trials, the results of nine of which were published in professional medical journals<sup>19,20,21,22,23,24,25,26</sup> and of one as an abstract in an international convention<sup>27,28</sup>. The results of all those clinical trials are consistent and demonstrate a significant decline in blood pressure throughout the day, in addition to the decline achieved through any other means of therapy. However, two assays were published with a small number of subjects in which the decline observed from the use of the device was not statistically different from that of the control device<sup>29</sup>.

<sup>18</sup> The first two assays were published in one article.

<sup>19</sup> Schein M, Gavish B, Herz M, et al. Treating hypertension with a device that slows and regularizes breathing: a randomized double-blind controlled study. *J Hum Hypertens*. 2001;15:271-278

<sup>20</sup> Grossman E, Grossman A, Schein MH, Zimlichman R, Gavish B. Breathing control lowers blood pressure. *J Hum Hypertens*. 2001;15:263-26.

<sup>21</sup> Rosenthal T, Alter A, Peleg E, Gavish B. Device-guided breathing exercises reduce blood pressure - ambulatory and home measurements. *Am J Hypertens*. 2001;14:74-76.

<sup>22</sup> Meles E, Giannattasio C, Failla M, et al. Nonpharmacologic treatment of hypertension by respiratory exercise in the home setting. *Am J Hypertens*. 2004;17:370-374.

<sup>23</sup> Viskoper R, Shapira I, Priluck R, et al. Non-pharmacological treatment of resistant hypertensives by device-guided slow breathing exercises. *Am J Hypertens*. 2003;16:484-487

<sup>24</sup> Elliott WJ, Izzo JL Jr, White WB, et al. Graded blood pressure reduction in hypertensive outpatients associated with use of a device to assist with slow breathing. *J Clin Hypertens (Greenwich)*. 2004;6:553-559.

<sup>25</sup> Effect Bae et al, Effect of Device-guided breathing exercise on blood pressure control: Korean multi-center study. JH et al. *Korean Hypertension journal*. 2006; 1:19-23.

<sup>26</sup> Schein, MH., Gavish, B., Baevsky, T., Kaufman, M., Levine, S., Nessing, A., Alter, A. Treating hypertension in type II diabetic patients with device-guided breathing: a randomized controlled trial. *Journal of Human Hypertension* 2008;23: 325-331.

<sup>27</sup> Aydin L, Kürklü A, Şengül A, Altuntaş Y, Erdine S. Device-guided paced breathing reduces blood pressure: ambulatory and office measurements. *J Hyperten* 2008;26:S371-S372

<sup>28</sup> Regarding referrals to professional articles included herein, it should be noted that these are scientific publications that appear in known medical journals that are considered reliable in the medical community since these journals use experts to substantiate and examine each article before it is published and a similar process is practiced for the abstracts mentioned herein.

<sup>29</sup> In 2007, a study conducted in the Netherlands was published (*Journal of Hypertension* 2007, 25:241–24) which, unsuccessfully, attempted to re-enact lowering blood pressure as discussed above in diabetics. As published in this study, 40% of patients (six out of fifteen) were unable to use the device properly. As preamble to the article, the journal added an editorial which extensively reviews the device's clinical evidence and states that the arguments of the study do not coincide with what is known so far about the device and that it is likely that the study's small scope (30 people, 15 in the therapy group) does not enable proving the aforementioned (*Journal of Hypertension* 2007, 25:57–61). The architects of the study later confessed to InterCure that they had not translated the device's auxiliary literature into Dutch in full but rather settled for a summary of a few lines thereof and had also guided people to use the device in a clinic. Based on its accumulated experience, InterCure believes that understanding the use of the device requires self teaching using the manual attached to the device in a language that is clearly understood by the user since it has been proven that the absence of proper device practice will not lower blood pressure. These conditions were not met in said study and therefore InterCure believes that it is highly likely that this explains the results of the study. In a trial using the same method conducted with therapy and control groups, each of 15 people, a difference was found between the groups which resembled the other trials of the device but with a statistically immaterial outcome due to the small number of participants. The results were published in *Blood Press*. 2009;18(5):273-9. It should be noted that the researchers did not report the method of using the device or using the data automatically accumulated in the device, which is a fundamental condition for understanding the results.

A recently published controlled study demonstrated the device's ability to reduce the sympathetic nervous system activity<sup>30</sup>, which coincides well with the mechanism in the device<sup>31</sup>.

As specified in this paragraph below, the average declines in blood pressure of 14/8 mmHg observed in the trials are clinically significant<sup>32</sup>. It should be noted that the results have been proven independently of the patient's gender and of taking medications and no undesired side effects have been observed. In general, the high blood pressure declined significantly within only 3-4 weeks of use of the device. It is important to state that these declines over time have clinical and economic importance in view of the fact that the risk of a cardiovascular event is doubled in the event of a 20 mmHg elevation in systolic pressure or 20 mmHg in diastolic pressure<sup>33</sup>. This is the reason why lowering the blood pressure reduces the risk of cardiovascular events, which can be quantified by the Ministry of Health as a saving. Based on the results of the trials, InterCure developed a statistical model that proves the economic benefit of using the device. The model was used by the British healthcare authorities in the process of assessing the economic profitability of the device which led to including it in the British NHS Drug Tariff in February 2012. Just as important is the ability to use the device over time and maintain reduced blood pressure. Nearly 100 testimonials of using the device between one to ten years have been delivered to the healthcare authorities in the process of making that assessment.

Following InterCure's assessment that its arguments regarding the efficiency of the device as a means of treating hypertension would have been dubiously accepted by the medical community and the medical regulatory authorities (due to their habit of treating hypertension through medications and not using a device as the one marketed by InterCure), InterCure planned and conducted four group double-blind randomized controlled trials which compared the use of the device to the use of a walkman playing calm music. In addition, InterCure tested the effect of the device on special patient populations using a variety of measurement methods in order to test and demonstrate the physiological source of the effect.

Along with the growing recognition from the medical community in the category of devices for treating hypertension, several articles were published recently in this subject, which positioned the device as a means of treating hypertension<sup>34,35,36</sup> and as a non-pharmacological means of treating hypertension<sup>37</sup>.

<sup>30</sup> Oneda B, Ortega KC, Gusmano JL, Araújo TG, Mion D Jr. Sympathetic nerve activity is decreased during device-guided slow breathing. *Hypertens Res.* 2010 Jul; 33:708-712

<sup>31</sup> Parati G, Gavish B, Izzo JL, Respiration and blood pressure, in *AHA Hypertension Primer 3rd ed.* Izzo JL and Black HR, eds. Lippincott, Williams and Wilkins, Baltimore, 2003; Ch. A40, p.117-120

<sup>32</sup> The average declines in blood pressure refer to the results of the first seven clinical trials concentrated in the article mentioned below. The declines in the other clinical trials remained consistent.

<sup>33</sup> Global burden of hypertension may reach 1.5 billion by 2025 <http://www.theheart.org/article/380077.do>, 2005

<sup>34</sup> RESPeRATE: nonpharmacological treatment of hypertension. Sharma M, Frishman WH, Gandhi K. *Cardiol Rev.* 2011; 19:47-51.

<sup>35</sup> Device-Guided Breathing and Hypertension. A Yet To Be Determined Positioning. Sica DA. *Cardiol Rev.* 2011; 19:45-46. [Editorial].

<sup>36</sup> Non-pharmacological Interventions for Patients with Resistant Hypertension. Abe N, Bisognano JD *US Cardiol* 2011; 8:52-55.

<sup>37</sup> Nondrug interventions for treatment of hypertension. Woolf KJ, Bisognano JD. *J Clin Hypertens (Greenwich).* 2011; 13:829-835.

### **The main points of the clinical trials and population of subjects**

The ten clinical trials conducted - four group double-blind randomized controlled trials one controlled trial and two uncontrolled trials - were described in the review published regarding the first seven studies<sup>38</sup>. In addition, a group randomized controlled trial and two uncontrolled trials were conducted. In total, these studies recruited over 500 hypertension patients.

In all the trials, a daily 15-minute practice<sup>39</sup> use of the device was tested over a period of eight weeks. In two trials, the control group used a walkman playing calm music, in two trials, the patients measured their blood pressure using a digital monitor, in one trial, both devices were used and in one trial, no devices were used and only the medications were administered.

In the first seven trials whose concentrated results were published<sup>40</sup>, 78% of the patients were already medicated for hypertension and one third of the medicated patients received more than three drugs. Although the majority of patients were treated through medications and/or change in lifestyle, their initial blood pressure as measured at a clinic was non-stabilized at 150/90 mmHg on average.

### **The principal trial results**

The users of the device with uncontrolled blood pressure demonstrated a significant decline in blood pressure measured at the clinic by an average 14 mmHg in systolic blood pressure that was non-stabilized before the trial (over 140 mmHg) and an average 8 mmHg in uncontrolled basic values of diastolic blood pressure (over 90 mmHg), compared to the corresponding average decline in blood pressure observed in the control group of 9 mmHg and 4 mmHg in systolic and diastolic blood pressure, respectively. The declines in blood pressure in the control group were smaller than those of the therapy group with a statistical significance level of  $p=0.008$  and  $p=0.002$ , respectively (namely, the risk of statistical error is 0.8% and 0.2%, respectively).

The results were similar for both men and women and for both subjects who were under medicinal therapy and those who were not.

The scope of the decline in systolic blood pressure corresponded to the cumulative time which the patient spent practicing therapeutic breathing - the more the device was used, the more the blood pressure was reduced. It was also found that timing the breathing with the guiding sounds (under proper use of the device) is an important component in lowering blood pressure using the device<sup>41</sup>.

A continuous decline in blood pressure was observed after 3-4 weeks of using the device.

<sup>38</sup> Elliott WJ, Izzo JL Jr. Device guided breathing to lower blood pressure: Case report and clinical overview. Medscape General Medicine, Pulmonary Medicine Section. Available on the Internet at: [www.medscape.com/viewarticle/539099](http://www.medscape.com/viewarticle/539099).

<sup>39</sup> In the first three trials, practice lasted about ten minutes. In the following trials and using the device at its default option, practice lasted 15 minutes.

<sup>40</sup> Elliott WJ, Izzo JL Jr. Device guided breathing to lower blood pressure: Case report and clinical overview. Medscape General Medicine, Pulmonary Medicine Section. Available on the Internet at: [www.medscape.com/viewarticle/539099](http://www.medscape.com/viewarticle/539099).

<sup>41</sup> Gavish B, Device-guided breathing in the home setting: Technology, performance and clinical outcomes. Biol. Psychol. 2010; 84:150-156.



Larger declines in blood pressure measured at a clinic were found in the older population (average declines of 18 mmHg and 8 mmHg in systolic and diastolic blood pressure, respectively in adults over 65) and in subjects with initially uncontrolled blood pressure, whether under medicinal therapy or not.

Blood pressure taken at a clinic and at home (up to six months of using the device), and specifically 24-hour ambulatory blood pressure monitoring demonstrated that the decline in blood pressure achieved through permanent use lasts throughout the day over months.

The user's ability to consistently operate the RESPeRATE through self training alone, without previous respiratory practice has been objectively proven in clinical trials by using the device's internal memory and in market researches with users.

In order to maintain reduced blood pressure over time, the patient must continue to use the device in the manner described above.

## **Reimbursement**

InterCure believes that there is demand for technology that may reduce the cost of medical treatment, including home medical devices that may reduce cost of treatment hypertension and diseases caused by hypertension. Accordingly, InterCure believes that medical insurers might decide to indemnify the purchases or InterCure products for part or all of the purchase of the device in order to lower the gross expenses in refunding money to policyholders for the purchase of drugs to lower blood pressure and treatments for the disease. Although InterCure does not base its business model on medical reimbursement for the purchase of the product, it is working to convince medical insurers to provide full or partial refund to policyholders who purchase the product. InterCure believes that a reimbursement from the medical insurers, if any, may increase sales.

In the US, the reimbursement procedure in insurance companies consists of a few stages. In the first stage, an application is made for the receipt of a CPT code from the American Medical Association (AMA). In the second stage, an application to an ICD-9 code is made to the coordinating committee of the Medicare centers. In the third stage, an application is made to the Statistical Analysis Medical Equipment (SADMERC) regional contractor for the receipt of a new code (HCPCS). After receiving the code with a patient's request to receive a device, the patient's date should be examined in order to verify he fits the criteria enabling him to get reimbursed. If the patient fits the criteria, a device will be supplied to the patient and an invoice will be issued to the insurer.

As of today, InterCure does not have a reimbursement code for its products in the US, and one cannot evaluate at this stage, whether it will receive such code in the future.

In the United Kingdom, InterCure filed an application to establish insurance indemnity as part of the British health basket. On 17 November 2011, InterCure announced that the British Department of Health approved its application for insurance indemnity for the product and as part of the health basket in Britain<sup>10</sup>. As a result, InterCure signed several distribution agreements in Britain, and on 1 February 2012, began selling the product in a manner in which patients in Britain who were required to pay GBP 200 out of pocket to purchase the product could receive the device free of charge or for a nominal fee upon presentation of a signed physician's prescription.

### *Our Strategy*

Our objective is to be a leading biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, currently for the treatment of MM, schizophrenia and Hepatitis C. In addition, through InterCure, we develop home therapeutic devices for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and market and sell a medical device product for the treatment of hypertension.. We continuously identify and in-license therapeutic candidates in order to maximize our potential for commercial success.

Under our current strategy in respect to our pharmaceutical and biopharmaceutical products, we plan to:

initiate a prospective phase 2 clinical study intended to assess the safety and efficacy of rHuEPO when given to patients with advanced MM;

initiate a prospective clinical study intended to assess the safety and efficacy of SAM-101 when given to patients with schizophrenia;

continually build our pipeline of therapeutic candidates, and

develop collaborations with large pharmaceutical companies to sublicense/develop, and market our rHuEPO, SAM-101 and DOS technology.

As per InterCure's medical device, the main targets are:

Establishing its developed therapeutic technology as part of the standard treatment protocol for hypertension;

Focusing on and specializing in online sales of InterCure's products;

Raising capital for expanding activities and growth;

Achieving profitability and creating a positive cash flow from operating activities and regaining growth in 2013 (following the completion of the debt refinancing of July 25, 2012); and

Examining the modification of InterCure's marketing and distribution models in order to use the insurance compensation in the UK (the British NHS Drug Tariff), as a profit growth engine and as a model to be used in other countries.

The Group's other main targets to be achieved through InterCure in the coming years include expanding the insurance compensation for the device in the UK hypertension market as well as in other markets, developing additional areas of therapy such as stress, heart failure and insomnia that leverage the technologies, products and commercialization infrastructures developed by InterCure and examining the expansion of InterCure's range of products by collaborating with companies in the field and sick funds.

In order to become profitable, to achieve a positive cash flow and regain growth in 2013 while supporting all the above targets, InterCure's work plan combines the following strategic tiers:

- Focus the majority of resources on the initial target market of hypertension;

- Strive to become profitable and grow by enhancing the investment in online advertising in a controlled fashion - an advertising channel which has been proven as positively contributing to InterCure's overall profits through direct sales and support of distribution channels and other targets;

- Leverage the receipt of insurance compensation in the UK (the British NHS Drug Tariff) as a profit growth target and as a model for other countries by adapting the marketing and distribution system, forming partnerships, all without making significant investments;

- Establishing the support of the medical community for the therapeutic technology in order to accelerate penetration into the insurance compensation market and include the technology in the therapeutic guidelines of the appropriate medical organizations; and

Subject to completing a capital raising round, penetrating new geographical markets, expanding the basket of products by developing new products and collaborating with companies in the field and sick funds.

### ***Products Under Development***

#### **rHuEPO for the treatment of MM**

##### *Market Opportunity*

We intend to develop the use of rHuEPO for the prolongation of MM patients' survival. In the United States alone, there are approximately 74,800 people living with MM, with about 22,350 new cases that are expected to be diagnosed in 2013 (Cancer Facts & Figures 2013). MM is the second most prevalent blood cancer representing approximately 1% of all cancers in white US residents and 2% of all cancers in African Americans. The average age at diagnosis is 65-70 and is also more common in men than women, and in African Americans than Caucasians.

Erythropoietin, a glycoprotein hormone produced mainly by the kidney, is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis by binding to its receptor (EPO-R) on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. The cloning of the EPO gene led to the introduction of rHuEPO into clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia.

Over the last decade, several reports (Mittelman PNAS 2001, Mittelman European Journal of Hematology 2004; Katz Acta Haematol 2005; Prutchi-Sagiv BJH 2006; Prutchi-Sagiv Exp Hematol 2008; Brines PNAS 2001; Baz Acta Haematol 2007; Prutchi-Sagiv Medical Hypothesis and Research 2005, Katz Eur. J. Immunol 2007) have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic properties, broadly beyond erythropoiesis.

A clinical observation made by Professor Moshe Mittelman and colleagues (Mittelman M, Zeidman A, Kanter P, Katz O, Oster H, Rund D, Neumann D. Erythropoietin has an anti-myeloma effect - a hypothesis based on a clinical observation supported by animal studies. Eur J Haematol. 2004 Mar;72(3):155-65) confirmed the high success rate of rHuEPO in treating the anemia in patients with MM. Six patients continued treatment with rHuEPO beyond the initial designed 12 week period with very poor prognostic features of MM, whose expected survival was less than 6 months, and surprisingly, they lived for 45–133 months cumulatively with the MM diagnosis and 38–94 months with rHuEPO (with a good quality of life).

This clinical observation was further supported by pre-clinical animal studies. These animal studies not only confirmed the anti-myeloma effect of rHuEPO but also detected a new unrecognized hitherto immune-mediated effect to rHuEPO, probably mediated via T cells (Mittelman M., Neumann D., Peled A., Kanter P. and Haran- Ghera N. (2001) Erythropoietin induces tumor regression and antitumor immune responses in murine myeloma models. (PNAS, vol. 98: 9. 5181 - 5186; Katz O, Barzilay E, Skaat A, Herman A, Mittelman M, Neumann D. Erythropoietin induced tumour mass reduction in murine lymphoproliferative models. Acta Haematol. 2005; 114 (3):177-9). Recently, it was also shown that treatment of stage II-III MM patients with rHuEPO is associated with a significant improvement of various immunological parameters and functions (Prutchi-Sagiv British Journal of Hematology 2006; Prutchi-Sagiv Experimental Hematology 2008; Lifshitz Molecular Immunology 2009).

Furthermore, several studies have been published by other investigators addressing survival and/or prognosis in cancer patients treated with rHuEPO. For example:

**Baz R et al:** A team from the Cleveland Clinic Myeloma Program analyzed their experience with rHuEPO in MM patients. This retrospective analysis provides data on 292 MM patients enrolled on different protocols between 1997 and 2003. The authors concluded that “rHuEPO was associated with improved overall survival in this population of anemic MM patients with SWOG stages II, III and IV.” They summarized by saying that “a prospective randomized trial is warranted to corroborate this finding” (Baz R et al: Recombinant human erythropoietin is associated with increased overall survival in patients with multiple myeloma (Acta Haematol 2007; 117: 162-7)).

#### *Development Status*

As of the date of the financial statements, the Company is in stages of planning and preparing for the implementation of a phase 2 clinical trial of the recombinant EPO ("rHuEPO") drug for treating Multiple Myeloma patients. As part of said preparations, the Company conducted a study which consists of collecting preliminary data on the existence of specific proteins in the blood of a group of Multiple Myeloma patients. The Company has expanded the study to additional centers in order to collect additional data beyond the original study plan. The data which was collected in the framework of the preliminary study will be combined, as necessary, in planning and preparing for the implementation of the phase 2 clinical trial which the Company expects to obtain the approval to commence it by the end of the fourth quarter of 2013.

We plan on performing a prospective, multi-center, double blind, placebo controlled phase 2 study intended to demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. The trial will enroll approximately 50 MM patients over a period of 2 and a half years. We have begun preliminary discussions with potential clinical sites and third party vendors for the planned study. The study is expected to cost \$1-1.5 million.

The drug development process is a multi-step process, including the following steps: pre-clinical, Phase 1, Phase 2, and Phase 3 clinical trials.

Given that we intend to develop a new indication for rHuEPO, which is already approved for another use, and the fact that the pre-clinical and phase 1 phases are intended to assess drug toxicity and safety, we may be exempted from carrying out these steps and the drug development process may begin with Phase 2 clinical trial.

*This is an estimation only and based on information our group has at the time of writing this report. Actual results may differ from the results implied in this report. There is no certainty that we may receive an exemption from carrying out one or more phases, nor is there certainty about the results of these experiments.*

#### **SAM-101 for schizophrenia**

*Market Opportunity*

We intend to develop SAM-101, a patent-protected combination of minocycline and antipsychotic drugs for the treatment of schizophrenia. According to the US National Institute of Mental Health (NIMH), schizophrenia is the most prevalent severe mental disease in the USA, affecting 1.1% of the adult population<sup>42</sup>. Schizophrenia is ranked as the third most disabling condition, higher than blindness, by the general global population<sup>43</sup>.

<sup>42</sup> The schizophrenia prevalence estimations ranges from 0.5%-1.5% as reported by DSM-IV(2000). The US Surgeons General reports a prevalence of 1.3% worldwide, regardless of race (1999)  
<http://www.nimh.nih.gov/statistics/1SCHIZ.shtml>

<sup>43</sup> Ustun et al (1999) The Global Burden of Mental Disorders. *American Journal of Public Health*, 89(9), 1315-1318  
this is ok



Schizophrenia is a chronic disorder that requires lifelong medication. While most of the available drugs are effective in remitting schizophrenia's "positive symptoms" (hallucinations, delusions, agitation), even the best available drug is only partially effective in remitting several of the most disturbing features of the disease, known as "negative symptoms" (apathy, poverty of speech, emotional withdrawal, depression) and severe cognitive impairment. SAM-101 is expected to overcome major limitations of currently available treatments for schizophrenia by providing an effective treatment, affecting both negative and positive symptoms, therefore preventing further deterioration in schizophrenic patients. In addition, SAM-101 showed lower side effects in the clinical trial mentioned below, which is expected to allow for higher compliance and improved patient quality of life. We believe that our innovative combination drug may open an opportunity for manufacturers to extend ethical drugs marketing time.

The global schizophrenia market in 2010 reached \$6.4 billion. The market declined thereafter owing to the launch of generic versions of the leading antipsychotics – risperidone, olanzapine, quetiapine and ziprasidone, in 2011. According to Datamonitor, pipeline products in phase 3 and 2 clinical trials are not expected to drive market growth, since most of them offer no or little significant advantage over current medications, which will shortly become generic. Nevertheless, a number of new companies will enter the schizophrenia market during the upcoming years. Combination therapies are recognized for clinical advantages including facilitated patient compliance and convenience, along with increased efficacy. Such developments play a key role in terms of pharmaceutical market contenders' business strategy, allowing for extended exclusivity rights. According to DataMonitor (2005), "If a combination treatment is shown to be clinically superior, pharmaceutical companies will be racing to have the first combination product".

#### *Development Status*

We in-licensed SAM-101 after it successfully completed a Phase 2a prospective, randomized, double-blind, placebo-controlled clinical trial conducted on about 70 schizophrenics in accordance with the Helsinki guidelines under the Shalvata Medical Center in Israel. The trial met its endpoints showing that SAM-101 improves the positive symptoms of the disease as well as the patients' cognitive state, minimizes the negative symptoms (social parameters and patient cognition) and reduces weight gain side effects among patients. Schizophrenia is a severe and chronic (psychotic) mental disorder and one of the most common. It affects the majority of social and mental functions, mood, perception, thought and cognitive functions. According to the United States National Institute of Mental Health, about 1.1% of the adult population in the United States has Schizophrenia<sup>44</sup>. The research company Decision Resources indicates that the Schizophrenia treatment industry in 2011 amounted to approximately \$7.4 billion<sup>45</sup>.

Since minocycline and antipsychotics have been approved in the United States, a combination of the two should be eligible for market approval using the 505(b)(2) route. This allows the FDA to rely on their own previous finding of safety and efficacy of the active pharmaceutical ingredients for the purposes of marketing approval of SAM-101.

The phase 2 trial that was conducted in Israel has shown that SAM-101 has additional clinical benefit compared to the available antipsychotic drug alone. We plan to perform a multi-center phase 2 clinical trial under the FDA, using our proprietary combination. In order to confirm the scope of work required for product market approval (New Drug Approval, NDA) and to identify the specific requirements for filing an Investigational New Drug (IND) application with the FDA and for eventual market approval of the combination drug, we will request a Pre-IND meeting with the FDA.

*This is an estimation only and based on information our group has at the time of writing this report. Actual results may differ from the results implied in this report. There is no certainty that we may receive an exemption from carrying out one or more phases, nor is there certainty about the results of these experiments.*

<sup>44</sup> <http://www.nimh.nih.gov/statistics/1SCHIZ.shtml>

<sup>45</sup> <http://decisionresources.com/Products-and-Services/Report?r=pcorcg0713>

## **DOS**

### *Market Opportunity*

We had been developing the DOS program for the treatment of Hepatitis C, prior to us out-licensing it to Presidio in March 2008. Chronic Hepatitis C is a serious life-threatening disease which affects around 130 to 170 million people worldwide, according to the World Health Organization. According to the BioSeeker Group, 20% to 30% of chronic hepatitis patients will eventually develop progressive liver disease that may lead to decomposition of the liver or hepatocellular carcinoma (liver cancer). According to the National Digestive Diseases Information Clearing House, of the U.S. population, 1.6 percent, or an estimated 4.1 million Americans, have antibody to HCV (anti-HCV), indicating ongoing or previous infection with the virus. Hepatitis C causes each year 10,000 to 12,000 people die from HCV in the US alone.

### *Development Status*

In March 2008, and as revised in August 2008, we signed an agreement to out-license the DOS program to Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio became responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a \$5.94 million, non-refundable, upfront payment in cash from Presidio. In addition, we should have received up to an additional \$59 million upon reaching certain development and commercialization milestones, royalties on direct product sales by Presidio, and a percentage of Presidio's income if the DOS program was sublicensed by Presidio to a third party. On August 22, 2012, Presidio requested to terminate its engagement with us effective as of August 24, 2012. Following a notice of the termination of the agreement, Presidio's entire DOS technology (including all the patents maintained by Presidio) will be revert back to the Company within 90 days from the date of said notice in accordance with the provisions of the agreement. DOS is a pre-clinical program focused on the development of novel Hepatitis C small molecule inhibitors. DOS applies proprietary, fully synthetic chemistry methodologies to rapidly synthesize and diversify complex chemical compounds such as natural products. Compounds in each family inhibited HCV replication in a pre-clinical cell-based assay with potencies against the most prevalent HCV genotypes comparable or superior to clinical stage drugs. They also retained their potency against isolates that are resistant to clinical stage drugs. It is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology. See "Item 10. Additional Information -Material Contracts."

We gained access to the DOS program through a license and asset purchase agreement with VivoQuest that was completed in September 2005. Under this agreement, we licensed lead HCV molecules, a proprietary compound library and medicinal chemistry technologies. The DOS small molecule chemistry technology developed at VivoQuest

was used to create these molecules. See “Item 10. Additional Information -Material Contracts.”

**Proteologics**

In November 21, 2012 we acquired approximately 31.35% of Proteologics' shares. Proteologics is a public company whose shares are traded on the TASE, engaged in the discovery and development of drugs comprised of various components of the UBIQUITIN system discovered by Dr. Avram Hershko and Dr. Aaron Ciechanover, both 2004 Nobel Prize laureates in Chemistry for the discovery of the UBIQUITIN system. As of April 24, 2013 we hold approximately 30.88% of Proteologics' issued and outstanding shares (the decrease results from options exercised by Proteologics' employees).

Proteologics focuses in research and development of drugs for a variety of diseases, based on the ubiquitin system. The ubiquitin system is a biochemical path which involves biological processes in the body, where disruptions to the system can give rise to a long list of diseases including metabolic problems, nervous developments and disturbances, malignant diseases, muscle atrophy and viral diseases.

The Ubiquitin system was first discovered in 1978 by Professor Avram Hershko and Professor Aaron Ciechanover, of the Faculty of Medicine in the Technion, and Professor Ernie Rose, who won the 2004 Nobel Prize in Chemistry for this research.

Proteologics has knowledge, experience and intellectual property relating to the ubiquitin system and it concentrates its efforts in discovering targets for drugs connected to this system. Proteologics is acting to discover proteins in the ubiquitin system which are a causal factor in the indication of a particular disease and which can be a target for the drug. After discovering the target protein, Proteologics works on developing a drug (either via a chemical molecule or via siRNA technology), which causes deactivation or inhibition of the actions of the target proteins, thereby giving rise to an improvement or remedying of the disease. According to Proteologics' reports for 2012, Proteologics believes that the knowledge accumulated by it regarding the ubiquitin system might assist it in discovering and developing drugs for a variety of diseases.

The Ubiquitin Proteasome System (UPS) is a major machinery of biological regulation, underlying a wide array of cellular pathways. UPS controls protein turn-over by selectively tagging, or ubiquitinating, proteins destined for different biological activities including proteasomal degradation. The organization of the ubiquitination cascade is hierarchical, involving one common E1 enzyme, which activates ubiquitin, multiple combinations of several E2 conjugating enzymes, and at least six hundred E3 ligases, which catalyze ubiquitination of specific substrates. The ubiquitination process is also counter-balanced by the activity of deubiquitinating enzymes (DUBs).

Regulated protein degradation is an essential aspect of normal physiology and alterations in UPS have shown to be implicated in the pathogenesis of numerous human diseases, including cancer as well as inflammatory, cardiovascular neurodegenerative and viral diseases and metabolic disorders. For example, the presence of ubiquitin-positive aggregates has been well recognized as a common feature in neurodegenerative diseases and in various stages of atherosclerosis. The potential of exploiting the ubiquitin system for therapeutic benefit blossomed with the approval of the proteasome inhibitor Velcade® (bortezomib) for the treatment of multiple myeloma and relapsed mantle cell lymphoma. In current drug discovery, E3 ligases and DUBs have gained the most attention due to their direct roles in regulating protein's stability. Proteologics unites a team of passionate scientists, Nobel laureates and business leaders bringing together their collective experiences in UPS-based drug discovery. Proteologics' technology platform integrates powerful capabilities in Lead Discovery and Lead Optimization. Once targets are validated, Proteologics utilizes a battery of cell-free ubiquitination assays to conduct high throughput screening of potent small molecules. Selected candidates are further optimized using proprietary selectivity assays for additional UPS components including a panel of E3 ligases, followed by SAR-based drug design, cell-based efficacy assays, and in vivo models of ADME-Tox and efficacy.

Proteologics has a scientific and development framework that is entirely dedicated to developing new drugs based on globally and corporate accumulated knowhow on the ubiquitination system. According to scientific literature, ubiquitin is a relatively small protein tag which attaches itself to another protein and labels it for destruction or other forms of control over cell mechanisms. Proteologics' research activity aims to discover proteins in the ubiquitination system which constitute a significant factor in the development of the disease and whose neutralization or inhibition leads to an improvement in or curing of the disease (target). The ubiquitination system is a central biochemical path that is involved in several biological processes whose disruption is liable to lead to a series of diseases with wide therapeutic consequences such as metabolism disorders, developmental and nerve related disorders, malignant diseases, muscular atrophy, inflammatory diseases, viral diseases and high blood cholesterol levels. These diseases are all attributable to ubiquitin functions and actually respond to the ubiquitination system's functioning. The ubiquitination system's critical role in cells on the one hand and the ability to recognize proteins in the ubiquitination system which constitute a node that controls critical cell processes on the other turn this system into a valuable focal point for developing new drugs.

In order to shorten R&D time and focus on drug discovery, Proteologics prioritizes targets published in scientific literature over in-house target identification. However, Proteologics' abilities to discover new targets allow it to operate in this field as well and rid it of the dependence on publications which it cannot control and, if circumstances justify it, enable it to proactively identify new drug targets.

Proteologics has one area of operations; research and development of drugs. Proteologics' efforts are focused on drugs based on the ubiquitin system, for a variety of diseases.

On February 17, 2010, Proteologics entered into a collaboration and license agreement with the international pharmaceutical company GSK (the "GSK Agreement"), in which the parties agreed to cooperate in six research and development programs for three years with an option to extend the license for another year. Proteologics and GSK are engaged in research and development in three programs (after one program was closed and two programs were frozen). On March 7, 2013, Proteologics and GSK agreed to extend the co-operation term for another year. It was also agreed to cease the PRT31-A and PRT31-B projects, and focus on PRT31-C project, which is, according to the estimation of the professional staff of both companies, the most promising program. Proteologics granted GSK an exclusive global license to use its future accumulated knowhow and IP underlying the molecules to be developed in the context of the collaboration between the companies. GSK was also granted a non-exclusive license to use Proteologics' R&D technology as needed for the performance of the agreement.

According to the agreement, GSK will provide Proteologics an immediate first payment of \$ 3 million and quarterly installments over a period of three years in a total of \$ 5.4 million (\$ 8.4 million in total) for financing the research and development with a possibility of extending the research and development period by another year for an additional up to \$ 1.7 million ("the extended period"). In addition, Proteologics will be entitled to receive receipts based on milestones and royalties on future sales by GSK as detailed in the agreement.

As mentioned above, on March 7, 2013, GSK and Proteologics agreed to extend the collaboration period by another year in order to focus on a single program. GSK's budget for the continued collaboration will be determined after a hearing is held at the joint committee based on the results of the trials that are currently being conducted by Proteologics but will not exceed \$ 1.7 million, which is the maximum budget amount set in the GSK agreement for the extended period.

### ***Revenues***

To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any commercial revenues from the sales of our drug candidates. Moreover, preliminary results of our pre-clinical or clinical tests do not necessarily predict the final results, and acceptable results in early preclinical or

clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing.



As per our medical device activity through our consolidated subsidiary - InterCure, and its products, RESPeRATE, the table below shows our consolidated revenues by geographic market in 2012, which were all generated since the acquisition date of InterCure in July 25, 2012:

	Year ended December 31, 2012 U.S dollars
United States	766
United Kingdom	167
Other countries	5
Total	938

### *Seasonality*

Sales of RESPeRATE are affected by seasonality, whereby sales of the Q4 and Q1 are higher than sales in other quarters after neutralizing sales promotion campaigns. Q4 is traditionally considered to have the largest scope of sales especially due to the holiday season between Thanksgiving and Christmas (a season in which sales in the US are particularly high), and also because during the winter blood pressure tends to rise as a result of the stenosis (narrowing) of the blood vessels due to the cold. Q1 is also traditionally considered good especially for health products. Other than seasonality, InterCure's sales are also affected, among other things, from the extent of advertising through the online channels and from sales promotion.

### *Purchasing and Raw Materials*

As of the date of the report and since 2003, InterCure has been manufacturing the device (and its different versions) on a turnkey basis by an independent subcontractor which is unrelated to InterCure's interested parties ("the subcontractor"). InterCure orders some of the device's raw materials for the subcontractor from time to time, mainly the more expensive ones, or negotiates with suppliers of raw materials due to profit considerations and offsets the price paid by it to the subcontractor.

In the event that a certain supplier or suppliers need to be replaced for whatever reason, InterCure will be required to train the new supplier and provide it with the knowhow underlying the manufacturing process and the new supplier will be required to purchase the raw materials for the manufacturing process. InterCure believes that a process of training a new supplier will take several months, in which case InterCure will be prepared in terms of inventory for the

relevant period.

InterCure's products include both purchased components ("shelf components") such as solid-state electronic components and tailored components developed according to customized specs such as injection of plastic part, machining etc. Most tailored components are manufactured in China whereas the shelf components are made in the U.S., Europe and the Far East and purchased by InterCure's main subcontractors.

Most components can be purchased and supplied within eight weeks at the most but the purchase and supply of a small number of components may take up to 22 weeks. InterCure prepares for the purchase of the components with a prolonged purchase process in advance by providing appropriate manufacturing forecasts to the relevant subcontractors, maintaining a minimum inventory of the various components and/or signing annual agreements with the component suppliers. As of the date of this report, there are two shelf components, the sound and CPU, which do not have an immediately available alternative manufacturer. If these components become unavailable, it will take several months and an immaterial expense to modify plans and locate similar components.

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### *Market Channels*

InterCure's marketing and sales activities derive, among other things, from its goals, commercialization strategy and its work plan.

As stated above, as of the date of this report, InterCure's main targets are to become profitable, derive positive cash flows from operating activities and recover growth in 2013 by increasing sales and exposure while continuing to establish the therapeutic technology developed as part of the standard therapeutic protocol for treating hypertension.

For that purpose, InterCure adopted the following business strategy and work plan:

- Focus the majority of resources on the primary market – hypertension;
- Focus on direct marketing channel (online advertising and/or via distributors);
- Strive to become profitable and grow by enhancing the investment in online advertising in a controlled fashion - an advertising channel which has been proven as positively contributing to InterCure's overall profits through direct sales and support of distribution channels and other targets;
- Leverage the receipt of insurance compensation in the UK as a profit growth target and as a model for other countries by adapting the marketing and distribution system, forming partnerships, all without making significant investments;
- Establishing the support of the medical community for the therapeutic technology in order to accelerate penetration into the insurance compensation market and include the technology in the therapeutic guidelines of the appropriate medical organizations.

InterCure's principal marketing efforts are in the USA, UK and Canada, countries in which the above strategy is implemented and which constitute the main markets in consideration of the scope of sales for InterCure. The marketing activity in the US market is executed with the assistance of InterCure Inc., an InterCure subsidiary. As at the date of this report, the scope of sales of InterCure products in locations other than USA, Canada and the UK are not material.

InterCure's activity through the different marketing and distribution channels is detailed below:

#### **1. Direct marketing, marketing interfaces and advertisement**

As part of the implementation of the business strategy described above, InterCure operates a direct marketing system which consists of advertising, direct sales, logistics and customer service.

InterCure's marketing system and advertising budgets are adapted on an ongoing basis to allow support for the direct sales, the expanding distribution channels and to increase the medical community's awareness to the device. This system relies on sophisticated IT systems developed by InterCure which enable the management, monitoring and analysis of advertising for continued optimization of the advertising budget, namely, deciding in which channels to invest more and in which less based on the profits of the different advertising channels<sup>46</sup>. Moreover, these IT systems

allow managing customer relations and form a logistic platform for taking orders electronically and through internal and external call centers in Israel and worldwide (mostly the U.S. and the UK), supplying the devices to the customer's home, all in integration with InterCure's ERP system.

As stated above, the marketing strategy described above continues to allow material product exposure and branding, support for other distribution channels and a certain increase in the medical community's awareness to the device while generating direct income for InterCure.

<sup>46</sup> Most ads include a specific link or contact number that allows the IT system to attribute responses to specific ads and individually calculate the return on the investment.

In 2012, more than 1.3 million unique visitors visited the product's website. InterCure sent about 15 million emails to customers who registered on the website (while adhering to the relevant regulations regarding sending emails, including compliance with the Can-Spam Act in the U.S.) and reached about 12,000 doctors. The vast majority of these visitors found the website through the large variety of InterCure's online advertising means, including search engine marketing where surfers seeking information by using search words relating to hypertension receive a text ad or sponsored link directing them to InterCure's website. In addition, InterCure advertises contextual ads, in eNewsletters and/or solo emails to subscribers of other companies (acting, to the best of InterCure's knowledge, in compliance with the relevant regulations in this field, including compliance with the Can-Spam Act in the U.S.). InterCure utilizes geo-targeting and retargeting techniques when possible. Moreover, InterCure operates a large array of online tools for turning visitors registered on the website into customers, such as by sending out email recommendations for non-medicinal therapy for hypertension (10 daily tips), emails on sales promotions, a highly active online forum, blogs, eNewsletters etc.

In summary, the investment in on-line marketing and the distribution mixture of InterCure result in positive contribution (gross profit after deducting media expenses) to the overhead.

## **2. Resellers in markets in which InterCure is active via direct sales**

In the context of the activities in the main target markets, the U.S. and the UK, InterCure also sells its product through a limited number of value adding resellers such as chains. These resellers purchase the product from InterCure at a discount and usually resell it for the same price offered to direct customers. InterCure estimates that most resellers were first exposed to the product through its direct advertising activity but purchased the products from established websites such as [www.amazon.com](http://www.amazon.com) ("Amazon") or [www.drugstore.com](http://www.drugstore.com)) which offer added security for some of the customers when purchasing new and unfamiliar products.

In 2012, these resellers accounted for 13% of total product units sold by InterCure, mostly through online shopping websites (in 2011 and 2010 - 11% and 14%, respectively).

## **3. Chain distribution**

Below is a description of the main chain stores that are InterCure customers:

The United States and Canada

Costco Wholesale Corporation (the largest club chain in the U.S. and the fourth largest wholesaler in the U.S. with sales of US\$ 88.9 billion in 2011, "Costco") - in July 2008, InterCure started selling the RESPeRATE through Costco's website, [www.costco.com](http://www.costco.com). In 2010, the device began selling in Canada through Costco's Canadian subsidiary at [www.costco.ca](http://www.costco.ca). Costco sold the device as a valued-added bundle for an end consumer price of approximately US\$ 200-270 based on sales promotion campaigns supported by InterCure. In 2010, InterCure noticed a decline in the chain's sales which it believes arose from the continued minimization of consumer advertising volumes. On March 4, 2012, InterCure announced the discontinuance of product sales through Costco U.S. However, InterCure continues to sell the product in Canada through Costco Canada, a separate legal entity.

Since Costco U.S. was InterCure's single largest customer in the U.S. which had accounted for 8-9% of InterCure's revenues during certain periods of collaboration, the discontinuation of sales had a negative impact on InterCure's sales.

## The United Kingdom

Boots UK Limited ("Boots") is the largest chain of pharmacies in the UK with some 2,500 pharmacies, including Alliance Boots, with a sales turnover of approximately £ 6.6 billion in the 2009/10 fiscal year<sup>47</sup>. In November 2009, InterCure began selling the RESPeRATE Ultra version of the device in over 600 Alliance Boots stores representing the vast majority of the chain's stores.

In the third quarter of 2012, InterCure decided to discontinue sales through Boots due to low profit margins. The revenues from product sales by Boots in 2011 and 2010 accounted for about 4% and 8% of InterCure's revenues, respectively. InterCure estimates that the discontinuance of sales through Boots will not have a material effect on its sales but will reexamine its decision in the future

Credenhill Limited ("Credenhill") - a veteran British importer and distributor of products for cardiovascular patients, licensed under the British NHS Drug Tariff. This license allows Credenhill to supply the product directly to the customer's home and claim the related expenses from the British NHS. As of February 2012, Credenhill has a twofold role in the RESPeRATE Rx's distribution channel: direct supply of the device to the patient's home through a distant pharmacy and wholesale supply of products to pharmacies across Britain, which supply the product to patients against a doctor's prescription.

Dispex Limited ("Dispex") - a wholesale purchase group of some 900 clinics with a special license from the British NHS to supply prescription products directly from the dispensing doctor. This license, which is mainly granted to doctors in areas with no available pharmacies, allows doctors to write prescriptions and supply the device simultaneously. These doctors may purchase the devices at a discount from a wholesaler and claim full reimbursement directly from the British NHS.

#### **4. Marketing to the medical community**

InterCure views the expansion of the medical community's recognition and support as a critical success factor in the medium and long term. However, given the need to minimize losses in the short term, InterCure has been forced to significantly reduce its investments in this area.

This issue received validation with the receipt of insurance compensation in the UK which allows each consumer with a signed doctor's prescription to receive the device free of charge (or for a fee of £ 7 in certain cases). In fact, the insurance compensation removed the product's price barrier for the consumer by shifting the decision to 40,000 physicians who treat hypertension, including hypertension specialists, cardiologists, nephrologists, GPs, internal physicians and primary care trusts.

In recent years through the date of signing InterCure's debt refinancing (July 2012), InterCure did not have the resources to allocate substantial sums to sales promotion in the medical market. Following the debt refinancing, InterCure is acting to promote this area.

In this target market, InterCure offers several activities in addition to the direct marketing activity which also has a direct effect on physicians and caregivers as media consumers themselves. InterCure has a variety of marketing activities directed exclusively at the medical community for educating the medical market using the following methods:

- Promoting the device by providing physicians with information that is delivered to the end consumer at the website.

- eDetailing as part of a special website for physicians, providing clinical information packages upon demand and sending out information leaflets to applicants.

- Participating in professional conventions for product presentation. In the reporting period, InterCure minimized the use of this method due to cost.

<sup>47</sup> [http://www.boots-uk.com/App\\_Portals/BootsUK/Media/PDFs/Annual\\_Review\\_FINAL.pdf](http://www.boots-uk.com/App_Portals/BootsUK/Media/PDFs/Annual_Review_FINAL.pdf)



Simultaneously, InterCure is reviewing possible collaborations with companies with suitable public relations resources without having to make large investments.

InterCure estimates that in the U.S., which currently does not offer insurance compensation, there are some 120,000 specialists, cardiologists, nephrologists, GPs and internal physicians who treat hypertension. In addition, there is a large population of professional caregivers who are interested in the device such as biofeedback therapists, chiropractors, naturopaths, psychologists etc.

In order to expand the medical community's support and recognition, InterCure is using the following techniques:

- Continued advertising of medical assays in the area of activity and of results of any new clinical trials;

Supporting clinical trials conducted by researchers and specialists which might affect public opinion in the relevant areas, including research of the following types:

Unfunded research - InterCure does not participate in funding, conducting or analyzing the research. InterCure provides the researchers paid trial kits (at a discount) upon demand which consist of a device, a manual and information on trials conducted on the device.

Collaborated research - research that is not funded by InterCure but for which InterCure provides the researchers devices free of charge and in return receives the right to monitor and counsel the research and analyze the results.

## **5. Exclusive distributors and resellers in the rest of the world**

As of the date of this report, InterCure does not have any exclusive distributors.

## **6. Dependency on distribution channels**

InterCure is not dependent on any particular distribution channel. Nevertheless, in 2011, InterCure's sales to Costco (U.S. and Canada) totaled approximately US\$ 540,000, accounting for about 17% of InterCure's total sales (approximately US\$ 906,000, accounting for about 24% of InterCure's total sales in 2010). On March 4, 2012, InterCure announced the discontinuance of sales through Costco U.S.

*Intellectual Property and Patent*

**General**

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for our drug candidates and our proprietary technologies. As part of our business strategy, our policy is to file patent applications in the US and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any commercial advantage or financial value attributable to the patent.

Generally, patent applications in the US are maintained in secrecy for a period of at least 18 months. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Granted patents can be challenged and ruled invalid at any time, therefore the grant of a patent is not of itself sufficient to demonstrate our entitlement to a proprietary right. The disallowance of a claim or invalidation of a patent in any one territory can have adverse commercial consequences in other territories.

If our competitors prepare and file patent applications in the US that claim technology also claimed by us, we may choose to challenge competing patent rights, which could result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope, validity and/or enforceability of third-party proprietary rights. Litigation would involve substantial costs.

## **Drug Development**

### **rHuEPO for the treatment of MM**

A main use patent, United States Patent 6,579,525 “Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer,” was filed by Mor Research Applications Ltd. and Yeda Research and Development Company Ltd., Israeli corporations, in Israel on April 8, 1998 and a PCT was filed on March 30, 1999. The patent was granted in the United States, Europe (Austria, Belgium, France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain, Sweden and Switzerland), Israel, Japan, Hong Kong and Canada. The issued patent will expire in 2019 (See “Item 4. Government and Industry Regulation” regarding our granted orphan drug designation). Pursuant to our agreement with Bio-Gal, we have exclusive worldwide rights to the above patent for the use of rHuEPO in multiple myeloma.

The main claims of this US issued patent are directed to: A method for the treatment of a multiple myeloma patient, comprising the administration of erythropoietin or recombinant human erythropoietin, for the inhibition of tumor growth, triggering of tumor regression or inhibition of MM cell metastasis in the said patient.

The original EPO patent for the treatment of anemia is currently owned by Amgen and Johnson & Johnson.

### **SAM-101 for the Treatment of Schizophrenia**

An international patent application entitled “Combined therapies of antipsychotic drugs and tetracyclines in the treatment of psychiatric disorders” was filed by Mor on October 18, 2007 (International application number PCT/IL2007/001251). The patent is currently pending in National Phase in the USA, Canada, Europe, India, and Israel.

The main claims of this patent include: 1. A pharmaceutical composition comprising as active ingredients at least one tetracycline and at least one antipsychotic drug; 2. The pharmaceutical composition with modified release formulation; 3. A method for treating a psychotic disorder comprising administering the pharmaceutical composition to a patient in need.

### **DOS**

The lead molecules that are included in the VivoQuest license are covered by four issued US patents and three pending US patent applications. As of April 8, 2011, the Company has determined to maintain these patents in the United States only. The patent applications describe both the structure of the compounds and their use for treating HCV infection. The issued VivoQuest patents will expire in 2023. Additional patent applications, if issued, will expire in 2023, 2024 and 2025. We have also filed additional patent applications that cover the lead compounds discovered since the licensing of the DOS from VivoQuest. These additional patent applications, if issued, will expire in 2026 and 2027. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for certain patent term extensions. Pursuant to the VivoQuest license, we will make royalty payments ranging from 2% to 8%, based on net sales of the compounds.

We believe that we will have sufficient time to commercially utilize the inventions from our small molecule development program directed to the treatment and prevention of Hepatitis C infection.

### **Medical Device**

InterCure has knowhow relating to the development of products in the medical devices segment which consists, among others, of information, data, reports, intellectual property, sketches, technical specs, software programs, algorithms, list of potential distributors and plans. InterCure takes all the necessary steps and invests considerable resources in order to protect its business and any other knowhow relating to its products and business by registering

patents in various countries around the world. In addition, InterCure enters into confidentiality agreements with third parties that are exposed to its information, in whole or in part, including its employees and suppliers and various subcontractors or makes sure that the engagement agreements have a confidentiality clause.

The following table summarizes information and data about InterCure's patents:

#	Patent name	Patent number	Expected date of patent expiration	Priority date	Date of application filing <sup>48</sup>	Countries of approval	Countries where filed
1	Apparatus and method for manipulating biological rhythmic patterns Stress detecting apparatus and method for monitoring respiration Systems and methods for beneficial modification of biorhythmic activity	US 5076281	31/12/2008	31.5.88	31.5.88	Israel, U.S.	Israel, U.S., Hong K
2	Modification of biorhythmic activity	US 5423328	19/01/2014	20.1.93	19.1.94	Israel, U.S., Japan	Israel, U.S., Japan
3	Modification of biorhythmic activity	US 5800337	22/01/2016	22.1.96	21.1.96	U.S.	U.S.
4	Interventive-diagnostic device	US 6090037	21/01/2017	21.1.96	21.1.97	Israel, U.S., Canada, Austria, Belgium, France, Germany, Switzerland, Italy, Sweden, Spain, Denmark, the Netherlands, the UK and Japan	Israel, U.S., Canada, France, Germany, S, Sweden, Spain, Den, Netherlands, the U
5	Interventive-diagnostic device	PCT/IL00/00400	2019	6.7.99	Israel: 6/7/1999. US: 6.7.00 15/10/2003	Israel, U.S., Europe(*), Hong Kong	Israel, U.S.
6	Interventive-diagnostic device	US 7717858	15/12/2024	6.7.99	6.7.00 21/4/2009	U.S.	U.S.
7	Interventive-diagnostic device	US 8183453	06/07/2020	6.7.99	6.7.00	U.S.	U.S.
8			06/07/2020	6.7.99	15/5/2012	US	US

	Interventive-diagnostic device			6.7.00			
9	Generalized metronome for modification of biorhythmic activity Apparatus and method for beneficial modification of biorhythmic activity Apparatus and method for breathing pattern determination using a microphone	PCT/IL03/00649 (10/524,056)	06/08/2023	9.8.02	6.8.03	Israel, U.S., Europe, Japan (*), South Korea (*), India, China, Hong Kong, Canada	India, China, Hong Kong, Canada
10	Apparatus and method for breathing pattern determination using a microphone	PCT/IL03/01053	2022	13.12.02	US: 13/12/2002 ROW: 10.12.03	Israel, U.S., Europe (*), Canada, China, Japan, India, New Zealand, Singapore, Australia, South Korea (*)	
11	Apparatus and method for breathing pattern determination using a microphone	PCT/IL05/000778 US 7850619	21/07/2025 07/07/2027	23.7.04	21.7.05	Israel (*), U.S., Europe (*), India (*), Canada (*), China (*), Singapore, Japan (*), Australia (*), South Korea (*)	Singapore, U.S.
12	Apparatus and method for breathing pattern determination using a non-contact microphone	US11/958083 allowed 12/3/2013	27/12/2028	23.7.04	17.12.07 21/7/2005	US	U.S.

<sup>48</sup> Relating to the next stage after the initial filing which is either international or in a specific country.



InterCure has a variety of patents registered in various countries and several pending patent applications filed in a variety of countries, as detailed above.

Patent related costs (including registration and management) in 2012 totaled approximately \$18,000 compared to approximately \$45,000 in 2011 and \$76,000 thousand in 2010.

InterCure's first patent, the device and method for effecting rhythmic body activity ("the first patent"), expired on May 30, 2009 in the U.S. and on May 31, 2008 in Israel. InterCure's other patents are in effect until 2013 or later, based on the international application filing date.

The first patent protects, among others, the technology and apparatus that include a biorhythmic activity sensor that processes the biorhythmic activity and transfers signals to the CPU, which transfers breathing pattern parameters and sound pattern synthesizer for producing music-like sound pattern signals having a rhythm which is non-identical to the rhythm of the biorhythmic activity.

The apparatus is based on the first patent's technology and on the patent protected modification of biorhythmic activity technology ("the second patent"). The second patent protects, among others, a system for modifying the natural biorhythmic activity by changing at least one feature of the biorhythmic activity other than frequency. InterCure's accumulated experience demonstrates that using the second patent's protected principles (modification of breathing pattern) is essential to the clinical activity observed in treating hypertension and heart diseases. This need has been recognized as early as the inception of InterCure's activity and in fact, all the clinically tested devices are based on the second patent's principles.

InterCure estimates that the expiration of the first patent did not and/or will not materially impair the device's IP protection given that the device will continue to be protected by patents Nos. 3 and 4 in effect until 2017 and by patent No. 10 in effect until 2023. More protection is provided by patent No. 6 which accurately describes the product's sensor, and by patent No. 7 which describes the sound patterns that guide the breathing patterns, in effect until 2020.

Moreover, on November 7, 2011, InterCure entered into a license agreement with Yazmonit Ltd. (a company controlled by Dr. Benjamin Gavish, director and interested party at the time) ("Yazmonit") whereby InterCure granted Yazmonit an indefinite license to use exclusively the patent and technology rights relating to an unutilized portion of InterCure's IP and the right to use the RESPeRATE trademark owned by it for a total consideration US\$ 25,000. See details of the license agreement in the Company's consolidated financial statements for 2012.

**Other Intellectual Property Rights**

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

***Licensing Agreements and Collaborations***

Our current key strategic alliances are discussed below. See “Item 5. Operating and Financial Review and Prospects - Obligations and Commitments” which describes contingent milestone payments we have undertaken to make to certain licensors over the life of the licenses described below.

### **Bio-Gal/XTEPO**

We signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal, a private biotechnology company based in Gibraltar, in March 2009. In December, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL could acquire from the shareholders of XTEPO all of their shares in XTEPO in exchange for the issuance to XTEPO's shareholders of ordinary shares of XTL representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are also obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful completion of Phase 2. Such payment of \$350,000 mentioned above shall be made to Yeda upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO at any time after the completion of the Phase 2 of an amount of minimum \$2 million. On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the closing conditions had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to Section 104 and 103 to the Israeli Tax Ordinance (Revised), 1961. (See note 14(c) to the consolidated financial statements: Intangible Asset).

### **MinoGuard License**

On March 24, 2011, the Company entered into a term sheet to acquire the assets of MinoGuard by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without any other payments. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia. The transaction was subject, among others, to completion of due diligence studies, examination of the regulatory track for the continued development of the combination drug and the approval of the Company's Board. On November 30, 2011, the agreement with MinoGuard was completed after all prerequisites abovementioned had been fully met. In accordance with the terms of the license agreement we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of its net sales and/or percentage from the Company third-party out-license receipts in the range of 7.5%-20% according to the clinical phase of the drug at the time of an out-license transaction. It should be noted that the Company has the sole discretion to pay any of the above amounts in cash or by way of issuing of its shares to MinoGuard. In addition to the above payments, if we shall not commence a phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of \$45,000 for the initial year, which will increase by \$90,000 per year and up to \$675,000 for the eighth year of license. The agreement states that receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter.

The term of the license commenced upon the signing of the license agreement and will be effective for an unlimited time. Upon the expiration of the last payment obligation of XTL the license will be considered perpetual and fully paid up.

The license may be terminated by either XTL without cause upon 30 days notice, or by the licensor for no commercial progress in the event that by the date of June 30th, 2013 neither commencement of phase II Clinical Trial with respect to the licensed product has occurred, nor has XTL entered into a Sublicense Agreement with a substantial third party.

The patent applications are pending as National Phase in Israel, US, Canada, Europe, and India. The table below details the current status of the patent applications:

<b>Countries in which application was filed</b>	<b>Filing Date</b>	<b>Application No.</b>	<b>Patent No.</b>	<b>Status</b>	<b>Expiration Date*</b>
Canada	18.10.2007	2666796	-	Filed	18.10.2027
Europe	18.10.2007	07827225.9	-	Examination	18.10.2027
India	18.10.2007	3100/DELNP/2009	-	Filed	18.10.2027
Israel	18.10.2007	198134	-	Examination	18.10.2027
PCT	29.03.2007	PCT/IL2007/000414	-	Expired	
PCT-1	18.10.2007	PCT/IL2007/001251	-	Expired	
US Prov.	19.10.2006	60/852646	-	Expired	
USA	18.10.2007	13/733130	-	Examination	18.10.2027

\* assuming that the patent will be registered on the basis of the PCT.

### **VivoQuest License**

In August 2005, we entered into a license agreement with VivoQuest covering a proprietary compound library, including certain HCV compounds. Under the terms of the license agreement, we have exclusive worldwide rights to VivoQuest's intellectual property and technology in all fields of use. To date we have made approximately \$0.9 million in license payments to VivoQuest under the license agreement. The license agreement also provides for additional milestone payments triggered by certain regulatory and sales targets. These additional milestone payments total \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our election. In addition, the license agreement requires that we make royalty payments to VivoQuest on product sales.

### **Presidio License**

In March 2008, and as revised August 2008, we signed an agreement to out-license the DOS program to Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio became responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a \$5.94 million, non-refundable, upfront payment in cash from Presidio. In addition, we should have received up to an additional \$59 million upon reaching certain development and commercialization milestones, royalties on direct product sales by Presidio, and a percentage of Presidio's income if the DOS program is sublicensed by Presidio to a third party. On August 22, 2012, Presidio requested to terminate its engagement with us effective as of August 24, 2012. Following a notice of the

termination of the agreement, Presidio's entire DOS technology (including all the patents maintained by Presidio) will be revert back to the Company within 90 days from the date of said notice in accordance with the provisions of the agreement. It is the Company's intention to assess the renewal of the activity in the Hepatitis C area and/or locate strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology.

### **Bicifadine License**

In January 2007, XTL Development had signed an agreement with DOV to in-license the worldwide rights for Bicifadine for the treatment of diabetic neuropathic pain. In accordance with the terms of the license agreement, XTL Development paid an initial up-front license fee of \$7.5 million in cash in 2007. In addition, XTL Development would have made milestone payments of up to \$126.5 million over the life of the license. These milestone payments may have been made in either cash and/or our ordinary shares, at our sole discretion, with the exception of \$5 million in cash, which would have been due upon or after regulatory approval. XTL Development was also obligated to pay royalties to DOV on net sales of Bicifadine. In November 2008, we announced that the Phase 2b clinical trial failed to meet its primary and secondary endpoints, and as a result we ceased development of Bicifadine for diabetic neuropathic pain in 2008 and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, XTL Development ceased the prosecution and maintenance of those patents relating to Bicifadine, in coordination with DOV. In March 2010, the agreement was formally terminated.

**Trademarks**

InterCure and InterCure Inc. have the following registered trademarks:

<b>Registered trademark details</b>	<b>International classification<sup>49</sup></b>	<b>Country</b>
RESPeRATE	10	Israel
InterCure	10	U.S.
RESPeRATE	10, 42	U.S.
InterCure	10, 42	EU
RESPeRATE	10	EU
RESPeRATE	10	South Korea
RESPeRATE	10	China
RESPeRATE	10	Japan

**URL addresses**

InterCure has different registered URL addresses, including [www.resperate.com](http://www.resperate.com), and a variety of domain suffixes, including of the main countries in which it operates. The expenses incurred in registering URL addresses are immaterial. InterCure renews them on an ongoing basis.

***Competition******Drug Development***

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance

of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier.

<sup>49</sup> There is an obligation to register the trademark under certain classification, each category refers to another type of goods or services



The anti-cancer drug market is very large. The National Institute of Health estimated that the total cost of cancer care in the United States in 2008 was \$201.5 billion<sup>50</sup>. In 2008, sales of anti-cancer drugs reached a total of approximately \$48 Billion<sup>51</sup> and are expected to grow to 80 billion dollars in 2011<sup>52</sup>.

In 2011, sales of drugs used to treat multiple myeloma in the US, France, Germany, Italy, Spain, England and Japan totaled \$4.4 billion (and is expected to rise to \$7.2 billion in 2021)<sup>53</sup>. According to their recent financial statements, actual sales of Velcade in 2012 by Johnson & Johnson<sup>54</sup> (which markets Velcade outside the US) amounted to \$1.5 billion. Also, based on the financial statements of the pharmaceutical Celgene<sup>55</sup> (which markets Revlimid), Revlimid sales in 2012 amounted to \$3.77 billion. Velcade sales by the Japanese pharmaceutical Takeda<sup>56</sup> (which markets velcade in the US) in 2011 amounted to \$0.73 billion. In July 2012, Onyx Pharmaceuticals Inc received FDA approval for its x Kyprolis drug. The sales of Kyprolis in 2012 (based on Onyx Pharmaceuticals Inc financial statements for that year) totaled \$64 million<sup>57</sup>.

### **Competing Products for Treatment of MM**

Although there are commercially available drugs for the treatment of MM, we plan to conduct our clinical trial so that rHuEPO will be tested and given only to patients who have been treated with all standard therapy for MM. Thus, the drugs below are not in direct competition to our drug. However, rHuEPO may improve the current treatments and therefore may be supplementary to them, as follows:

**Thalidomide** is effective in approximately one-third of patients (for a certain period of time) with advanced disease and is synergistic with other agents active in multiple myeloma. Its exact mechanism of action is unclear, but inhibition of angiogenesis, modulation of cytokines, and immunological effects are probably involved. Thalidomide, as a single agent or in combination with steroids, is now the standard first line treatment for relapsed or refractory myeloma (if not used before) and is also being used as frontline and maintenance treatment. Newer derivatives of thalidomide, such as revlimid or lenalidomide (formerly CC5013), have potentially greater biological activity and fewer adverse effects, including teratogenicity. Preliminary studies show a response in 30-50% of patients with refractory disease. Thalidomide has severe side effects such as flu-like symptoms, constipation, neuropathy and thrombophilia, and has not yet demonstrated survival advantage.

**Lenalidomide (Revlimid)** is used with dexamethasone to treat patients with multiple myeloma who have already had another treatment. It is a small molecular analog of thalidomide that was originally found based on its ability to effectively inhibit tumor necrosis factor production. Lenalidomide is 50,000 times more potent than thalidomide in inhibiting tumor necrosis factor-alpha, and has less severe adverse drug reactions. Nonetheless, lenalidomide, like its parent compound thalidomide, causes venous thromboembolism (VTE), a potentially serious complication with their use.

**Bortezomib (Velcade)** inhibits the proteasome, an intracellular organelle responsible for protein disposal. The response rate to bortezomib in extensively treated myeloma is around 50%. The drug has recently been approved by the FDA based on phase 2 clinical results. The drug has several serious side effects, including neuropathy.

<sup>50</sup> <http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer>

<sup>51</sup> IMS Health <http://www.reuters.com/article/idUSN1453543620080515>

<sup>52</sup> IMS Health <http://www.thepharmaletter.com/file/46150/multiple-myeloma-market-will-more-than-double-to-53-billion-in-2018.html>

<sup>53</sup> <http://decisionresources.com/News-and-Events/Press-Releases/Multiple-Myeloma-100212>

<sup>54</sup> <http://files.shareholder.com/downloads/JNJ/2362182016x0xS200406-13-38/200406/filing.pdf> (page 38)

<sup>55</sup> <http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-sec>

<sup>56</sup> [http://www.takeda.com/investor-information/annual/pdf/index/ar2012\\_en.pdf](http://www.takeda.com/investor-information/annual/pdf/index/ar2012_en.pdf) (page 45)

<sup>57</sup> <http://www.sec.gov/Archives/edgar/data/1012140/000104746913001966/a2212722z10-k.htm>

**Carfilzomib (Kyprolis):** This is a new generation or a novel derivative of proteasome-inhibitor, i.e. the new modern “Bortezomib”. It was already approved by the FDA as a second or third line therapy for relapsed or resistant myeloma. This was based on phase 2 clinical trials, and trials, including in Israel, are going on. According to the information gained so far, it appears that some of the previously resistant MM patients to Velcade (Bortezomib) might respond to Carfilzomib. It is still too early to determine whether the novel drug indeed prolongs life (overall survival) or only prolongs the progression-free survival.

**Pomalidomide (Pomalyst)** has been approved by the FDA just recently, also for the treatment of relapsed/resistant MM, as a second-third line treatment. This agent belongs to the INiDs family of drugs, and in essence, is considered as the novel lenalidomide.

It is important to emphasize that studies with Carfilzomib and Pomalidomide are ongoing and their real role in the treatment of MM has not been completely clarified.

**Traditional chemotherapy** treatment includes melphalan and prednisone, now used sparingly because of its propensity to compromise collection of haematopoietic stem cells, other combinations, and regimens containing high dose corticosteroids. The latter-including dexamethasone; vincristine, doxorubicin, and dexamethasone; and cyclophosphamide, vincristine, doxorubicin, and methylprednisolone -are preferred for transplant candidates.

**High dose chemotherapy**, particularly melphalan, with autologous haematopoietic stem cell transplantation improves response rates and their duration and survival compared with conventional chemotherapy. It is now commonly used as consolidation treatment. Unfortunately, even after haematopoietic stem cell transplantation, relapse is only a matter of time, although a minority of patients seems to survive over a decade in remission (“operational cure”). Maintenance treatment after transplantation with corticosteroids or interferon is often prescribed in an attempt to delay relapse. Although this probably does prolong the duration of remission, it is unclear if it confers a survival benefit.

**Allogeneic haematopoietic stem cell transplantation** might potentially cure a proportion of patients through immunologically mediated graft versus myeloma effect. However, this procedure remains highly experimental at the present time. High mortality related to treatment has been a problem historically, but the use of safer preparative regimens of reduced intensity could improve long term results.

### **Competing Products for Treatment of Schizophrenia**

SAM-101, if approved, will compete with currently available marketed atypical anti-psychotics from Eli Lilly, Johnson & Johnson, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc., AstraZeneca and others, as well as with generic brands of typical and atypical anti-psychotics. In addition there are a number of potentially competitive compounds under development, which includes: Cariprazine, which is being developed by Forest Laboratories, Inc.; Bifeprunox, which is being developed by Solvay Pharmaceuticals, Inc., and Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd.

## **Medical Device**

### **Competing Products for the Treatment of Hypertension (in connection with our subsidiary – InterCure)**

As of the date of this report, recommended changes in behavior such as physical exercise or dietary changes and medications for lowering blood pressure represent the standard care in the hypertension market.

As aforementioned and according the company best knowledge, InterCure is the only company to have developed and to market a non-medicinal non-invasive device for treating hypertension which has been clinically tested by it and which has been cleared by the FDA.

In the third quarter of 2010, InterCure learned that the British chain Lloyds Pharmacy ("Lloyds") which had distributed InterCure's device in the past, co-developed with Harvard medical Devices Ltd. ("the manufacturing company") and began advertising a competing device for the non-medicinal treatment of hypertension for a cheaper price than the device developed by InterCure ("the competing device"). Following an examination by InterCure's advisors, the competing device does not interactively guide respiration during use (a patented method developed by InterCure with proven efficiency in lowering blood pressure). However, InterCure's advisors' examination also revealed that the competing device comprises elements copied from InterCure's product in alleged violation of copyright. InterCure has taken several regulatory steps and is examining its possible legal course of actions against the competing device. In the first quarter of 2011, sales of the competing device commenced under a private brand name of Lloyds Pharmacy - Kinetik - owned by the manufacturing company. At this stage, the Group, through InterCure, cannot assess whether and how the sales of the competing device will affect its sales in the UK.

To the best of InterCure's knowledge, there are certain products and therapies that target hypertension but do not directly compete with InterCure's products such as:

Hypertension medications for lowering blood pressure which represent the major share in the hypertension market. It should be noted that InterCure does not offer its products as an alternative for hypertension drugs.

Baroreflex Activation Therapy - CVRx has developed a barostimulation device implanted in the body near the main artery which stimulates the nervous system and directly affects the baroreflex. According to the manufacturer, the future product price is planned to reach thousands of dollars (in the vicinity of US\$ 20,000 not including the procedure itself) and is designed for hypertensive resistant patients who fail to respond to hypertension drugs. The manufacturer's first product is CE Marked and is undergoing clinical trials for FDA approval.

Renal Sympathetic Nerve Ablation - a catheter-based technique promoted by Medtronic designed to reduce the sympathetic nervous system's activity by applying radiofrequency pulses to the renal arteries and de-nerving them. According to InterCure's estimates, the future product price and cost of procedure are expected to be in excess of \$20,000 for hypertensive resistant patients only. The product is currently in clinical trial stages.

Biofeedback relaxation devices operating on heartbeat variations without regulatory approvals and/or that claim to treat hypertension. These devices are designed for relaxation which is not viewed as medical therapy and therefore they are exempt from obtaining regulatory approvals. However, to the extent that InterCure's devices are used (or will be used in the future) by people also for relaxation purposes, these devices form competition. The leading devices in this field include the following:

StressEraser - a device which measures heartbeat variations and outlines a suitable graph using a screen, previously sold for US\$ 300. This device also guides the users to adjust their exhalation to the heart-breathing rate to about six times per minute. In 2009, the company that manufactured this device discontinued its operations and to the best of InterCure's knowledge, the remaining inventory of devices was sold at \$120-\$180.

Heartmath's FreezeFramer & emWave – are devices that are basically similar in their manner of operations to StressEraser - sold at \$180-\$120 per unit.

Devices that claim to reduce hypertension such as Zona which includes a spring like squeeze ball claimed until recently that training with the device in time reduces hypothermia. To the Company's best knowledge these types of devices have not received regulatory approval for marketing them as hypertension reducing devices, and are sold at \$300-\$150 a unit. As at the date of this report, the internet website of the abovementioned device has been changed and no longer makes explicit claims that it reduces hypertension, only that it trains the cardiovascular system. InterCure assumes that the amendment is the result of inquiries made by regulatory bodies.

Mobile applications and software for relaxation and breathing pattern manipulation - in the reporting period and following the proliferation of smart phones, a variety of mobile apps for relaxation and breathing pattern manipulation were introduced, all without a respiration sensor connection. InterCure has been monitoring the developments in this relatively new market.

InterCure is coping with the competition mainly by creating barriers to entry based on its registered patents, continuing to protect its intellectual property, establishing the brand name in the medical and consumer markets and developing follow-up products to retain its relative edge.

### *Supply and Manufacturing*

### **Drug Development**

We currently have no manufacturing capabilities and do not intend to establish any such capabilities.

### **rHuEPO for the treatment of MM**

We believe that we will either be able to purchase Recombinant Erythropoietin (rHuEPO) from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our planned development program for the treatment of MM.

### **SAM-101 for the Treatment of Schizophrenia**

We believe that we will either be able to purchase the selected antipsychotic and minocycline from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our future development for the treatment of schizophrenia.

### **DOS**

Under the terms of the license agreement, Presidio became responsible for all further development and commercialization activities and costs relating to the DOS program. As mentioned above, On August 22, 2012, Presidio requested to terminate its engagement with us effective as of August 24, 2012 and we are assessing the renewal of the activity in the Hepatitis C area and/or locating strategic partners for the continued development and marketing of drugs for Hepatitis C virus on the basis of Presidio's reverted DOS technology. If we will renew our activity in the Hepatitis C virus area, we will enter into a contract with a manufacturer to produce our pre-clinical and clinical supply needs.

## **General**

At the time of commercial sale, to the extent possible and commercially practicable, we plan to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under cGMP regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for conducting clinical trials or for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect our contractor's ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control. We anticipate that we will similarly rely on contract manufacturers for our future proprietary product candidates.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.



Contract manufacturers are subject to ongoing periodic inspections by the FDA, the US Drug Enforcement Agency and corresponding state and local agencies to ensure strict compliance with cGMP and other state and federal regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations.

If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

### **Medical Devices**

As of the date of this report, InterCure meets all its production needs through subcontractors and particularly a major subcontractor in China which has been manufacturing the RESPeRATE Ultra versions since November 2008. In 2012, InterCure made an average of less than 1,000 product units a month. The Chinese production line's monthly manufacturing capacity is about 10,000. In the event of increased demand, the manufacturing capacity can be enhanced within several weeks given that the product's assembly line and testing process is not complicated. The time needed to prepare for increased production mainly depends on the ability of the component suppliers to respond to increased order volumes and the availability of components with variable manufacturing technology. InterCure estimates that in the event of a major increase in product demand, the subcontractor will be able to add another production line within three months without material costs. InterCure is dependent on the manufacturer. However, in a few months, InterCure can transfer the manufacturing to another manufacturer. Due to such dependency, InterCure owns a significant inventory in its warehouse, which is sufficient for more than 6 months of sales, in accordance to InterCure's current run-rate.

### ***Government and Industry Regulation***

#### **Drug Development**

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates and technologies, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the US, any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA, under the Federal Food, Drug and Cosmetic Act of 1938, as amended. The FDA regulates,

among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. According to the FDA, before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The Company was granted an Orphan-drug designation from the FDA in May 2011, for its Recombinant Erythropoietin in the US. Orphan-drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the US. The designation provides the drug developer with a seven-year period of US marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy, or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication, as well as with tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

The Company may apply the European Medicines Agency in order to obtain Orphan-drug designation for its Recombinant Erythropoietin in Europe. Orphan designation is granted by the European Medicines Agency, following a positive opinion from the Committee for Orphan Medicinal Products, to a medicinal product that is intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Community when the application for designation is submitted. Orphan drug designation provides the sponsor with access to the Centralized Procedure for the application for marketing authorization, protocol assistance, up to a 100% reduction in fees related to a marketing authorization application, pre-authorization inspection and post-authorization activities, and could provide ten years of market exclusivity in the EU, once approved for the treatment of multiple myeloma.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND (investigational new drug), or at any time prior to receiving marketing approval of the NDA (new drug application). To receive fast track designation, an applicant must demonstrate that the drug:

- is intended to treat a serious or life-threatening condition;

- is intended to treat a serious aspect of the condition; and

has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

*Phase 1:* The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.

*Phase 2:* Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

*Phase 3:* Studies establish safety and efficacy in an expanded patient population.

*Phase 4:* The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations, such as children.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors, and the number of sites participating in the trial;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;

longer treatment time required to demonstrate efficacy or determine the appropriate product dose;

insufficient supply of the drug candidates;

adverse medical events or side effects in treated patients; and

ineffectiveness of the drug candidates.

In addition, the FDA may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk. Any drug is likely to produce some toxicity or undesirable side effects when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend time, money and effort to ensure compliance with cGMP, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, then the FDA will not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA approval, and the advertising of our products will be subject to comprehensive regulation by the FDA. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetic Act. Violations of the Federal Food, Drug, and Cosmetic Act or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the US, we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the EU, registration procedures are available to companies wishing to market a product in more than one EU member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country. Our current development strategy calls for us to seek marketing authorization for our drug candidates outside the United States.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the US or abroad.

## **Medical Devices**

### **Compliance with laws and regulations**

To the best of InterCure's knowledge, it is in compliance with the material legal requirements and regulations applicable to it in its various countries of operation, as specified below. InterCure's activity is subject to compliance with the laws of the State of Israel by virtue of its incorporation in Israel and the offering of its securities to the Israeli public as well as to compliance with the authorities' standards and regulations applicable to the products that it markets in the U.S., Europe, Canada and other markets of operation. The requirements underlying the approval for the sale of InterCure's products and the duration of the inspections performed by the authorities and the costs thereof vary from country to country. The absence of a license to market InterCure's products or services in a specific country and the subsequent inability to sell these products or services will adversely affect InterCure's revenues.

In addition, InterCure's publications are supervised by statutory entities that are governed by the relevant truth in advertising laws (such as the U.S. Federal Trade Commission, "FTC") and non-statutory non-profit consumer protection organizations whose rules are not legally binding but may have a significant effect on InterCure's advertising activity. InterCure maintains constant contact with these non-statutory non-profit organizations in the U.S. and the UK in order to ascertain that it complies with their local standards.

In 2003, the European Parliament passed a directive proscribing the use of lead and other hazardous substances. This regulation, known as the restriction of the use of certain hazardous substances in electrical and electronic equipment, "RoHS"), became a binding standard in the countries of the EU effective from early 2008. This directive applies to the majority of electrical and electronic products, apart from those used in military/space, medical, server and automobile applications. In addition, InterCure complies with the European WEEE in the UK - Directive EC/2002/96 - which aims to prevent the accumulation of waste electrical and electronic equipment and increase the recovery and recycling potential of this type of waste. The Directive also prescribes provisions for reusing, recycling or partially using products at the end of their lifecycle.

InterCure has all the regulatory approvals needed for marketing its products in the U.S., Europe, Canada and other countries as specified above.



### **The U.S. market - the FDA, FTC and other organizations**

To the best of InterCure's knowledge, based on commonly available publications, the FDA, which is a federal organization forming part of the U.S. Department of Health and Human Services, is entrusted with protecting the health of the U.S. public by enacting and enforcing high product standards through various regulatory requirements and the provisions of the Federal Food, Drug and Cosmetic Act ("**the FDC Act**"). The provisions of the FDC Act are designed to secure the safety and efficacy of such products as drugs for consumption by humans and for veterinarian purposes, biological products and medical devices. Foreign companies which manufacture medical devices for export to the U.S. are required to meet the FDA's regulatory requirements as well as other potential regulatory requirements in various U.S. states before exporting their medical devices and even afterwards, since the FDA does not recognize regulatory approvals granted by foreign institutions.

Among others, FDA requirements consist of manufacturing medical devices in conformity with QA regulations, obtaining scientific reports of medical devices, appointing a U.S. agent and allowing FDA representatives to supervise the manufacturing process at the plant.

In the U.S., the FDA classifies medical devices into three classes based on their level of risk or indication. The method of supervision varies for each class to assure the safety and effectiveness of products. The first class imposes very few requirements on the manufacturer or importer for obtaining FDA approval whereas the third class imposes numerous requirements. The first and second classes require filing a 510K application, unless the product is exempt. The third class requires filing a Premarketing Approval ("**PMA**") application. A 510K application consists of proof that the device in question is substantially equivalent in terms of safety and effectiveness to a device already marketed in the U.S. A PMA application is required for devices of the third class which are life supporting or have a critical role in preventing injury, devices which substantially bear a higher risk or are unlike any other previously cleared device. The PMA process is significantly longer and costlier than the 510K process, but it provides the original applicant several years of "exclusiveness". In addition, in certain cases, the FDA allows devices with a relatively low risk that have applied for a new indication under the PMA track to apply for a 510K approval consisting of clinical trials for proving the new indication. This process, as undergone by InterCure, actually represents an interim class between the standard 510K process and the PMA process. In this case, it is not enough for an applicant to prove that its product is substantially equivalent to InterCure's product to obtain marketing approval but also has to prove the effectiveness and safety of the new product based on the sought indication through clinical trials.

In May 2000, after having completed the first three clinical trials conducted in Israel, InterCure obtained its first FDA approval for marketing the RESPeRATE with a specific indication for lowering blood pressure accompanied by medicinal/non-medicinal therapy under a doctor's prescription. In July 2002, InterCure obtained approval for marketing the device without a doctor's prescription after having completed another clinical trial conducted in several medical centers in the U.S. The device which is marketed in the U.S. obtained a 510K classification approval by the FDA after its safety and effectiveness in treating hypertension had been proven. This is the first device ever approved with an indication for treating hypertension and stress.

InterCure is committed to market this product only for the purposes for which it was approved and to act in compliance with the Medical Device Reporting Regulations which require it to report any incidents of death or severe injury resulting from the use of the product. Moreover, InterCure's production facilities are required to meet FDA regulations and are potentially subject to inspection by the FDA, as is InterCure's compliance with the Quality Systems Registrars ("**QSR**"). Among others, InterCure is required to operate in accordance with written procedures, manufacture its products according to the manufacturer's instructions, inspect the manufacturing process and investigate and document any malfunctions therein. InterCure is listed at the FDA as manufacturer and developer. Its main subcontractor is also listed at the FDA as a contractual manufacturer. InterCure's non-compliance with FDA requirements, including QSR requirements, will affect its ability to manufacture, supply and/or sell its products.

Moreover, non-compliance with regulatory requirements regarding medical devices will lead to both civil and criminal sanctions initiated against InterCure, including issuing a public warning against its product, refusal to grant approval to marketing and selling new products or cancellation of existing marketing and selling licenses.

The following table presents the data of FDA approvals obtained by InterCure:

<b>Name of FDA approved</b>	<b>RESPI-LOW Biofeedback</b>	<b>RESPERATE MODEL RR-150</b>
<b>Medical Device</b>	Device	
The indication	Relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. Adjunctive treatment for high blood pressure.	Relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. Adjunctive treatment for high blood pressure.
Approval Process	510(K) ; Class II	510(K) ; Class II
Approval Number	K000405	K020399
Effective Date of Approval	5/2000	7/2002

### **The European common market - CE Marking**

The CE Mark is the EU's stamp of approval for products which represents the manufacturer's statement that the product meets the required criteria and technical specs of the relevant authorities such as health, safety and environmental protection. The CE Marking guarantees free trade between EU countries and EFTA countries (Iceland, Lichtenstein and Norway) and allows the law enforcement and customs authorities in European countries to proscribe the marketing of similar products without a CE Marking. Based on the Medical Devices Directive (93/42/EEC), effective from June 14, 1998, manufacturers of medical devices must comply with this directive. A "medical device" is defined as an apparatus or substance used to treat humans, including for diagnosis and therapy purposes. The control process and the receipt of a CE Marking require the product to meet certain technical specs and to comply with the manufacturer's quality management system. The notified bodies are in charge of granting the CE Marking and subject the companies to annual inspections.

In June 2007, InterCure received a letter from the Medicines and Healthcare products Regulatory Agency ("MHRA") stating that the latter has objections as to the classification of InterCure's device in the UK as class I (as recently defined) or class IIa<sup>58</sup>. A class IIa medical device must be externally inspected by a notified body approved by the European authorities to assure compliance with standards and safety requirements as well as technical and clinical aspects of the device.

In December 2007, the device was reclassified as class IIa and received the CE Marking (number 0473), including a specific indication for treating hypertension, after having met the inspection of the notified body approved by the European authorities - Intertek Services Ltd. AMTAC Certification 1. The MHRA later approved that the new classification meets its requirements. This approval must be renewed annually. As explained below, InterCure is also subject to the inspection of the notified body Intertek<sup>59</sup>, for approving the product marketed in Europe and to assure the continued validation of the ISO approvals.

<sup>58</sup> According to the Medical Device Directive ("**MDD**") classification method, each active therapeutic device designed to transfer or exchange energy is defined as class IIa. An active therapeutic device is defined as any apparatus used (independently or together with another medical device) to support, alter, replace or rehabilitate biological activities or structures in order to treat or ameliorate a disease, injury or disability

<sup>59</sup> A British company specializing in providing certification services pursuant to European and ISO standards

The following table presents data of European approvals obtained by InterCure:

<b>Name of FDA approved Medical Device</b>	RESPeRATE and RESPeRATE ULTRA
The Indication	Relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure together with other pharmacological and/or nonpharmacological interventions. Over-the-counter.
Notified Body	Intertek 0473
Approval Process	Class IIa ; Annex V
Number of Approval	605 CE
Effective Date of Approval	15.11.2007
Date of the last audit conducted by the notified body and results	13-14.3.2013 The audit was successfully completed with no comments

#### **The Canadian market - Health Canada and CSA**

The device has received the approval of Health Canada, a department of the government of Canada with responsibility for national public health, similarly to the FDA in the U.S. and to the Israeli Department of Medical Devices. The device has been classified by Health Canada as class II. In addition to proof of product safety and effectiveness, this level also requires ISO 13485 approval regarding the company's QA system and a special approval for compliance with Canadian Medical Devices Conformity Assessment System ("CMDCAS"). InterCure is in compliance with these standards and the device has received the Canadian authorities' marketing approval in Canada in March 2004, which is renewed annually. The Ultra version of the device which is adapted to the Canadian market has received the Canadian authorities' marketing approval in Canada.

The following table presents data of Canadian approvals obtained by InterCure:

<b>Name of FDA approved Medical Device</b>	RESPeRATE, RESPeRATE DUO, RESPeRATE ULTRA and RESPeRATE ULTRA DUO
The Indication	Relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure together with other pharmacological and/or nonpharmacological interventions. Over-the-counter.

Number of Approval	63948
Effective Date of Approval	11.3.2004 (last amended 18.8.2008)

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**The Israeli market - Israeli Ministry of Health, Department of Medical Devices**

InterCure's Israeli activities are subject to the approval of the Israeli Department of Medical Devices at the Ministry of Health ("the Department"). A medical device is defined as an apparatus, an instrument, a chemical substance, a biological or technological product used for medical treatment or required for the operation of a device or instrument used for therapy which is not principally designed to operate on the human body as a medication. The Department is the Government entity in charge of providing approvals for and overseeing the marketing of medical devices in Israel and for approving clinical trials in Israel. The RESPeRATE has the Department's marketing approval in Israel, first granted on May 6, 1997, renewed in 2008 and is in effect until January 31, 2013. In December 2012, InterCure began the product's renewal process and estimates, based on its regulatory counsel, that the renewal will be received in the coming months. The renewal of the approval is technical by nature and does not involve time or material expenses.

The following table presents data of Israeli approvals obtained by InterCure:

<b>Name of FDA approved Medical Device</b>	RESPeRATE
The Indication	Relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. Adjunctive treatment for high blood pressure.
AMR Number	2370000
Effective Date of Approval	28.1.2008
End of Approval	31.1.2013

**Other countries**

InterCure markets its product under the same high standards even in countries where it is not subject to product regulations.

**Israeli legislation**

The Law for the Encouragement of Industrial Research and Development

The Law for the Encouragement of Industrial Research and Development prescribes a series of requirements applicable to petitioners of benefits for funding research and development such that recipients of benefits pursuant to the Law for the Encouragement of Industrial Research and Development are required to pay the Israeli Ministry of Finance royalties on any income deriving from the sale of the product developed in the context of the approved program or resulting therefrom, including product related or product inherent services. In addition, the Law for the Encouragement of Industrial Research and Development prescribes that any product developed as a result of the research funded by the Ministry of Industry Trade and Labor will only be manufactured in Israel, unless the Ministry of Industry Trade and Labor's Research Committee approves the transfer of the product's manufacturing rights outside of Israel. Such approval may be granted for a certain portion of the consideration in the transaction for transferring or selling the knowhow outside of Israel or for the receipt of knowhow from third parties or collaboration in research and development activities.

Approved enterprise

In August 1999, InterCure received an approved enterprise status, as defined in the Law for Encouragement of Capital Investments, 1959 ("the Law") under the alternative track. On July 19, 2005, the final performance approval relating to this letter of approval was received. Total approved investments added up to NIS 865,200. The year of operation as determined in the final performance approval is 2001.



According to the Law, InterCure is entitled to various tax benefits by virtue of the "approved enterprise" status granted to part of its production facilities under the alternative track. These tax benefits comprise tax exemption for a period of two years and tax at reduced rate for further five years from the beginning of the benefit period for that part of taxable income earned from approved enterprise that was recognized by the Investment Center. InterCure is eligible for deduction of accelerated depreciation on fixed assets used by the approved enterprise. As of the reporting date, the benefit period has not yet begun.

The above benefits are conditional upon the fulfillment of the conditions stipulated by the Law, regulations published thereunder and the letter of approval according to which the investment in the approved enterprise was made, among others, InterCure is required to report to the Investment Center on any change in its condition, in carrying out the plan or making the investments that may have a significant effect on accomplishing the plan. Receiving the benefits is conditional upon the proper management of appropriate accounting records; change in the composition of right holders, including as a result of a public offering in a cumulative rate of over 49% and a private placement in any rate whatsoever, between the period of carrying out the plan and the end of the benefit period is subject to the approval of the Investment Center (a company that issues shares and/or convertible debentures on a stock exchange representing up to 49% of ownership of the Company is relieved from receiving an advance approval and is required to report to the Investment Center within 60 days from the issue date). Non-compliance with the conditions may cancel all or part of the benefits and refund of the amount of the benefits including interest. As of the reporting date, InterCure is meeting all the conditions in the letter of approval and it believes that it will continue to satisfy them in the future too. On January 6, 2005, InterCure received a letter of approval for an expansion plan under the alternative track. The performance date was scheduled for January 6, 2007. Total approved investments under this plan added up to NIS 362,000.

As of the date of the end of the plan, InterCure has practically made all the approved investment.

On July 8, 2009, the final performance approval relating to this letter of approval was received. Total approved investments added up to NIS 255,693. The year of operation as determined in the final performance approval is 2005.

The above benefits are conditional upon the fulfillment of the conditions stipulated by the Law, as abovementioned. Further, an additional condition for receiving the benefits under the approval from July 8, 2009 is implementing the marketing plan as described in InterCure's letter from 2005 and maintaining the scope of sales and their ratios as set forth in the above letter.

In August 2005, InterCure filed a request with the Investment Center to receive the status of an enterprise that specializes in high-tech sales. On July 31, 2006 (update No. 1 to the letter of approval from January 6, 2005 which was received on August 3, 2006), the Investment Center approved the request and InterCure was recognized as an enterprise with high-tech sales characteristic. For computing the base turnover according to erosion of base turnover procedure, InterCure may deduct in any of the tax benefit years the base turnover by 10% provided that the conditions

of the procedure are fulfilled. The detailed approval is relevant for approved plans that were implemented through 2004.

On January 28, 2006, InterCure filed a request to be regarded as a beneficiary enterprise (approved) according to Amendment No. 60 to the Law. In 2011, InterCure no longer handles the request.

#### Business license

In accordance with the provisions of the Business Licensing Law, 1968, InterCure is not required to obtain a business license.

### Quality and safety standards

InterCure is required to meet the following international quality standards for manufacturing medical devices: ISO 13485:2003 (CMDCAS in Canada) and SAFETY IEC 60601-1 or EMC IEC 60601-1-2 (QSR) and more. InterCure is listed at the FDA as a manufacturer of medical devices.

### Quality control

InterCure's products are developed, manufactured and assembled in conformity with controlled engineering documentation and their quality is assured by professionally trained and skilled employees and advisors. InterCure's subcontractors supply the complete products and/or assemblies/components manufactured by them for InterCure in strict adherence to the quality requirements based on the above mentioned quality standards. The chief subcontractor also meets international quality standards and is listed at the FDA as a manufacturer of medical devices. InterCure's products, including the sensors, are 100% quality assured.

### **Organizational structure**

Our wholly-owned subsidiary, XTEPO, is an Israeli privately-held company incorporated in November 2009 for the execution of the Bio-Gal transaction and which holds the exclusive license of the use patent of rHuEPO drug for multiple myeloma.

Our wholly-owned subsidiary, XTL Biopharmaceuticals, Inc. and its wholly-owned subsidiary XTL Development, Inc., are each incorporated in Delaware. Since November 2008, these companies have not been active.

Our subsidiary, InterCure Ltd., is an Israeli public company, incorporated in November 1994. As of the date of this report we hold approximately 45.41% of its issued and outstanding ordinary shares.

We hold as of the date of signing this report approximately 30.88% of Proteologics Ltd issued and outstanding ordinary shares. Proteologics is an Israeli public company which was incorporated in May 1999.

## **Property, Plant and Equipment**

Since August 2010 we lease offices of approximately 255 square meters, in Herzliya, Israel. The basic lease period is for 36 months with an option for an additional 24-month period. In April 2013 the company signed on the additional 24 month option according the agreement until August 2015. In addition, the Company has the right to terminate the agreement after 12 months and/or upon introducing an alternative tenant in its place, pursuant to approval of the landlord.

InterCure's listed domicile is at 16 Hatidhar Street, Raanana 43652 Israel, at CFO Direct Ltd. InterCure Inc. operates out of its Manhattan offices in New York. In May 2010, InterCure Inc. signed an office lease agreement for a period of three years. InterCure Inc. is considering renewing the lease agreement or alternatively relocating to new offices.

To our knowledge, there are no environmental issues that affect our use of the properties that we lease.

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

None.

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

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in “Item 3. Key Information–Risk Factors” and “Item 4. Information on the Company.” See also the “Special Cautionary Notice Regarding Forward-Looking Statements” set forth above.

You should read the following discussion and analysis in conjunction with our audited consolidated financial statements, including the related notes, prepared in accordance with IFRS (International Financial Reporting Standards) for the years ended December 31, 2012, 2011 and 2010, and as of December 31, 2012 and 2011, contained in “Item 18. Financial Statements” and with any other selected financial data included elsewhere in this annual report.

In April 2009, the Company was de-listed from NASDAQ after the Bicifadine trial did not meet its endpoints. At the same time, the Company became primarily listed on TASE (Tel Aviv Stock Exchange) and therefore is not entitled to the exemptions previously granted in Israel due to its listing on NASDAQ.

Pursuant to the requirement to comply with all the Israeli listing requirements, the Company adopted IFRS (International Financial Reporting Standards) as the accounting policy of the Company starting on 2009 and effective since January 1, 2007.

### ***Selected Financial Data -***

The tables below present selected financial data for the fiscal years ended as of December 31, 2012, 2011 and 2010. We have derived the selected financial data for the fiscal years ended December 31, 2012, 2011 and 2010 from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with IFRS issued by the IASB. You should read the selected financial data in conjunction with “Item 3. Key Information” and “Item 8. Financial Information” and “Item 18. Financial Statements.”

## Consolidated Statements of Comprehensive Income:

	Year ended December 31,		
	2012	2011	2010
	U.S dollars in thousands (except per share data)		
Revenues	938	-	-
Cost of revenues	(380	) -	-
Gross profit	558	-	-
Research and development costs	(99	) (158	) (64
Selling and marketing expenses	(848	) -	-
General and administrative expenses	(2,769	) (1,078	) (1,222
Other gains, net	802	12	30
Operating loss	(2,356	) (1,224	) (1,256
Finance income	60	24	6
Finance costs	(15	) (7	) (7
Financial income (costs), net	45	17	(1
Earnings from investment in associate	569	-	-
Loss for the year	(1,742	) (1,207	) (1,257
Other comprehensive income:			
Foreign currency translation adjustments	114	-	-
Total other comprehensive income	114	-	-
Total comprehensive loss for the year	(1,628	) (1,207	) (1,257
Loss for the year attributable to:			
Equity holders of the Company	(1,390	) (1,207	) (1,257
Non-controlling interests	(352	) -	-
	(1,742	) (1,207	) (1,257
Total comprehensive loss for the year attributable to:			
Equity holders of the Company	(1,276	) (1,207	) (1,257
Non-controlling interests	(352	) -	-
	(1,628	) (1,207	) (1,257
Basic and diluted loss per share (in U.S. dollars)	(0.006	) (0.006	) (0.011
Weighted average number of issued ordinary shares	217,689,926	201,825,645	113,397,846



## Consolidated Statements of Financial Position Data:

As of December 31,  
2012    2011    2010  
U.S dollars in thousands

Cash, cash equivalents and bank deposits	3,312	1,495	1,066
Working capital	2,143	955	259
Total assets	11,086	4,073	3,797
Long term liabilities	13	-	-
Total shareholders' equity	7,353	3,444	2,834
Non-controlling interests	2,071	-	-

**Overview**

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, particularly the treatment of multiple myeloma, or MM, schizophrenia and Hepatitis C. Also, through our consolidated subsidiary - InterCure, we develop a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension. To date, our revenues were generated only from the medical device activity (since July 25, 2012) and we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any commercial revenues from the sales of our drug candidates.

We were established as a corporation under the laws of the State of Israel in 1993, and commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Since commencing operations, our activities have been primarily devoted to developing our technologies and drug candidates, acquiring pre-clinical and clinical-stage compounds, raising capital, purchasing assets for our facilities, and recruiting personnel. We are a development stage company. We have had no drug product sales to date and the sales of our medical devices are insufficient to generate operating income yet. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, from our initial public offering and from our placing and open offer transaction, and private investments in public equities.

We have incurred negative cash flow from operations each year since our inception and we anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our marketing efforts of our medical devices and potential in-licensing and acquisition opportunities.



We started to generate revenues in the medical device activity in 2012 through our subsidiary, InterCure which we acquired in July 25, 2012 (Intercure has been generating revenues for the sale of medical devices since 2000). Cost of revenues is related to the sale of medical devices.

Our research and development expenses in 2012, 2011 and 2010 consisted of primarily expenses related to the preparations for the rHuEPO drug clinical trial development plan. As part of the preparations, the Company conducted a research which includes collection of data relating to the level of specific proteins in the blood of a group of patients with multiple myeloma, which will assist in focusing the Phase 2 clinical trial protocol. This collected research data will be integrated in the Phase 2 clinical trial. The costs of such preparations comprise of, among others, costs in connection with medical regulation, patent registration costs, medical consulting costs and payments to medical centers. Additionally, we had amortization expenses of the exclusive right to examine a medical technology in the field of the immune system in 2010 and 2011.

Our selling and marketing expenses, which are wholly derived from our operation in the medical device field through InterCure, consist primarily of advertising, mainly direct/online advertising, salaries, sales promotions, fees and contingent options to Giboov, which provides us with marketing and sale services and other expenses. We expense our selling and marketing expenses as they are incurred.

Our general and administrative expenses consist primarily of salaries, consultant fees, and related expenses for executive, finance and other administrative personnel, professional fees, director fees and other corporate expenses, including investor relations, business development costs and facilities related expenses. We expense our general and administrative expenses as they are incurred.

Our results of operations include non-cash compensation expense as a result of the grants of XTL's and InterCure's stock options. Compensation expense for awards of options granted to employees and directors represents the fair value of the award (measured using the Black-Scholes valuation model) recorded over the respective vesting periods of the individual stock options. Expenses related to options granted by InterCure to Giboov are measured using the monte carlo valuation model and are recorded over the expected performance period required to achieve sales targets. We expect to incur decrease on the non-cash compensation for the future, primarily due to the fact that most expenses related to options granted in 2012 are recorded using the graded vesting method (see details below).

For awards of options and warrants to consultants and other third-parties, according to IFRS 2, the treatment of such options and warrants is the same as employee options compensation expense (see note 2p to the consolidated financial statements). We record compensation expense based on the fair value of the award at the grant date according to the Black-Scholes valuation model. According to the IFRS 2, in non-performance-based options, the Company recognizes options expenses using the graded vesting method (accelerated amortization). Graded vesting means that portions of a single option grant will vest on several dates, equal to the number of tranches. The company treats each tranche as a separate share option grant; because each tranche has a different vesting period, and hence the fair value of each tranche is different. Therefore, under this method the compensation cost amortization is accelerated to earlier periods in the overall vesting period. As per performance-based stock options granted to Giboov, expenses are recorded based on the fair value of the award at the grant date according to the Monte Carlo valuation model. In each reporting date we revise our estimations for the fulfillment of the sales target set in the agreement with Giboov and recognize the impact of the revision to original estimates, if any, in the statement of comprehensive income (loss) with a corresponding adjustment in equity.

Our planned clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our product candidates in the near future or generate licensing revenues from upfront payments associated with out-licensing transactions. In addition, we expect losses in our drug development activity to continue as we continue to fund development of our drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our periodical results may fluctuate and a period-by-period comparison of our operating results may not be a meaningful indication of our future performance.

On November 21, 2012 we acquired from Teva all its stake in Proteologics representing 31.35% of the share capital of Proteologics, which is accounted for using the Equity method of accounting in accordance with International accounting standard IAS 28 "investment in associates". From the acquisition date, Proteologics contributed to our results of operations a loss at the amount of approximately \$144,000 which was offset by a gain on bargain purchase at the amount of approximately \$713,000, included in "Earnings from investment in associate" in our statement of comprehensive income.

## Results of Operations

### *Years Ended December 31, 2012, 2011 and 2010*

*Revenues.* Sales in the year ended December 31, 2012 totaled approximately \$938,000, originating from the subsidiary InterCure whose financial statements were consolidated starting from July 25, 2012. InterCure's main sales are in the U.S. and the UK, which from the date of consummation of the transaction (July 25, 2012) through December 31, 2012, sales to those markets totaled approximately \$766,000 and \$167,000, respectively. The Company had no sales in 2010 and 2011. We do not anticipate to recognize material revenue in 2013 from our drug development activity, if any.

InterCure's sales in the year ended December 31, 2012 (including sales prior the acquisition by us in July 25, 2012) totaled approximately \$2,267,000, compared to approximately \$3,171,000 and \$3,728,000 in the years ended December 31, 2011 and 2010, respectively.

*Cost of Revenues.* Cost of revenues for the year ended December 31, 2012 totaled approximately \$380,000 (or \$225,000 excluding the amortization of identifiable intangible assets and other PPA adjustments). We had no cost of revenues for the years ended December 31, 2011 and 2010 as we did not generate revenues in these years.

*Gross profit.* Gross profit entirely derives from InterCure whose average gross profit ranges between 74% and 78%. The percentage of gross profit out of revenues is affected by the mix of direct/online sales which provides relatively high gross margin percentage and sales by resellers which generally provides lower gross profit margins. The gross profit (including amortization of identifiable intangible assets related to technology and other PPA adjustments totaled approximately \$ 155,000) was 60%. The gross profit in the period, excluding the amortization of identifiable intangible assets related to technology and other PPA adjustments, is about 76%.

*Research and Development Costs.* Research and development expenses in the year ended December 31, 2012 totaled approximately \$99,000, compared to approximately \$158,000 in 2011. Research and development expenses comprise mainly expenses involving the preparations for initiating the phase 2 clinical trial of the rHuEPO drug designed to treat cancer patients with Multiple Myeloma comprising, among others, research costs incurred in tracing blood proteins in Multiple Myeloma patients, costs in connection with medical regulation, clinical insurance costs and other medical consulting costs. The decrease in expenses compared to last year is mainly explained by the termination of the exclusive right to examine a medical technology relating to the immune system in late 2011. Research and development expenses relating to InterCure from the date of consummation of the transaction through December 31, 2012 are immaterial. Research and development expenses in 2010 totaled approximately \$64,000, arising mainly from expenses relating to the preparations for initiating the phase 2 clinical trial of the rHuEPO drug which include costs in

connection with medical regulation, patent registration costs, medical consulting costs and amortization of an exclusive right to examine a medical technology relating to the immune system.

Excluding non-cash share based compensation costs and amortization expenses, we expect to increase our level of research and development costs during 2013 mainly due to the plan to receive approval to initiate the phase 2 clinical trial on rHuEPO for the treatment of multiple myeloma, costs related to SAM-101 development and costs related to new technologies, if in-licensed/acquired.

*Selling and Marketing Expenses.* Sales and marketing expenses in the year ended December 31, 2012 totaled approximately \$848,000, originating entirely from InterCure whose financial statements were consolidated for the first time on July 25, 2012. We measure "average contribution" as the ratio between gross profit less direct/online advertising expenses divided by direct/online advertising expenses. Selling and marketing expenses include advertising expenses totaling approximately \$415,000 (mainly direct/online advertising expenses) and the gross profit amounted to approximately \$713,000 (net of amortization of identifiable intangible assets and other Purchase Price Allocation adjustments), resulting an average contribution of 72%. Selling and marketing expenses also include expenses in respect of the service agreement signed with Giboov in a total of approximately \$77,000 and share-based payment of \$132,000 for options granted to Giboov. The Company had no sales and marketing expenses in 2011 and 2010.

*General and Administrative Expenses.* General and administrative expenses for the year ended December 31, 2012 totaled approximately \$2,769,000 (approximately \$2,448,000 without InterCure), compared to approximately \$1,078,000 for the year ended December 31, 2011. The increase is mainly a result of the increase in expenses in respect of share-based payments to directors, service providers and employees. Expenses related to service providers including, among others, legal and professional and technological consulting fees in connection with the InterCure transaction, filing an application for relisting the ADRs on the NASDAQ and expenses in respect of grants to employees in connection with raising capital in the period, as specified above. General and administrative expenses attributable to InterCure for the period from the date of consummation of the transaction through December 31, 2012 totaled approximately \$321,000 and consist mainly of salary expenses, professional services, rent expenses, insurance and expenses in respect of share-based payments to directors and employees.

General and administrative expenses for the year ended December 31, 2010 totaled approximately \$1,222,000. The decrease in general and administrative expenses in 2011 compared to 2010 is principally explained by the decrease in professional service expenses, decrease in directors and officers insurance expenses of which reflects the decrease in the annual premium in view of the improvement in the Company's indices, a decrease in patent maintenance expenses principally for the rHuEPO drug, a decrease in expenses for share-based payments to employees and service providers accounted for by the graded vesting method, while on the other hand an increase in salary costs/consulting fees of executive officers which were updated in the second half of 2010 according to agreements and an increase in rent expenses.

Excluding non-cash share based compensation costs, we expect to increase our level of general and administrative costs during 2013 compared to 2012 mainly due to the fact that InterCure's operation is consolidated with ours. We may license additional technologies in the upcoming year.

*Other gains (losses), net.* Other gains in the year ended December 31, 2012 totaled approximately \$802,000, primarily originating from a gain from a bargain purchase in connection with the InterCure transaction totaling \$795,000. Bargaining purchase gain is the excess of the fair value of the investment acquired over the fair value of the consideration provided for such purchase in accordance with IFRS 3R, "Business Combinations (Revised)" ("IFRS3R"), as further detailed below. In the years ended December 31, 2011 and 2010, the Company derived other

gains totaling approximately \$12,000 and \$30,000, respectively.

*Finance income (expenses), net.* Finance income (expenses) for the years ended December 31, 2012, 2011 and 2010 totaled approximately \$45,000, \$17,000 and \$(1,000), respectively. The increase in finance income in 2012 compared to 2011 and 2010 derives mainly from interest income on short-term bank deposits whose carrying amount during 2012 was significantly higher compared to 2011 and 2010 as a result of the capital raising completed by the Company in March 2012 in the private placement and of the exercise of warrants (series 2) in the period.

*Earnings from investment in associate.* Earnings from investment in an associate totaling approximately \$569,000 arise from the Company's investment in Proteologics which is accounted according to the equity method. As at December 31, 2012, the Company holds approximately 31.24% of Proteologics' issued and outstanding share capital. On the date of acquisition, the Company recorded a gain from a bargain purchase totaling approximately \$713,000. From the acquisition date November 21, 2012 through December 31, 2012, the Company's share in Proteologics' losses totaled approximately \$144,000 (approximately NIS 546,000).

*"Income Taxes"* We had no income tax expense for the years ended December 31, 2012, 2011 and 2010 due to the losses incurred and we did not recognize any deferred tax benefits, since it is not "more likely than not" that we will be able to generate profits in the future to realize the deferred taxes.

### **Critical Accounting Policies**

*Basis of presentation of the financial statements.* The financial statements of the Company and its subsidiaries ("the Group") as of December 31, 2012 and 2011 and for each of the three years in the period ended December 31, 2012 have been prepared in accordance with International Financial Reporting Standards which are standards and interpretations issued by the International Accounting Standards Board ("IFRS") and include the additional disclosure required in accordance with the Israeli Securities Regulations (Annual Financial Statements), 2010.

The significant accounting policies described below are consistent with those of all periods presented, unless it is indicated otherwise.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires the Group's management to exercise its judgment in the process of applying the Group's accounting policies. The areas that involve judgment which has significant effect or complexity or where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 3 to the consolidated financial statements and hereinafter under the heading " CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS". Actual results could significantly differ from the estimates and assumptions used by the Group's management.

The Group's operating cycle is 12 months.

The Group analyses the expenses recognized in the statement of comprehensive income by classification based on the function of expense.



We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

*Subsidiaries consolidation and business combinations*

Subsidiaries are entities whose financial and operating policies are controlled by the Company, control which often involves holding more than half of the voting rights. When examining whether the Company controls another entity, the existence and effect of potential voting rights that are exercisable or convertible immediately are taken into account.

The Company examines whether it controls another entity even when it does not hold more than 50% of the voting rights, but can control the entity's financial and operating policies by de-facto control. De-facto control can be created under circumstance in which the ratio of the Company's voting rights in the entity to the percentage and dispersion of the holdings of the other shareholders grants the Company the power to control the entity's financial and operating policies.

Subsidiaries are fully consolidated starting from the date on which control therein is attained by the Company. Their consolidation ceases when such control is discontinued.

The Company's accounting treatment of business combinations uses the acquisition method. The consideration transferred for the acquisition of a subsidiary ("the acquiree") is calculated as the total of fair values of the assets transferred by the Company, the liabilities incurred by Group to the acquiree's previous owners and the equity rights issued by the Company. The transferred consideration includes the fair value of each asset or liability arising from a contingent consideration arrangement. The acquisition related costs are recognized in profit or loss as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed by the Company in a business combination (excluding certain exceptions prescribed in IFRS 3R, "Business Combinations (Revised)" ("IFRS3R")) are initially measured at fair value on the acquisition date. For each business combination, the Company decides whether to recognize non-controlling interests in the acquiree, which represent existing ownership rights and entitle their holders to a relative portion of the entity's net assets upon liquidation, at their fair value or at the relative portion of the existing ownership instruments in amounts recognized for the acquiree's net identifiable assets. This decision is individually made for each business combination. All the other components of non-controlling interests are measured at fair value on the acquisition date unless another measurement basis is required by IFRS. In respect of the acquisition of Intercure, the company elected to recognize the non-controlling interest at fair value.

The excess of the overall amount of the transferred consideration, the amount of any non-controlling interests in the acquiree, and the fair value of any previous equity rights in the acquiree on the acquisition date in excess of the net amount of identifiable assets acquired and liabilities assumed on the acquisition date, all measured as above, is recognized as goodwill.

In the event that the net amount of identifiable assets acquired and liabilities assumed on the acquisition date exceeds the overall amount of the transferred consideration, the amount of any non-controlling interests in the acquiree, and the fair value of any previous equity rights in the acquiree on the acquisition date as discussed above, the difference is recognized directly in profit or loss on the acquisition date. In 2012 the company recognized such gain on the acquisition of Intercure at the amount of \$795.

Intra-group balances and transactions, including revenues, expenses and dividends in respect of transactions between the Group companies, are eliminated. Gains and losses arising from intra-group transactions that have been recognized as assets (such as inventories and property, plant and equipment) are also eliminated.

*Transactions with non-controlling interests which do not result in loss of control*

Transactions with non-controlling interests in subsidiaries which do not result in loss of control in the subsidiaries are accounted for as transactions with owners. In these transactions, the difference between the fair value of any consideration paid or received and the amount of adjustment of the non-controlling interests to reflect the changes in their relative rights in the subsidiaries is directly recognized in equity and attributed to the equity holders of the parent.

*Associate*

An associate is an entity over which the Group exercises significant influence, but not control, which is usually expressed in holding 20%-50% of the voting rights. The investment in an associate is presented using the equity method of accounting. According to the equity method of accounting, the investment is initially recognized at cost and its carrying amount varies to the extent that the Group recognizes its share of the associate's earnings or losses from the acquisition date.

The associate's accounting policies are consistent with those of the Group's accounting policies, except for the early adoption of IFRS 9 in the associate's financial statements. The early adoption of IFRS 9 had no effect on the associate's financial statements.

The Group's share in the earnings or losses of associates after the acquisition date is carried to profit or loss and its share in the other comprehensive income movements after the acquisition date is carried to other comprehensive income against the carrying amount of the investment.

At each reporting date, the Group determines if there are indicators of impairment in the investment in the associate. In such case, the Group calculates the amount of the impairment as the difference between the recoverable amount of the investment in the associate (the higher of the value in use and the fair value less selling costs) and its carrying amount and recognizes the amount of impairment in profit or loss in the line item of "Earnings from investment in associate".

*Intangible assets*

1. Brand name and technology

Brand name and technology acquired in a business combination are recognized at fair value on the acquisition date. Brand name and technology have a finite useful life and are presented at cost net of accumulated amortization. The amortization is calculated using the straight-line method over the expected useful life (9-10 years).

2. Computer software

Acquired licenses to use computer software are capitalized based on costs incurred in acquiring the specific software and preparing it for use. These costs are amortized using the straight-line method over the estimated useful life (five years). Costs relating to computer software upkeep are recognized as expenses as incurred.

3. Exclusive technology testing right

An acquired exclusive immune system technology testing right has a finite life of 15 months in effect from September 1, 2010 and is amortized using the straight-line method over its useful life. On November 30, 2011, the amortization of this right was concluded. See details in Note 14d to the consolidated financial statements.

4. Unamortized intangible assets (licenses and patent rights)

The amortization of an asset on a straight-line basis over its useful life begins when the development procedure is completed and the asset is available for use. These assets are reviewed for impairment once a year or whenever there are indicators of a possible impairment, in accordance with the provisions of IAS 36, "Impairment of Assets".

5. Research and development:

Research expenditures are recognized as expenses when incurred. Costs arising from development projects are recognized as intangible assets when the following criteria are met:

- it is technically feasible to complete the intangible asset so that it will be available for use;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as an expense when incurred. Development costs that were previously recognized as an expense are not recognized as an asset in a later period. During the reporting period, the Group did not capitalize development costs to intangible assets.

### *Impairment of non-financial assets*

Intangible assets which are not yet available for use are not depreciated and impairment in their respect is tested every year. Depreciable assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that sustained impairment are reviewed for possible reversal of the impairment at each date of the statement of financial position.

As for testing impairment of acquired intangible assets, see *intangible assets* above.

### *Inventories*

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs. The Group periodically evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly.

### *Share capital*

The Company's Ordinary shares are classified as share capital. Incremental costs directly attributable to the issuance of new shares or options are shown in equity as a deduction, net of tax, from the issuance proceeds.

When Group companies purchase Company shares (treasury shares), the consideration paid, including incremental costs directly attributable to the purchase (less the effect of taxes on income), is deducted from the equity attributable to equity holders of the parent until the shares are eliminated or reissued. When these shares are reissued in subsequent periods, the consideration received, less incremental costs directly attributable to the transaction and less the effect of taxes on income, is included in equity attributable to equity holders of the parent.

### *Share-based payment*

The Group operates a number of share-based payment plans to employees and to other service providers who render services that are similar to employees' services that are settled with the Group's equity instruments. In this framework, the Group grants employees, from time to time, and, at its discretion, options to purchase shares of the Group companies. The fair value of services received from employees in consideration of the grant of options is recognized as an expense in the statement of comprehensive income (loss) and correspondingly carried to equity. The total amount recognized as an expense over the vesting term of the options (the term over which all pre-established vesting conditions are expected to be satisfied) is determined by reference to the fair value of the options granted at grant date, except the effect of any non-market vesting conditions.

Non-market vesting conditions are included in the assumptions used in estimating the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions of the share-based payment arrangement are to be satisfied.

In each reporting date, the Company revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions and recognizes the impact of the revision to original estimates, if any, in the statement of comprehensive income (loss) with a corresponding adjustment in equity.

When the options are exercised, the Company issues new shares. The proceeds net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

Share-based payment transactions in which the Company acquired assets as consideration for the Company's equity instruments are measured at the value of the assets acquired (see Note 14d to the consolidated financial statements).

### *Provisions*

A provision in accordance to IAS 37 is recognized when the Group has a present obligation (legal or constructive) as a result of event occurred in the past, probable to be required to use economic resources to settle the obligation and can be reliably estimated. The group recognizes a provision for warranty when the product is sold to the customer or when the service is provided to the customer. Initial recognition is based on past experience. The estimated provision is tested re-tested every year.

### *Revenue recognition*

Revenues are recognized in profit or loss when the revenues can be measured reliably, it is probable that the economic benefits associated with the transaction will flow to the Company and the costs incurred or to be incurred in respect of the transaction can be measured reliably. In cases where the Company acts as an agent or as a broker without being exposed to the risks and rewards associated with the transaction, its revenues are presented on a net basis. Revenues are measured at the fair value of the consideration received less any trade discounts, volume rebates and returns.

Following are the specific revenue recognition criteria which must be met before revenue is recognized:

Revenues from the sale of goods - Revenues from the sale of goods are recognized when all the significant risks and rewards of ownership of the goods have passed to the buyer and the seller no longer retains continuing managerial involvement. The delivery date is usually the date on which ownership passes.

### **New and amended IFRS standards and IFRIC interpretations**



Below are standards and amendments and interpretations to existing standards that are not yet effective and have not been early adopted by the Group:

1. IFRS 10, "Consolidated Financial Statements" ("IFRS 10")

IFRS 10 supersedes all existing guidance on the control and consolidation of financial statements in IAS 27, "Consolidated and Separate Financial Statements" ("IAS 27") and SIC 12, "Consolidation - Special Purpose Entities". IFRS 10 redefines "control". The new definition focuses on the requirement that power and variable returns should exist in order for control to exist. "Power" is the current ability to direct the activities which significantly affect the returns. IFRS 10 contains, inter alia, guidance relating to differentiating between participating rights and protective rights as well as guidance relating to cases where an investor is acting on behalf of another party or on behalf of a group of parties (agent/principal relationships). The core principle whereby a consolidated entity presents the accounts of a parent company and its subsidiaries as a single entity remains unchanged as well as the mechanics of consolidation. The Group will adopt IFRS 10 for the first time for the annual period commencing on January 1, 2013. The adoption of IFRS 10 is not expected to have a material impact on the Group's consolidated financial statements.

2. IAS 27 (Revised), "Separate Financial Statements" ("IAS 27R")

IAS 27R supersedes IAS 27 and only addresses separate financial statements. The existing guidance for separate financial statements has remained unchanged in IAS 27R. The Group will adopt IAS 27R for the first time for the annual period commencing on January 1, 2013. Since IAS 27R does not address consolidated financial statements, its initial adoption is not expected to have any effect on the Group's consolidated financial statements.

3. IAS 28 (Revised), "Investments in Associates" ("IAS 28R")

IAS 28R replaces IAS 28 in its previous format. The key changes contained in IAS 28R compared to IAS 28 relate to adding explicit references to the application of the equity method when accounting for investments in joint ventures as a result of the new guidance prescribed by IFRS 11. The Group will adopt IAS 28R for the first time for the annual period commencing on January 1, 2013. The adoption of IAS 28R is not expected to have a material impact on the Group's consolidated financial statements.

4. IFRS 12, "Disclosure of Interests in Other Entities" ("IFRS 12")

IFRS 12 prescribes disclosure requirements addressing accounting issues prescribed in IFRS 10 and IFRS 11, "Joint Arrangements" ("IFRS 11") and supersedes the existing disclosure requirements in IAS 28. The disclosure requirements prescribed in IFRS 12 include: significant judgments and assumptions; rights in subsidiaries; rights in joint arrangements and in associates; and rights in structured entities not consolidated in the financial statements. The Group will adopt IFRS 12 for the first time for the annual period commencing on January 1, 2013. The initial adoption of IFRS 12 is expected to expand certain disclosures in the Group's consolidated financial statements regarding its rights in other entities.

5. IFRS 13, "Fair Value Measurement" ("IFRS 13")

IFRS 13 focuses on improving the consistency and minimizing the complexity of fair value measurements by providing an accurate definition of the term "fair value" and offering a single source of guidance for the measurement of fair value and for the disclosure requirements of fair value measurement to be used by all the various IFRS standards. The requirements prescribed in IFRS 13 do not expand the use of fair value accounting but do provide guidance as to its adoption in cases where its use is required or allowed by other IFRS standards.

The Group will adopt IFRS 13 for the first time for the annual period commencing on January 1, 2013. IFRS 13 will be adopted prospectively from said annual period. The disclosure requirements of IFRS 13 need not be applied to comparative figures relating to periods before the date of its initial adoption. The initial adoption of IFRS 13 is not expected to have a material effect on the Group's consolidated financial statements.

6. IAS 19 (Revised 2011), "Employee Benefits" ("IAS 19R")

IAS 19R introduces significant changes in the manner of recognizing and measuring defined benefit plans and benefits in respect of employee dismissal and provides new disclosure requirements for all types of employees benefits within the scope of IAS 19 as follows:

The remeasurement of the net defined benefit liability (formerly - actuarial gains and losses) will be recognized in other comprehensive income and not in profit or loss.

The "corridor" approach which allowed the deferral of actuarial gains or losses has been eliminated. Income from the plan assets is recognized in profit or loss based on the discount rate used to measure the employee benefit liabilities. The return on plan assets excluding the aforementioned income recognized in profit or loss is included in the remeasurement of the net defined benefit liability.

The distinction between short-term employee benefits and long-term employee benefits is based on the expected settlement date and not on the date on which the employee first becomes entitled to the benefits.

Past service cost arising from changes in the plan is recognized immediately.

The Standard is to be applied retrospectively in financial statements for annual periods commencing on January 1, 2013, or thereafter. Earlier application is permitted.

The Group estimates that IAS 19R is not expected to have a material impact on the financial statements.

7. IFRS 9, "Financial Instruments" ("IFRS 9")

The first part of IFRS 9 which deals with classification and measurement of financial assets was published in November 2009 and the second part of IFRS 9 which includes guidance on financial liabilities and derecognition of financial instruments was published in October 2010. IFRS 9 replaces the parts of IAS 39, "Financial Instruments: Recognition and Measurement" ("IAS 39") that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into one of the two following categories: financial assets measured after initial recognition at fair value and financial assets measured after initial recognition at amortized cost. The decision to which category a financial asset should be classified is made on initial recognition. This classification is driven by the model the entity manages its financial instruments (its business model) and the contractual characteristics of the cash flows from the instrument. For financial liabilities, IFRS 9 retains most of the IAS 39 requirements. The main change is that, in cases where an entity has a financial liability that is designated at fair value through profit or loss, the part of a change in fair value due to changes in the liability's credit risk (an entity's own credit risk) is recorded directly in other comprehensive income rather than the statement of income, unless this creates an accounting mismatch. There is not subsequent recycling of the amounts in other comprehensive income to profit or loss. But, accumulated gains or losses may be transferred within equity.

In December 2011, an amendment to IFRS 9 and to IFRS 7, "Financial Instruments: Disclosures" ("the amendment") was published. The amendment deferred the mandatory effective date of IFRS 9 and the transitional provisions upon implementation and added certain transition disclosure requirements ("the additional disclosures").

According to IFRS 9, after its amendment, as above, both parts of IFRS 9 will apply for annual periods beginning on or after January 1, 2015. Entities may elect to apply IFRS 9 early but it is not possible to apply the second part of IFRS 9 early without applying at the same time the first part of IFRS 9. However, the first part of IFRS 9 may be applied earlier without being required to apply at the same time the second part of IFRS 9.

Based on the transition provisions of IFRS 9 and given that the Group has not yet early adopted the Standard for the annual period ended on December 31, 2012, upon the future adoption of IFRS 9, the Group will not be required to adjust comparative figures but will be required to provide the additional disclosures.

The Group is assessing the possible impact of IFRS 9 on its financial statements and the timing of its implementation.

8. IAS 1 (Revised), "Presentation of Financial Statements" ("IAS 1R")

IAS 1R modifies the manner of disclosure of items of other comprehensive income in the statement of comprehensive income according to the following principles.

The items presented in other comprehensive income should be separated into two groups based on whether they can be reclassified in the future to profit or loss. Accordingly, items which cannot be reclassified in the future to profit or loss will be presented separately from the re-classifiable items.

Entities that choose to present the items of other comprehensive income before the respective tax will be required to separately present the tax effect of each of the abovementioned groups  
The title of the statement of comprehensive income was changed to "statement of profit or loss and other comprehensive income"; however, IAS 1 allows entities to use other titles.

The Group will adopt IAS 1R for the first time for the annual period commencing on January 1, 2013 retrospectively for all reported periods. Since all of the Group's items of other comprehensive income may be reclassified in the future to profit or loss, the initial adoption of IAS 1R is expected to have a material impact on the Group's consolidated financial statements.

## **CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

### **1. Critical accounting estimates and assumptions**

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

Intangible assets - in determining the fair value of assets acquired in share-based payment transactions and in testing impairment of these research and development assets, the Company's management is required to estimate, among others, the probable endpoints of trials conducted by the Company, the commercial technical feasibility of the development and the resulting economic benefits. Actual results and estimates to be made in the future may significantly differ from current estimates.

Share-based payments - in evaluating the fair value and the recognition method of share-based payment, the Company's management is required to estimate, among others, different parameters included in the computation of the fair value of the options and the Company's results and the number of options that will vest. Actual results and estimates to be made in the future may significantly differ from current estimates.

Provisions for returns and warranty - the provision for returns and warranty for sold products is calculated as a percentage of sales based on past experience and is carried to profit or loss.

### **2. Judgments that have a critical effect on the adoption of the entity's accounting policies**

The existence of control over InterCure - the Group's management has estimated the degree of effect it has in InterCure and has determined that it is able to govern InterCure's financial and operating policies despite holding less than 50% of InterCure's issued and outstanding share capital, following an examination of InterCure's entire equity instruments. This conclusion was reached mainly since the Company is able to convert a loan (in the money) that it had granted InterCure into shares, a conversion which will confer the Company a stake of approximately 54.72% of InterCure's issued and outstanding share capital.

Investment in Proteologics - the Group's management has assessed the degree of influence it has in Proteologics and whether it exercises de-facto control over Proteologics despite holding less than 50% of Proteologics' issued and outstanding share capital. After the examination of the rate and dispersion of holdings of the other shareholders and

Proteologics' entire equity instruments and the level of the Company's representation on Proteologics' board of directors and management, the Company's management determined that the Company does not exercise de-facto control over Proteologics.

## **Impact of Inflation and Currency Fluctuations**

We generate most of our revenues and hold most of our cash, cash equivalents and bank deposits in US dollars. While a substantial amount of our operating expenses are in US dollars, we incur a portion of our expenses in New Israeli Shekels (especially since we moved the company head office to Israel in 2009). In addition, we also pay for some of our services and supplies in the local currencies of our suppliers. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to protect against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. The Company's treasury's risk management policy, excluding InterCure, is to hold NIS-denominated cash and cash equivalents and short-term deposits in the amount of the anticipated NIS-denominated liabilities for nine-twelve consecutive months from time to time and this in line with the directives of the Company's Board. InterCure is focuses on actions to reduce to minimum the negative effects arising from this risk and therefore holds cash and cash equivalents in currencies in which it operates, in accordance with management's assessments. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel. Additionally, our future activities could lead us to perform a clinical trial in Israel, which may lead us to reassess our use of the US dollar as our functional currency.

As of December 31, 2012, if the Group's functional currency had weakened by 10% against the NIS with all other variables remaining constant, post-tax loss for the year would have been approximately \$89,000 lower (2011 - post-tax loss approximately \$30,000 lower; 2010 - post-tax loss approximately \$11,000 higher), mainly as a result of exchange rate changes on translation of other accounts receivable, net and exchange rate changes on NIS-denominated cash and cash equivalents and short-term deposits. Loss was more sensitive to movement in the exchange rate in relation to the NIS in 2012 than in 2011 mainly because of the increased amount of the NIS-denominated balances in the items of cash, receivables and payables of the Group.

## **Governmental Economic, Fiscal, Monetary or Political Policies that Materially Affected or Could Materially Affect Our Operations**

The income of the Company is subject to corporate tax at the regular rate; the guidance of the amendment to the Israeli Income Tax Ordinance, 2005 from August 2005 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2009 are as follows: 2009 - 26% and 2010 and thereafter - 25%.

On July 14, 2009, the "Knesset" (Israeli Parliament) passed the Law for Economic Efficiency (Amended Legislation for Implementing the Economic Plan for 2009 and 2010), 2009, which prescribes, among others, an additional gradual reduction in the corporate tax rates starting 2011 to the following tax rates: 2011 - 24%, 2012 - 23%, 2013 - 22%,



2014 - 21%, 2015 - 20%, 2016 and thereafter - 18%.

In December 2011, following the enactment of the Law for the Changing the Tax Burden (Legislative Amendments), 2011 (hereafter - "Tax Burden Distribution Law"), the phased reduction in the corporate tax was eliminated, and corporate tax rate in 2012 and thereafter was set to 25%.

As of December 31, 2012, XTL Biopharmaceuticals Ltd. did not have any taxable income. As of December 31, 2012, our net operating loss carry forwards for Israeli tax purposes registered on behalf of XTL Biopharmaceuticals Ltd amounted to approximately \$26 million. Under Israeli law, these net-operating losses may be carried forward indefinitely and offset within XTL Biopharmaceuticals Ltd only, against future taxable income, including capital gains from the sale of assets used in the business, with no expiration date. Also, InterCure has carryforward business losses and capital losses which total approximately \$ 14 million as of December 31, 2012.

In order to obtain tax exemption for the share swap transaction with Bio-Gal pursuant to Sections 104 and 103 to the Israeli Income Tax Ordinance (Revised), 1961, we signed an agreement with the Israeli Tax Authority on July 15, 2010. Below is the summary of the principal conditions for the share swap and the transfer of the intangible asset:

The balance of the Company's business losses and capital losses for tax purposes was reduced to approximately NIS 80 million (approximately \$ 22 million) and approximately NIS 0.7 million (approximately \$ 0.19 million), respectively. This item is not to derogate from the Tax Assessing Officer's authority to establish that the balance of losses is actually lower than the abovementioned amounts.

1. Any losses incurred to the Company prior to the share swap, after their reduction as discussed in paragraph 1 above, will not be offset against any income originating from Xtepo (the transferred company) or against a capital gain from the sale of shares of Xtepo.
2. Xtepo shareholders will not be allowed to sell their shares in the Company for a period of two years from the end of the year of completion of the transaction ("the Lock-up Period"), subject to any changes in legislation.
3. The Company and Xtepo both undertake to maintain their main economic activity as it was prior to the transaction during the Lock-up Period.
4. The Company will not be permitted to sell its holdings in Xtepo for the duration of the Lock-up Period.

The Lock-up Period ended in December 31, 2012.

It is indicated that the guidance to Sections 104 and 103 to the Israeli Income Tax Ordinance which deal with restructuring and mergers impose statutory limitations and various conditions on the entities participating in the change in structure/merger, among others, restrictions on dilution of holdings from raising by a prospectus or by private placements. The summary of the principles detailed above does not constitute a substitute to the overall articles.

Additionally on January 1, 2013, Xtepo shareholders decided to engage in a new voluntary lock-up agreement ("New Lock-Up Agreement") for additional period of 3 years ("New Restriction Period"), in which accordingly selling restrictions shall apply to the shares held by them. Hereunder are the principle restrictions regarding the quantities eligible for sale during the agreement period:

During the first year of the New Restriction Period (starting on January 1, 2013 up to December 31, 2013) 15% of  
1. the total shares held by Xtepo shareholders shall be eligible for sale in a manner that every month each shareholder shall be entitled to sell up to 1.25% ( $15\% * 1/12$ ) of the total restricted shares.

During the second year of the New Restriction Period (starting on January 1, 2014 up to December 31, 2014) shares  
2. that constitute 25% of the total amount of shares held by Xtepo shareholders shall be eligible for sale in a manner that every month each shareholder shall be entitled to sell up to 2.08333% ( $25\% * 1/12$ ) of the total restricted shares.

During the third year of the New Restriction Period (starting on January 1, 2015 up to December 31, 2015) the  
3. remaining shares held by Xtepo shareholders shall be eligible for sale in a manner that every month each shareholder shall be entitled to sell up to 5% ( $60\% * 1/12$ ) of the total restricted shares.

The New Lock-up Agreement terminates upon the occurrence of one of the following events: (1) the end of the New Restriction Period as defined above; (2) the shareholders receipt of written notification from the Trustee that the Trustee wishes to terminate their position under the New Lock-Up Agreement within 30 days, and the Company has not found a replacement trustee within the said period; or (3) a majority of the shareholders who are party to the New Lock-Up Agreement agree to terminate the agreement.

Since April 7, 2009, we did not have a “permanent establishment” and activity in the US, and our subsidiaries do not perform any activity. Our board of directors consists of a majority of Israeli residents and our management is domiciled in Israel. However, for the period we did have a “permanent establishment” in the US, any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. The maximum US corporate income tax rate (not including applicable state and local tax rates) is currently at 35%. In addition, if we had income attributable to the permanent establishment in the US, we may be subject to an additional branch profits tax of 30% on our US effectively connected earnings and profits, subject to adjustment, for that taxable year if certain conditions occur, unless we qualified for the reduced 12.5% US branch profits tax rate pursuant to the United States-Israel tax treaty. We would be potentially able to credit any foreign taxes that may become due in the future against its US tax liability in connection with income attributable to its US permanent establishment and subject to both US and foreign income tax.

## **B. Liquidity and Capital Resources**

We have financed our operations from inception primarily through various private placement transactions, our initial public offering, a placing and open offer transaction, option and warrant exercises, and private investments in public equities. As of December 31, 2012, we had received net proceeds of approximately \$80.2 million from various private placement transactions, including net proceeds of approximately \$ 1.5 million from the Bio-Gal transaction in August 2010, net proceeds of approximately \$45.7 million from our initial public offering in September 2000, net proceeds of approximately \$15.4 million from the 2004 placing and open offer transaction, net proceeds of approximately \$1.75 million from our public offering on the Tel Aviv Stock Exchange (TASE) in March 2011 and proceeds of approximately \$4.0 million from the exercise of options and warrants.

As of December 31, 2012, we had approximately \$3.3million in cash, cash equivalents, and short-term bank deposits (approximately \$ 2.4 million excluding cash in InterCure), an increase of \$1.8 million (\$ 0.9 million excluding cash in InterCure) from December 31, 2011.

Cash used in operating activities for the year ended December 31, 2012, was \$1.5 million, as compared to \$1.3 million for the year ended December 31, 2011. Following the first-time consolidation of InterCure's accounts in the consolidated financial statements, InterCure's share in the cash flows used in operating activities totaled approximately \$167,000, arising mainly from the repayment of current account payables and other accounts payable and inventory purchases. Cash flows used in the Group's operating activities, excluding InterCure, in the year ended December 31,

2012 totaled approximately \$1.3 million with no material change from 2011.

For the year ended December 31, 2012, the net cash used in investing activities totaled at approximately \$1.3 million, as compared to net cash used in investing activities of \$1.4 million for the year ended December 31, 2011. The decrease in cash flows used in investing activities in 2012 compared to 2011 arises mainly from cash received in the consolidation of InterCure's accounts, from fewer investments in bank deposits in 2012 offset by investment in Proteologics in the amount of approximately \$1,658,000.

For the year ended December 31, 2012, net cash provided by financing activities totaled approximately \$4.3 million, which originate from the capital raised in the private placement of March 2012 and the exercise of warrants (series 2) and warrants (series A) in the period. For the year ended December 31, 2011, net cash provided by financing activities totaled approximately \$1.7 million and was derived from funds raised through the public prospectus of March 2011 in Israel, less issuance expenses paid in the period.

Continuation of our current operations is dependent upon the generation of revenues including revenues from our medical device activity through our consolidated subsidiaries InterCure's, or additional financial resources through agreements for the monetization of our rHuEPO for multiple myeloma, SAM-101 for schizophrenia, and residual in the DOS program or through external financing. The Company has no revenues from drug development operations at this stage and it is dependent on external financing sources. The Company has incurred continuing losses and its entire income at this stage originates from InterCure, a subsidiary which was consolidated for the first time in these financial statements (following the completion of the transaction of July 2012, see also Note 5 to the consolidated financial statements). The Company depends on external financing resources to continue its activities. During the period the Company raised through a private placement and exercise of tradable and non-tradable warrants from March 2012 to the date of the approval of the financial statements total net proceeds of approximately \$ 4.3 million (see information in Note 19 to the consolidated financial statements). In the opinion of the Company's management and based on its business plans, the balances of cash and cash equivalents with the balances of short-term deposits, will enable the Company to fund its activities through at least into the third quarter of 2014. However, the actual amount of cash the Company will need to fund its operations is subject to many factors, including, but not limited to, the timing, design and execution of the clinical trials of its existing drug candidates, any future projects which may be in-licensed or any other business development activities. For example, changing circumstances and/or acquisition of new technologies may cause the Company to consume capital significantly faster than the management's current anticipation and the Company may need to spend more money than currently expected because of, among others, circumstances beyond its control.

The Company will incur additional losses in 2013 from research and development activities, examination of additional technologies and from current operation which will be reflected in negative cash flows from operating activities. Accordingly, in order to complete the clinical trials to bring a product to market, the Company will be required to raise additional cash in the future through the issuance of securities. However, if the Company is not able to raise additional capital at acceptable terms, the Company may be required to exercise tradable securities held by it or reduce operations or sell or out-license to third parties some or all of its technologies.

Our forecast of the period of time through which our cash, cash equivalents and short-term investments will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need in future to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the accuracy of our financial forecasts in our drug development activity as well as in our medical device activity;

- the timing and cost of the in-licensing, partnering and acquisition of new product opportunities;

- the timing of expenses associated with product development and manufacturing of the proprietary drug candidates that we have acquired rHuEPO for the treatment of MM, SAM-101 for the treatment of schizophrenia, and those that may be in-licensed, partnered or acquired;

- our plans regarding the development of the DOS program for the treatment of hepatitis C.

- our ability to achieve our milestones under licensing arrangements; and

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

Changes in the global economic environment, especially in our main target markets of our medical device products - the US and the UK.

- Sales of the medical device manufactured by InterCure

We have based our estimate on assumptions that may prove to be inaccurate. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing may be obtained through strategic relationships, public or private sales of our equity or debt securities, and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of our ordinary shares or other securities convertible into shares of our ordinary shares, the ownership interest of our existing shareholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan and which would raise substantial doubt about our ability to continue as a going concern. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. See “Item 3. Key Information - Risk Factors - Risks Related to Our Financial Condition.”

### **C. Research and Development, Patents and Licenses**

Research and development costs in 2012, 2011 and 2010 substantially derived from costs related to the preparations to the rHuEPO drug clinical trial development plan. As part of said preparations, the Company conducted a study which consists of collecting preliminary data on the existence of specific proteins in the blood of a group of Multiple Myeloma patients. The Company has expanded the study to additional centers in order to collect additional data beyond the original study plan. The data which was collected in the framework of the preliminary study will be combined, as necessary, in planning and preparing for the implementation of the phase 2 clinical trial which the Company expects to obtain the approval to commence it by the end of the fourth quarter of 2013. The costs of such preparations comprise of, among others, costs in connection with medical regulation, patent registration costs, medical consulting costs and payments to medical centers. Additionally, we had amortization expenses of the exclusive right to examine a medical technology in the field of the immune system in 2010 and 2011.

#### ***rHuEPO for the Treatment of MM***

According to the clinical trial’s preliminary plan we received as part of the Bio-Gal transaction we are planning on performing a prospective, multi-center, double blind, placebo controlled, 50-patient phase 2 study intended to assess safety of rHuEPO when given to patients with advanced MM and demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We intend to receive approval to commence such trial by the end of the fourth quarter of 2013 and we expect it to last two-and-a-half years and its cost is estimated at \$1-1.5 million. We have not yet submitted the preliminary plan, which may be updated, to the authorities and/or the applicable IRB.

While we have begun preliminary discussions with potential clinical sites and third party vendors for the planned study, we have not yet determined the final size and scope of the study, and as a result, we cannot certify the above



estimations regarding the clinical trial period and cost to complete the study.

***SAM-101 for the Treatment of Schizophrenia***

According to the preliminary development plan we received as part of the MinoGuard transaction, it is planned to perform a multi-center phase 2b clinical trial under the FDA, using our proprietary combination. This preliminary plan is subject to changes in accordance with our regulatory advisors and the FDA/other regulatory agencies requirements.

***DOS Program for the Treatment of Hepatitis C***

Under the terms of the license agreement, Presidio became responsible for all further development and commercialization activities and costs relating to the DOS program, which is still in preclinical development. The technology reverted to us in November 2012. We intend to examine the renewal of activity in the field of Hepatitis C and/or locate strategic partners for the continued development and marketing of drugs for treating Hepatitis C based on the DOS technology. The timing and results of pre-clinical studies are highly unpredictable. Due to the nature of pre-clinical studies and our inability to predict the results of such studies, we cannot estimate when such pre-clinical development will end.

The information above provides estimates regarding the costs associated with the current estimated range of the time that will be necessary to complete the development phase for rHuEPO for the treatment of MM and develop SAM-101 for the treatment of schizophrenia. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 3 under the heading “Risk Factors-Risks Related to our Business.”

The following table sets forth the research and development costs for the years 2010-2012 including all costs related to the clinical-stage projects, our pre-clinical activities, and all other research and development. We have started preparations for rHuEPO clinical development in the last quarter of 2010 (after the completion of the Bio-Gal transaction on August 2010). We in-licensed SAM-101 in November 2011 (see "Item 4. Licensing Agreements and Collaborations") and we estimate that we will incur significant costs on its development in the upcoming years. Whether or not and how quickly we commence and complete development of our clinical stage projects is dependent on a variety of factors, including the rate at which we are able to engage clinical trial sites and the rate of enrollment of patients. As such, the costs associated with the development of our drug candidates will probably increase significantly.

For a further discussion of factors that may affect our research and development, see “Item 3. Risk Factors - Risks Related to Our Business,” and “Item 4. Information on the Company - Business Overview - Products Under Development” above.

	Research and development Expenses in thousand US\$		
	Years ended December 31,		
	2012	2011	2010
rHuEPO	93	70	32
SAM-101	-	-	-
Anti TNF (Yeda Option)	-	88	32
Other (RESPeRATE, through InterCure)	6	-	-
Total Research and development	99	158	64

#### D. Trend Information

Please see “Item 5. Operating and Financial Review and Prospects” and “Item 4. Information on the Company” for trend information.

#### E. Off-Balance Sheet Arrangements

As of December 31, 2012, InterCure has letter of credit amounting to approximately \$200,000, in favor of inventory supplier, for its current operations.

Other than that, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

**F. Tabular disclosure of contractual Obligations**

As of December 31, 2012, we had known contractual obligations, commitments and contingencies of approximately \$329,000 which relate to our offices and vehicle operating lease obligations, of which \$155,000 is due within the next year, with the remaining balance due as per the schedule below.

According to the vehicle operating lease agreements we have the sole right to terminate these agreements with 1-2 months paid notice. We also have the sole right to extend such office lease period by additional 24 months. In April 2013 we notified to our offices' landlord that we wish to extend the lease agreement, according to the option given to us. The table below reflects our obligations under the extension of the lease period.

In May 2010, a subsidiary, InterCure Inc., signed an agreement for the lease of offices for a period of three years. The monthly lease fees are approximately \$5,500. InterCure Inc. is considering the renewal of the lease agreement or alternatively the relocation of the offices.

We do not carry any contractual obligations, commitments or contingencies relates to research and development operation.

		Payment due by period as of December 31, 2012 (in thousands of US\$)			
	Total	<b>Less than <u>1</u> <u>year</u></b>	<b>1-3 <u>years</u></b>	<b>3-5 <u>years</u></b>	<b>More than <u>5</u> <u>years</u></b>
Contractual obligations					
Operating lease obligations	329	155	174	—	—
Total	329	155	174	—	—

\*) Including the contractual obligation related to the renewal of the Company's office agreement from April 2013 in amount of approximately \$187,000.

Additionally, the VivoQuest license agreement provides for contingent milestone payments triggered by certain regulatory and sales targets. These milestone payments total \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our sole discretion. In addition, the license agreement requires that we make royalty payments on product sales. Pursuant to our

out-licensing agreement with Presidio, until it was effectively cancelled in November 2012, Presidio was obligated to pay us for any contingent milestone consideration owed to VivoQuest pursuant to the XTL and VivoQuest license agreement.

We have undertaken to make contingent milestone payments to DOV Pharmaceutical, Inc. of up to approximately \$126.5 million over the life of the license. These milestone payments may be made in either cash and/or our ordinary shares, at our election, with the exception of \$5 million in cash, which would due upon or after regulatory approval. We were also obligated to make royalty payments on future product sales net sales. We ceased development of Bicifadine in November 2008 and since then both XTL Development and DOV ceased the prosecution and maintenance of those patents relating to the Bicifadine. In March 2010, we formally terminated the license agreement. Therefore, we will not be obligated to make any of the aforesaid payments.

Pursuant to our asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal Ltd., we are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful of Phase 2. Such payment of \$350,000 mentioned above shall be made to Yeda upon the earlier of (i) six months from the Successful Completion of Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO at any time after the completion of the Phase 2 of an amount of minimum \$2 million.

According to the agreement with MinoGuard we are obligated to pay milestone payments to MinoGuard of up to \$2.5 million based on development and marketing milestones as well as 3.5% royalty of our net sales of the product and 7.5%-20% from our third-party out-license receipts, depends on the phase of the drug at the time of an out-license transaction. It should be noted we have the sole discretion to pay any of the above amounts in cash or by way of issuing of our shares to MinoGuard.

According to our strategic collaboration master agreement with the Institute and Mor, we are obligated to pay the Institute for the services provided by them the cost basis related to the Institute's activity in the framework of any project plus an additional 10% of the total royalties to which Mor is entitled pursuant to its agreements with the Company in connection with each technology for which rights were granted to the Company.

On September 24, 2012, InterCure announced the signing of a three-year non-exclusive strategic service agreement with Giboov Ltd. ("the service provider"), a private company wholly-owned by Messrs. Shay Ben-Yitzhak and Avner Yassur, for the provision of online selling and marketing services of InterCure's products ("the services").

According to the strategic agreement, which is territorially unlimited, the service provider will provide InterCure online sale services in return for a monthly fee of \$ 40,000 plus VAT in return for the services ("the consideration") whereby in the first four months of the strategic agreement period, no consideration will be paid and will later be paid provided that revenues are derived from online sales in an amount of at least \$ 50,000. In addition, InterCure will provide monthly online advertising budgets for the online sale activity performed by the service provider, which will not be less than \$130,000, and all under the mechanism as described in the agreement.

In the context of the strategic agreement, the service provider will be allocated up to 20,185,184 unlisted stock options ("the stock options") that are exercisable into shares of InterCure for an exercise price (dividend adjusted) of NIS 0.54 per stock option which will vest according to the service provider's compliance with annual sales targets. In the context of the strategic agreement, the service provider's shareholders were given a put option to sell to InterCure the service provider's entire share capital for a period of 18 months from the effective date of the strategic agreement. On the date of signing the strategic agreement, InterCure was granted a call option to purchase the service provider's entire share capital for a period of one year from the effective date of the strategic agreement. The agreement's allocation items were approved by the general meeting of InterCure's shareholders on October 28, 2012. InterCure will be able to cancel the agreement if the service provider fails to meet the sales targets prescribed in the strategic agreement effective from March 2014 or in the event of material breach of the agreement, fraud, damage etc. For further details regarding the agreement with Giboov, see note 18(a) to the consolidated financial statements.

In addition, in 2007, XTL Development and the company committed to pay a transaction advisory fee to certain third party intermediaries in connection with the in-license of Bicifadine from DOV. In October 2007, XTL Development entered into definitive agreements with the third party intermediaries with respect to the binding term sheets signed in 2007 (the "Definitive Agreements"). Under the terms of the Definitive Agreements, the transaction advisory fee was structured in the form of SARs, in the amount equivalent to (i) 3% of our fully diluted ordinary shares at the close of the transaction (representing 1,659,944 ordinary shares NIS 0.1 par value), vesting immediately and exercisable one year after the close of the transaction, and (ii) 7% of our fully diluted ordinary shares at the close of the transaction (representing 3,873,203 ordinary shares NIS 0.1 par value), vesting on a certain milestone event. Payment of the SARs by XTL Development can be satisfied, at our discretion, in cash and/or by issuance of our registered ordinary shares. Upon the exercise of a SAR, the amount paid by XTL Development will be an amount equal to the amount by which the fair market value of one ordinary share on the exercise date exceeds the \$1.7 grant price for such SAR (fair market value equals (i) the greater of the closing price of an "ADR" on the exercise date, divided by two, or (ii) the

preceding five day ADR closing price average, divided by two). Any vested SARs will expire on January 15, 2017. As of December 31, 20112012, the 3% tranche was vested and recorded in our financial statements as capital reserve according to IFRS 2 (see note 2m to the financial statements). The 7% tranche was not vested. In March 2010, we formally terminated the license agreement and therefore all unvested SAR (the 7% tranche) have automatically expired. See also “Item 10. Additional Information - Material Contracts.”

**Item 6. Directors, Senior Management and Employees****A. Directors and Senior Management**

The following sets forth information with respect to our directors and executive officers as of April 24, 2013.

Name	Age	Position
Amit Yonay	43	Chairman of the Board of Directors
Dr. Ben-Zion Weiner	69	Non Executive Director
Dafna Cohen	43	Non Executive and External Director
Jaron Diamant	45	Non Executive and External Director
Marc Allouche	39	Non Executive Director
David Grossman	38	Executive Director and Chief Executive Officer
Ronen Twito	38	Deputy CEO and Chief Financial Officer
Prof. Moshe Mittelman	58	Medical Director

Amit Yonay has served as a director in our company since March 2009. Mr. Yonay has also served as the Chairman of the Board of Directors in InterCure Ltd. since July 2012. Since 2007, he has been actively involved in independent investments primarily in the real estate and capital markets with an emphasis toward distressed asset opportunities. Mr. Yonay had served from 2000 to January 2007, as the Head Israeli Sell-Side Analyst with ING Financial Markets (NYSE: ING, Euronext: INGA) in Israel. Mr. Yonay received a BSc in Electrical Engineering from Binghamton University and an MBA from Tel Aviv University in Finance and International Business.

Dr. Ben-Zion Weiner was nominated on April 2012 as director in our company. From January 2012 until December 2012, Dr. Weiner served as Special Advisor to the Chief Executive Officer of Teva Pharmaceutical Industries Ltd. ("Teva") (Nasdaq: TEVA, TASE: TEVA). For about 30 years Dr. Weiner has served as VP R&D of Teva. He was twice granted the Rothschild Prize for Innovation, in 1989 for the development of Alpha D3® for dialysis and osteoporosis patients and in 1999 for the development of Copaxone® for multiple sclerosis. Since May 2012, Dr. Weiner has served as Director at Mesoblast Limited (ASX: MSB; OTC: MBLTY). From August 2010 until March 2013, Dr. Weiner served as director of Gefen Biomed Investments Ltd. In 1975, Dr. Weiner received a Ph.D. in chemistry from the Hebrew University, where he also received B.Sc. (1968) and M.Sc. (1970) degrees.

Dafna Cohen has served as a director in our company since March 2009. From 2010 until 2011 she served as director of Global Treasury at Mediamind Technologies (Nasdaq: MDMD), From 2005 to 2009 she served as Director of Investment and Treasurer of Emblaze Ltd. (LSE: BLZ). From 2000 to December 2004, Ms. Cohen was an Investment Manager for Leumi Partners. From 1994-2000, Ms. Cohen worked in the derivatives sector of Bank Leumi. In addition, Ms. Cohen serves as a director of Formula Systems Ltd (Nasdaq: FORTY, TASE: FORTY) since November 2009. Ms. Cohen serves as a Director at Europort (TASE: ERPT.B1) since January 2012. From March 2011 to July



2012 Ms. Cohen was a director of Inventech Central (TASE: IVTC). Ms. Cohen received a BA in economics and political science and an MBA in finance and accounting from Hebrew University, Jerusalem.

Jaron Diament has served as a director in our company since March 2009. He has served as the Chief Executive Officer of Tagor Capital Ltd., a public real estate investment company (TASE: TGCP), and a board member of all of its non-Israel real estate investments since December 2009. From September 2006 to December 2009, Mr. Diament served as Chief Financial Officer of Tagor Capital Ltd. In addition, Mr. Diament serves as an external director of Mega Or Holdings Ltd. (TASE: MGOR) since September 2007 and served as an independent director in Jobokit Holdings Ltd. (TASE: JBKT) since May 2011 until July 2012. Mr. Diament received a BA in economics and accounting from Tel Aviv University.

Marc Allouche has served as a director in our company since March 2009. He is the founder and managing partner of NFI Blue Consulting, an investment banking & business advisory firm. NFI focuses on creating and advising Israel-related investment and business opportunities on a world wide scale, with particular expertise on the Israel-Europe axis, and this notably within two asset classes: private equity and real estate. Previously, he served as the head of the Alternative Investments Division of Harel Insurance Investments & Financial Services Ltd., from 2008 to 2009, focusing on private equity and real estate investments. From 2006 to 2007, Mr. Allouche served as Executive Vice President of investments & strategic development of SGPA, a French private equity group and, concurrently, was CEO of one of its portfolio companies, operating in the retail sector in France, for turnaround purposes. From 2002 to 2005, from Paris, Mr. Allouche was founder and managing director of the Private Equity Advisory Group of Russel Bedford International, in charge of international corporate finance, transaction services and restructuring advisory services. From 2000 to 2001, Mr. Allouche served as Vice President at Nessuah Zannex Venture Capital Company Ltd., in strategic alliance with US Bancorp Piper Jaffray, managing a life sciences venture capital fund and, concurrently, was also managing director of one of its med-tech portfolio companies for turnaround purposes. From 1998 to 2000, Mr. Allouche was involved in the creation and the management of the Technology Group of KPMG International - Somekh Chaikin in Israel, a corporate finance division dedicated to high-tech and biotech companies. From 1996 to 1998, Mr. Allouche was a Senior Consultant at the Audit and the Transaction Services divisions of Price Waterhouse in Paris. Mr. Allouche received a BA in economics and a MBA with major in corporate finance and accounting from Dauphine University, Paris. He is also a Chartered Public Accountant in France.

David Grossman has served as a director in our company and as Chief Executive Officer of our company since February 2009. He served as a Vice President of Eurocom Investments LP, a private equity fund, from March 2006 to December 2008. Also from March 2006 to December 2008, Mr. Grossman was Vice President of Sahar Investments Ltd, (TASE: SAIN, today Enlight Energy: ENLT) which focused on investments in the Life Sciences arena. From July 2003 to March 2006, Mr. Grossman was a Senior Analyst at Israel Health Care Ventures (IHCV), an Israeli healthcare venture capital fund. Since November 2012, Mr. Grossman serves as a director in Proteologics Ltd. (TASE: PRTL). Since July 2012, Mr. Grossman serves as a director in InterCure Ltd. (TASE: INCR). Since August 2011, Mr. Grossman serves as an external director and member of the audit committee of Rosetta Green Ltd. (TASE: RSTG). From January 2009 to April 2011, Mr. Grossman was a director and member of the audit committee of Bio Light Israeli Life Science Investments Ltd. (TASE: BOLT), and from May 2007 to July 2008 was a Director and member of the audit committee of Gilat Satcom Ltd. (AIM: GLT). Mr. Grossman received a BA business administration with a focus on information technology, from the Interdisciplinary Center Herzliya.

Ronen Twito has served as Chief Financial Officer in our company since July 2009 and since April 2012 he has served also as Deputy CEO. Mr. Twito has served also as a deputy CEO of InterCure Ltd (TASE: INCR) since July 2012 and CEO since November 2012. Prior to joining XTL, he served as Corporate Finance Director at Leadcom Integrated Solutions Ltd., an international telecommunications company, specializing in management and implementation of network deployment services (then listed on the AIM and TASE) from November 2004 to May 2009. Previously he served as an Audit Manager at Ernst & Young Israel from January 2000 to November 2004. Mr. Twito possesses over 12 years of finance and management experience in both publicly traded and private companies, which includes IPOs, dual listings, bonds placement, public fund raising, consolidated financial statement and M&As. Mr. Twito is an Israeli Certified Public Accountant and is a member of the Institute of CPAs in Israel. He holds a BSc in Business & Management – Accounting, and a B.Ed in Teaching of accounting, both from the Collman Management College.



Prof. Moshe Mittelman has served as the Medical Director at our company since August 2010. He is also a Hematology consultant and Director of the Department of Medicine at the Tel Aviv Sourasky (Ichilov) Medical Center, Israel. Since 1997, Moshe has been Clinical Associate Professor of Medicine at the Sackler School of Medicine, Tel Aviv University. A well-known hematologist focusing on cancer and erythropoietin (EPO) research, Prof. Mittelman was one of the first hematologists to apply rHuEPO in the clinical practice, which allowed him to make the pioneering observation of prolonged survival in multiple myeloma (MM) rHuEPO -treated patients . This led to extensive research both in the lab as well as with patients, showing hitherto unrecognized immune effects to EPO. This research project has resulted in a series of scientific papers published in prestigious journals. Prof. Mittelman is also a well-known speaker in international conferences. Prof. Mittelman's work led to the founding of Bio-Gal, Ltd. which has now merged with XTL. Prof. Mittelman has also served as President of the Israel Society of Internal Medicine, Secretary of the Israel Society of Hematology and a Hematology Consultant for the Israel Ministry of Health. Prof. Mittelman is also a consultant to various biotech companies. During the years 2008-2010, he has been a member of the national committee of the Health Basket in Israel. Since 2007, Prof. Mittelman serves as director in Gaon Holdings Ltd. (TASE: GAON), a public holding company.

## **Employment Agreements**

We have an agreement dated January 18, 2010, which came into effect upon the completion of the Bio-Gal transaction, and effective as of January 1, 2010, with David Grossman, our Chief Executive Officer. Mr. Grossman is currently entitled to an annual base fee of NIS 491,000. Upon the successful completion of cash fund raising of at least US\$ 10 million in equity on NASDAQ or any other recognized and approved stock exchange (the "Fund Raising"), Mr. Grossman's Annual fees shall be raised to NIS 580,000. In the event that the Company completes the Fund Raising and also Another Transaction (as defined below), then Mr. Grossman's annual fee shall be raised to NIS 630,000. ("Another Transaction" shall mean any business combination transaction, merger or acquisition, intellectual property licensing transaction or joint venture, etc.). In the event that we completed a Fund Raising of a cash amount of more than US\$3 million within 24 months of the signing date, Mr. Grossman would have been entitled to receive a one time bonus equal to 1% of the Fund Raising amount but not more than \$150,000. However, such an event did not occur and therefore on March 19, 2012 the shareholder meeting approved a board resolution that if the Company effects any fund raising during the thirty six (36) month period from the date of this resolution, the Company will pay to Mr. Grossman a bonus equal to 1.2% of the above fund raising amount, up to a maximum amount of \$200,000. Until the date of this report Mr. Grossman received a bonus in amount of approximately \$ 38,000. Mr. Grossman is also entitled to receive benefits comprised of managers' insurance as commonly acceptable for officer holders, and the use of a company car. There is a non-compete clause surviving one year after termination of employment. The agreement is not limited in time and may be terminated by either party on a four months prior written notice. In March 2010, our shareholders approved the agreement and the granting of options to Mr. Grossman to purchase a total of 1,610,000 ordinary shares at an exercise price equal to NIS 0.075 per share. These options were vested over a two-year period, with 33.33% having vested on the grant date, and the remaining 66.67% vested on a monthly basis, commencing from the effective date, over a period of 2 years thereafter. In May 2012 our shareholders approved the grant of additional 1,500,000 options to purchase a total of 1,500,000 ordinary shares at an exercise price of NIS 0.90 per share. These options shall vest over a three-year period on a quarterly basis (12 quarters), commencing the effective date for as long as Mr. Grossman's agreement with us is not terminated. Due to the fact that Mr. Grossman served as a CEO from February, 2009 without any consideration, Mr. Grossman received a one time signing payment of NIS 430,000. On 26 and 27 February 2011, the company's audit committee and board of directors approved, respectively, the company CEO's request and in accordance with the terms of the Agreement that they signed with him

that the contractual arrangement of the CEO will be that of providing management services as an independent contractor and only if the financial consideration that will be paid to him does not exceed the cost to the company for his employment as an employee as stipulated above and that the company CEO undertakes to indemnify the company if an employer-employee relationship will be established between himself and the company. On September 3, 2012, in a special meeting of InterCure's shareholders, 75,000 share options to purchase 75,000 InterCure's ordinary shares were allocated to Mr. Grossman. The exercise price of these share options is NIS 0.54. These options shall vest over a three-year period on a quarterly basis (12 quarters), commencing the effective date for as long as Mr. Grossman directorship in InterCure is not terminated.

We have an employment agreement dated July 29, 2009, and effective as of June 24, 2009, with Ronen Twito, our Deputy CEO and Chief Financial Officer. Mr. Twito is currently entitled to an annual base salary of NIS 467,000. Upon the successful completion of cash fund raising of at least US\$ 10 million in equity on NASDAQ or any other recognized and approved stock exchange (the "Fund Raising"), Mr. Twito's Annual Salary shall be raised to NIS 550,000. In the event that the Company completes Fund Raising and also Another Transaction (as defined below), then Mr. Twito's annual salary shall be raised to NIS 600,000. ("Another Transaction" shall mean any business combination transaction, merger or acquisition, intellectual property licensing transaction or joint venture, etc.). In the event of a Fund Raising which is of a cash amount more than US\$3 million but less than US\$10 Million, Mr. Twito's annual salary shall be raised, to an amount based on a linear calculation of US\$3 Million – US\$10 Million applied to the annual salary increase of NIS 456,000 – NIS 550,000 (or in the event Another Transaction is achieved, NIS 600,000). In the event that we complete a Fund Raising of a cash amount of US \$15 million, then Mr. Twito shall be entitled to a cash bonus in a NIS amount equal to US\$ 200,000. In the event that the actual fundraising is of an amount of more than US\$3 million but less than US \$15 million, then Mr. Twito shall be entitled to a linear portion of the cash bonus calculated based on the actual fundraising between US\$3 Million and US\$15 Million. On February 12, 2012 our board of directors passed a resolution that if the Company effects any fund raising during the thirty six (36) months period from the date of this resolution, the Company will pay to Mr. Twito a bonus equal to 1.2% of the above fund raising amount, up to a maximum amount of \$200,000. Until the date of this report Mr. Twito received a bonus in amount of approximately \$51,000. Mr. Twito is also entitled to receive benefits comprised of managers' insurance (pension and disability insurance), as commonly acceptable for officer holder, and the use of a company car. There is a non-compete clause surviving one year after termination of employment. The employment agreement is not limited in time and may be terminated by either party on three months prior written notice. In July 2009, our Board of Directors granted options to Mr. Twito to purchase a total of 1,400,000 ordinary shares at an exercise price equal to NIS 0.075 per share. These options were vested over a three-year period, with 33.33% having vested after 5 month from the agreement date, and the remaining 66.67% were vested on a monthly basis, commencing from the effective date, over a period of 3 years thereafter. In April 2012 our Board of Directors approved the grant of additional 1,710,000 options to purchase a total of 1,710,000 ordinary shares at an exercise price of NIS 0.90 per share. These options shall vest over a three-year period on a quarterly basis (12 quarters), commencing the effective date for as long as Mr. Twito's employment with the Company is not terminated. Mr. Twito has served also as a deputy CEO and CFO of InterCure since July 2012 and CEO since November 2012. In July 2012, InterCure's Board of Directors approved the grant of 1,000,000 options to purchase a total of 1,000,000 InterCure's ordinary shares at an exercise price of NIS 0.54 per share. These options shall vest over a three-year period on a quarterly basis (12 quarters), commencing the effective date for as long as Mr. Twito's position in InterCure is not terminated.

We have an agreement dated on July 12, 2010, and effective as of August 27, 2010, with Prof. Moshe Mittelman, our Medical Director. Prof. Mittelman is entitled to a monthly fee of \$ 2,500. His entitlement began 90 days after the date of completion of the Bio-Gal transaction, i.e., November 3, 2010. The agreement is limited to the date of successful completion of the phase 2 clinical trial on the rHuEPO. A "successful completion of the phase 2 clinical trial" is defined as: six (6) months after the trial of the rHuEPO on the last patient in accordance with trial protocol, or on an earlier date if XTL notifies Yeda of XTL's desire to discontinue the trial. In August 2010, our Board of Directors approved the agreement as well as granting options to Prof. Mittelman to purchase a total of 640,000 ordinary shares at an exercise price of NIS 0.1 per share. These options were vested over a twenty four-month period, on a monthly basis, commencing from August 27, 2010.

## **B. Compensation**

The aggregate compensation paid by us to all persons who served as directors or officers for the year 2012 (10 persons) was approximately \$0.6 million. This amount includes payments of approximately \$0.1 million made for social security, pension, disability insurance and health insurance premiums, severance accruals, payments made in lieu of statutory severance, payments for continuing education plans, payments made for the redemption of accrued vacation, and amounts expended by us for automobiles made available to our officers. This amount includes also a bonus payment in a total of approximately \$90,000 to senior officers (Mr. David Grossmann and Mr. Ronen Twito) based on agreements signed with them regarding funds raising during the period.

All members of our Board of Directors who are not our employees are reimbursed for their expenses for each meeting attended. Our directors are eligible to receive share options under our share option plans. Non-executive directors do not receive any remuneration from us other than their fees for services as members of the board, additional fees if they serve on committees of the board and expense reimbursement.

In April 2012, we granted to one of our director, Dr. Ben-Zion Weiner, 4,408,000 options to purchase our ordinary shares of NIS 0.1 par value, pursuant to the shareholder meeting of May 29, 2012, exercisable at an exercise price of NIS 0.9. The options shall vest and be exercisable over three-year period on a quarterly basis, commencing from the date of the mentioned shareholders meeting, for the duration of three years.

In March 2012, we granted to our external directors, Mr. Diamant Jaron and Ms. Dafna Cohen, 150,000 options each, to purchase our ordinary shares of NIS 0.1 par value, pursuant to the shareholder meeting of March 19, 2012, exercisable at an exercise price of NIS 0.58633 (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the said options are vested and 67% of said options shall vest and be exercisable on a monthly basis, commencing from the date of the mentioned shareholders meeting, for the duration of two years.

In March 2009, pursuant to a shareholders' meeting, the monetary compensation was set for each of Mr. Grossman, Mr. Schweiger, Mr. Allouche, Mr. Yonay, Mr. Diamant and Ms. Cohen as follows: annual consideration of \$10,000 (to be paid in 4 equal quarterly payments), payments of \$375 for attendance at each board or committee meeting in person or held by teleconference, \$187.5 for unanimous board resolutions and reimbursement of reasonable out-of-pocket expenses. Mr. Grossman serves as the Company's Chief Executive Officer since February 11, 2009 and is entitled to a compensation package as detailed above in the Employment Agreements paragraph, and therefore is not entitled to Directors fee. It should be noted that Dr. Ben-Zion Weiner is not entitled to any fees other than the options granted to him in April 2012.

We granted to three of our directors, Mr. Yonay, Mr. Schweiger (former director) and Mr. Allouche, 150,000 options each, to purchase our ordinary shares of NIS 0.1 par value, pursuant to the shareholder meeting of March 2, 2010,

exercisable at an exercise price of NIS 0.298 (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the said options are vested and 67% of said options shall vest and be exercisable on a monthly basis, commencing from March 2, 2010, for the duration of two years. On November 22, 2010, Mr. Shweiger ceased his directorship in the Company and therefore 63,747 of the total options granted to him were forfeited in accordance. Upon his departure, Mr. Shweiger exercised the vested 86,253 options.

On September 3, 2012, in a special meeting of InterCure's shareholders, 75,000 share options to purchase 75,000 InterCure's ordinary shares were allocated to Mr. Yonay. The exercise price of these share options is NIS 0.54. These options shall vest over a three-year period on a quarterly basis (12 quarters), commencing the effective date for as long as Mr. Yonay directorship in InterCure is not terminated.

For further details regarding share options granted to our employees, directors and service providers, see note 20 to the consolidated financial statements.



In accordance with the requirements of Israeli Law, we determine our directors' compensation in the following manner:

first, our compensation committee reviews the proposal for compensation.

second, provided that the compensation committee approves the proposed compensation, the proposal is then submitted to our Board of Directors for review, except that a director who is the beneficiary of the proposed compensation does not participate in any discussion or voting with respect to such proposal; and

finally, if our Board of Directors approves the proposal, it must then submit its recommendation to our shareholders, which is usually done in connection with our shareholders' general meeting.

The approval of a majority of the shareholders voting at a duly convened shareholders meeting is required to implement any such compensation proposal.

### **C. Board practices**

#### ***Election of Directors and Terms of Office***

Our Board of Directors currently consists of six members, including our non-executive Chairman. Other than our two external directors, our directors are elected by an ordinary resolution at the annual general meeting of our shareholders. The nomination of our directors is proposed by a nomination committee of our Board of Directors, whose proposal is then approved by the board. The current members of the nomination committee are Amit Yonay (chairman of the nomination committee), Jaron Diament (chairman of the audit committee) and Dafna Cohen. Our board, following receipt of a proposal of the nomination committee, has the authority to add additional directors up to the maximum number of 12 directors allowed under our Articles. Such directors appointed by the board serve until the next annual general meeting of the shareholders. Unless they resign before the end of their term or are removed in accordance with our Articles, all of our directors, other than our external directors, will serve as directors until our next annual general meeting of shareholders. In July 2011, at an annual general meeting of our shareholders, Amit Yonay, Marc Allouche, and David Grossman were re-elected to serve as directors of our company. Dafna Cohen and Jaron Diament were elected to serve as external directors of our company at the March 2009 extraordinary general meeting. Dafna Cohen and Jaron Diament are serving as external directors pursuant to the provisions of the Israeli Companies Law for a three-year term ending in March 2012. On March 19, 2012 at an annual general meeting of our shareholders, Amit Yonay, Marc Allouche and David Grossman were re-elected to serve as directors of our company until the next shareholders meeting and our external directors, Dafna Cohen and Jaron Diament, were re-elected to serve as external directors of our company for an additional period of three years. After this date, the external directors term of service may be renewed for an additional last three-year term.

None of our directors or officers has any family relationship with any other director or officer.

Our Articles permit us to maintain directors' and officers' liability insurance and to indemnify our directors and officers for actions performed on behalf of us, subject to specified limitations. We maintain a directors and officers insurance policy which covers the liability of our directors and officers as allowed under Israeli Companies Law.

There are no service contracts or similar arrangements with any director that provide for benefits upon termination of directorship.

***External and Independent Directors***

The Israeli Companies Law requires Israeli companies with shares that have been offered to the public either in or outside of Israel to appoint two external directors. No person may be appointed as an external director if that person or that person's relative, partner, employer or any entity under the person's control, has or had, on or within the two years preceding the date of that person's appointment to serve as an external director, any affiliation with the company or any entity controlling, controlled by or under common control with the company. The term affiliation includes:

an employment relationship;

a business or professional relationship maintained on a regular basis;

control; and

service as an office holder, other than service as an officer for a period of not more than three months, during which the company first offered shares to the public.

No person may serve as an external director if that person's position or business activities create, or may create, a conflict of interest with that person's responsibilities as an external director or may otherwise interfere with his/her ability to serve as an external director. If, at the time external directors are to be appointed, all current members of the Board of Directors are of the same gender, then at least one external director must be of the other gender. A director in one company shall not be appointed as an external director in another company if at that time a director of the other company serves as an external director in the first company. In addition, no person may be appointed as an external director if he/she is a member or employee of the Israeli Security Authority, and also not if he/she is a member of the Board of Directors or an employee of a stock exchange in Israel.

External directors are to be elected by a majority vote at a shareholders' meeting, provided that either:

the majority of shares voted at the meeting, including at least one-third of the shares held by non-controlling shareholders voted at the meeting, vote in favor of election of the director, with abstaining votes not being counted in this vote; or

the total number of shares held by non-controlling shareholders voted against the election of the director does not exceed one percent of the aggregate voting rights in the company.

The initial term of an external director is three years and may be extended for two additional three-year terms. An external director may be removed only by the same percentage of shareholders as is required for their election, or by a court, and then only if such external director ceases to meet the statutory qualifications for their appointment or violates his or her duty of loyalty to the company. At least one external director must serve on every committee that is empowered to exercise one of the functions of the Board of Directors.

An external director is entitled to compensation as provided in regulations adopted under the Israeli Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with service provided as an external director.

Dafna Cohen and Jaron Diamant serve as external directors pursuant to the provisions of the Israeli Companies Law. They both serve on our audit committee, our nomination committee and our compensation committee.

### *Audit Committee*

The Israeli Companies Law requires public companies to appoint an audit committee. The responsibilities of the audit committee include identifying irregularities in the management of the company's business and approving related party transactions as required by law. An audit committee must consist of at least three directors, including all of its external directors. The chairman of the Board of Directors, any director employed by or otherwise providing services to the company, and a controlling shareholder or any relative of a controlling shareholder, may not be a member of the audit committee. An audit committee may not approve an action or a transaction with a controlling shareholder, or with an office holder, unless at the time of approval two external directors are serving as members of the audit committee and at least one of the external directors was present at the meeting in which an approval was granted.

Our audit committee is currently comprised of three independent non-executive directors. The audit committee is chaired by Jaron Diament, who serves as the audit committee financial expert, with Dafna Cohen and Marc Allouche as members. The audit committee meets at least four times a year and monitors the adequacy of our internal controls, accounting policies and financial reporting. It regularly reviews the results of the ongoing risk self-assessment process, which we undertake, and our interim and annual reports prior to their submission for approval by the full Board of Directors. The audit committee oversees the activities of the internal auditor, sets its annual tasks and goals and reviews its reports. The audit committee reviews the objectivity and independence of the external auditors and also considers the scope of their work and fees.

We have adopted a written charter for our audit committee, setting forth its responsibilities as outlined by the regulations of the SEC. In addition, our audit committee has adopted procedures for the receipt, retention and treatment of complaints we may receive regarding accounting, internal accounting controls, or auditing matters and the submission by our employees of concerns regarding questionable accounting or auditing matters. In addition, SEC rules mandate that the audit committee of a listed issuer consist of at least three members, all of whom must be independent, as such term is defined by rules and regulations promulgated by the SEC. We are in compliance with the independence requirements of the SEC rules.

The Israeli Companies Law regulations require each public company to appoint a committee that examines the financial statements (the "Committee") which shall be compounded from at least Three (3) members, of which the majority among them shall be independent directors and the Committee's Chairman shall be an external director. The Committee's duties are, among others, to examine the Company's Financial Statements and to recommend and report to the board of directors of the Company regarding any problem or defect found in such Financial Statements.

In addition to the above-said, all of Committee's members must apply with the following requirements:

All members shall be members of the board of directors of the Company.  
At least one of the Committee's members shall have a Financial and Accounting expertise and the rest of the Committee's members must have the ability to read and understand Financial Statements.

The Company is in full compliance with the above-said requirements.

### Financial Statement Examination Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint a financial statement examination committee, which consists of members with accounting and financial expertise or the ability to read and understand financial statements. According to a resolution of our Board of Directors, the Audit Committee has been assigned the responsibilities and duties of a financial statements examination committee, as permitted under relevant regulations promulgated under the Companies Law. From time to time as necessary and required to approve our financial statements, the Audit Committee holds separate meetings, prior to the scheduled meetings of the entire Board of Directors regarding financial statement approval. The function of a financial statements examination committee is to discuss and provide recommendations to its board of directors (including the report of any deficiency found) with respect to the following issues: (i) estimations and assessments made in connection with the preparation of financial statements; (ii) internal controls related to the financial statements; (iii) completeness and propriety of the disclosure in the financial statements; (iv) the accounting policies adopted and the accounting treatments implemented in material matters of the company; (v) value evaluations, including the assumptions and assessments on which evaluations are based and the supporting data in the financial statements. Our independent auditors and our internal auditors are invited to attend all meetings of Audit Committee when it is acting in the role of the financial statements examination committee.

### Compensation Committee

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. 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.

Similar to the rules that apply to the audit committee, the compensation committee may not include the chairman of the board, or any director employed by the company, by a controlling shareholder or by any entity controlled by a controlling shareholder, or any director providing services to the company, to a controlling shareholder or to any entity controlled by a controlling shareholder on a regular basis, or any director whose primary income is dependent on a controlling shareholder, and may not include a controlling shareholder or any of its relatives. Individuals who are not permitted to be compensation committee members may not participate in the committee's meetings other than to present a particular issue; provided, however, that an employee that is not a controlling shareholder or relative may participate in the committee's discussions, but not in any vote, and the company's legal counsel and corporate secretary may participate in the committee's discussions and votes if requested by the committee.

The roles of the compensation committee are, among others, to: (i) 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; (ii) recommend to the directors any update of the Compensation Policy, from time to time, and examine its implementation; (iii) decide whether to approve the terms of office and of employment of office holders that require approval of the compensation committee; and (iv) decide, in certain circumstances, whether to exempt the approval of terms of office of a chief executive officer from the requirement of shareholder approval.



The compensation policy requires the approval of the general meeting of shareholders with a "Special Majority", which requires a majority of the shareholders of the company who are not either a controlling shareholder or an "interested party" in the proposed resolution, or that shareholders holding less than 2% of the voting power in the company voted against the proposed resolution at such meeting. However, under special circumstances, the board of directors may approve the compensation policy without shareholder approval, if the compensation committee and thereafter the board of directors decided, based on substantiated reasons after they have reviewed the compensation policy again, that the compensation policy is in the best interest of the company.

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.

Mr. Jaron Diament is the chairman of our compensation committee. Mr. Marc Allouche and Mrs. Dafna Cohen serve as the other members of our compensation committee

#### Approval of Compensation to Our Officers

The Israeli Companies Law prescribes that compensation to officers must be approved by a company's Board of Directors.

As detailed above, our compensation committee consists of three independent directors: Mr. Jaron Diament, Mr. Marc Allouche and Mrs. Dafna Cohen. The responsibilities of the compensation committee are to set our overall policy on executive remuneration and to decide the specific remuneration, benefits and terms of employment for directors, officers and the Chief Executive Officer.

The objectives of the compensation committee's policies are that such individuals should receive compensation which is appropriate given their performance, level of responsibility and experience. Compensation packages should also allow us to attract and retain executives of the necessary caliber while, at the same time, motivating them to achieve the highest level of corporate performance in line with the best interests of shareholders. In order to determine the elements and level of remuneration appropriate to each executive director, the compensation committee reviews surveys on executive pay, obtains external professional advice and considers individual performance.

#### *Internal Auditor*

Under the Israeli Companies Law, the board of directors must appoint an internal auditor, nominated by the audit committee. The role of the internal auditor is to examine, among other matters, whether the company's actions comply with the law and orderly business procedure. Under the Israeli Companies Law, an internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's shares;
  
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
  
- an executive officer or director of the company; or
  
- a member of the company's independent accounting firm.

We comply with the requirement of the Israeli Companies Law relating to internal auditors. Our internal auditors examine whether our various activities comply with the law and orderly business procedure.

## D. Employees

As of April 24, 2013, the Company had four full-time employees (one of whom is an officer, which is engaged with the Company as a service provider and one of whom joined the Company in April 2013). As of the same date InterCure had 12 full-time employees and service providers and one part-time service provider. We and our Israeli employees are subject, by an extension order of the Israeli Ministry of Welfare, to a certain provisions of collective bargaining agreements between the Histadrut, the General Federation of Labor Unions in Israel and the Coordination Bureau of Economic Organizations, including the Industrialists Associations. These provisions principally address cost of living increases, recreation pay, travel expenses, vacation pay and other conditions of employment. We provide our employees with benefits and working conditions equal to or above the required minimum. Other than those provisions, our employees are not represented by a labor union. See also “Item 5. Operating and Financial Review and Prospects - 2009 Restructuring” and “Item 6. Directors, Senior Management and Employees – Employment Agreements” above.

For the years ended December 31, 2012, 2011 and 2010, the number of our full-time employees engaged in the specified activities, by geographic location, are presented in the table below.

	Year ended December 31,		
	2012*)	2011	2010
Research and Development			
Israel	-	-	-
US	-	-	-
	-	-	-
Selling and Marketing			
Israel	5	-	-
US	1	-	-
	6	-	-
Financial and general management			
Israel	5	3	3
US	1	-	-
	6	3	3
Total	12	3	3
Average number of full-time employees	11	3	3

\*) Includes the employees in InterCure, which was consolidated for the first time since July 25, 2012. The average number was calculated based on InterCure's employees during the full year of 2012.

**E. Share Ownership**

The following table sets forth certain information as of March 31, 2013, regarding the beneficial ownership by our directors and executive officers. All numbers quoted in the table are inclusive of options to purchase shares that are exercisable within 60 days of March 31, 2013.

	Amount and nature of beneficial ownership				
	Ordinary shares beneficially owned excluding options	<b>Options<sup>1</sup> exercisable within 60 days of March 31, 2013</b>	Total ordinary shares beneficially owned including options	Percent of ordinary shares beneficially owned	
Amit Yonay Chairman of the Board	—	150,000	2 150,000	*	
Marc Allouche Director	—	150,000	2 150,000	*	
Dafna Cohen External Director	—	108,338	3 108,338	*	
Jaron Diament External Director	—	108,338	3 108,338	*	
Dr. Ben-Zion Weiner Director	570,434	1,469,332	4 2,039,766	*	
David Grossman Director and Chief Executive Officer	—	2,110,000	5 2,110,000	*	
Ronen Twito Deputy CEO and Chief Financial Officer	—	1,970,000	6 1,970,000	*	
Moshe Mittelman Medical Director	5,562,715	640,000	7 6,202,715	2.6	%
All directors and executive officers as a group (8 persons)	6,133,149	6,706,00	8 12,839,157	5.4	%

(1) Options to purchase ordinary shares

(2) 150,000 options at an exercise price of NIS 0.298 per ordinary share of NIS 0.1 par value, exercisable until March 1, 2020.

(3) 108,338 options at an exercise price of NIS 0.58633 per ordinary share of NIS 0.1 par value, exercisable until March 18, 2022.

(4) 1,469,332 options at an exercise price of NIS 0.9 per ordinary share of NIS 0.1 par value, exercisable until May 28, 2022.

(5)

1,610,000 options at an exercise price of NIS 0.075 per ordinary share of NIS 0.1 par value, exercisable until January 17, 2020, and 500,000 options at an exercise price of NIS 0.9 per ordinary share of NIS 0.1 par value, exercisable until May 28, 2022.

1,400,000 options at an exercise price of NIS 0.075 per ordinary share of NIS 0.1 par value, exercisable until June (6) 23, 2019, and 570,000 options at an exercise price of NIS 0.9 per ordinary share of NIS 0.1 par value, exercisable until April 11, 2022.

(7) 640,000 options at an exercise price of NIS 0.1 per ordinary share of NIS 0.1 par value, exercisable until August 26, 2020.

\*Represents Less than 1% of ordinary shares outstanding.

### ***Share Option Plans***

We maintain the following share option plans for our and our subsidiary's employees, directors and consultants. In addition to the discussion below, see Note 20 of our consolidated financial statements, included at "Item 18. Financial Statements."

Our Board of Directors administers our share option plans and has the authority to designate all terms of the options granted under our plans including the grantees, exercise prices, grant dates, vesting schedules and expiration dates, which may be no more than ten years after the grant date. Options may not be granted with an exercise price of less than the fair market value of our ordinary shares on the date of grant, unless otherwise determined by our Board of Directors.

As of December 31, 2012, we have granted to employees, directors and consultants options that are outstanding to purchase up to 12,506,000 ordinary shares of NIS 0.1 par value, pursuant to two share option plans and pursuant to certain grants apart from these plans also discussed below under Non-Plan Share Options.

#### *2001 Share Option Plan*

Under a share option plan established in 2001, referred to as the 2001 Plan, we granted options during 2001-2011, at an exercise price between \$ 0.0198 and \$4.655 per ordinary share of NIS 0.1 par value. Up to 2,200,000 option of NIS 0.1 par value were available to be granted under the 2001 Plan. On July 29, 2009, the option pool was increased by 5,000,000 unissued additional ordinary shares of NIS 0.1 par value, as well as forfeited and expired options that reverted to the pool due to departure of employees. As of December 31, 2012, 4,110,000 options are outstanding. Options granted to Israeli employees were in accordance with section 102 of the Tax Ordinance, under the capital gains option set out in section 102(b)(2) of the ordinance. The options are non-transferable.

The option term is for a period of ten years from the grant date. The options were granted for no consideration. The options vest over a three or two year period. As of December 31, 2012, 4,101,663 options are fully vested. On May 2, 2011, the 2001 Share Option Plan has expired and no options may be granted under this plan.

#### *2011 Share Option Plan*

On August 29, 2011, the Company's Board approved the adoption of an employee stock option scheme for the grant of options exercisable into shares of the Company according to section 102 to the Israeli Tax Ordinance ("2011 Plan"), and to maintain up to 10 million shares in the framework of the 2011 Plan, for options allocation to employees, directors and Company consultants.

The 2011 Plan shall be subject to section 102 of the Israeli Tax Ordinance. According to the Capital Gain Track, which was adopted by the Company and the abovementioned section 102, the Company is not entitled to receive a tax deduction that relates to remuneration paid to its employees, including amounts recorded as salary benefit in the

Company's accounts for options granted to employees in the framework of the 2011 Plan, except the yield benefit component, if available, that was determined on the grant date. The terms of the options which will be granted according to the 2011 Plan, including option period, exercise price, vesting period and exercise period, shall be determined by the Company's Board on the date of the actual allocation. As of April 24, 2013 we have granted 8,276,000 share options under the 2011 Plan at an exercise price between \$ 0.16 and \$0.34 per ordinary share of NIS 0.1 par value.

*Non-Plan Share Options*

In addition to the options granted under our share option plans, there are 120,000 of NIS 0.1 par value outstanding options, as of December 31, 2012, which were granted to consultants and a member of our Scientific Advisory Board, not under an option plan during 2011. The options were granted at an exercise price of \$0.15. As of December 31, 2012, 72,000 options of NIS 0.1 par value are fully vested.

For further details regarding share options granted to our employees, directors and service providers, see note 20 to the consolidated financial statements.

**ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS****A. Major shareholders**

As of April 19, 2013, there were 1,898,239 ADRs outstanding, held by approximately 9 record holders, whose holdings represented approximately 16.54% of the total outstanding ordinary shares, of which 7 record holders were in the US.

The following table sets forth the number of our ordinary shares owned by any person known to us to be the beneficial owner of 5% or more of our ordinary shares as of April 24, 2013. The information in this table is based on 229,503,079 outstanding ordinary shares as of such date. The number of Ordinary Shares beneficially owned by a person includes Ordinary Shares subject to options held by that person that were currently exercisable. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

Name	Number of shares owned	Percent of ordinary shares	
Alexander Rabinovitch <sup>(1)(2)(3)</sup>	43,132,361	18.79	%
David Bassa <sup>(2)</sup>	21,705,987	9.46	%
Shalom Manova <sup>(2)</sup>	17,136,242	7.47	%

<sup>(1)</sup> 23,574,902 of our ordinary shares are held through Green Forest Ltd., which to the best of our knowledge held jointly by Alexander Rabinovitch and Sagit Rabinovitch.

<sup>(2)</sup> Alexander Rabinovitch, David Bassa and Shalom Manova hold our shares since August 3, 2010 as part of the completion of the Bio-Gal transaction.

In addition to his holding as stated in the table above, Mr. Alexander Rabinovitch, through Green Forest Ltd., holds 573,750 warrants (series 2). Each warrant (series 2) is exercisable into one ordinary share of NIS 0.1 par value <sup>(3)</sup>from the date of registration for trade on the Tel-Aviv stock exchange (March 9, 2011) to December 31, 2013, at an exercise price equal to NIS 1.0 per share, linked to the US dollar. On a fully diluted basis, assuming exercise of all outstanding warrants, the total holding shall represent 17.06% of the share capital of the Company.

**B. Related Party Transactions**

To our knowledge, there are no related party transactions existing as of April 24, 2013.



## **Item 8. Financial Information**

### **Consolidated Statements and Other Financial Information**

Our audited consolidated financial statements appear in this annual report on Form 20-F. See “Item 18. Financial Statements.”

### **Legal Proceedings**

Neither we nor our subsidiaries are a party to, and our property is not the subject of, any material pending legal proceedings.

## **Dividend Distributions**

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any such cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors. Cash dividends may be paid by an Israeli company only out of retained earnings as calculated under Israeli law. We currently have no retained earnings and do not expect to have any retained earnings in the foreseeable future.

## **Significant Changes**

On January 21, 2013, InterCure announced that the examination conducted as part of the process of concluding the engagement with Mr. Erez Gavish, the former CEO ("Mr. Gavish"), revealed several issues which require inspection in connection with InterCure's actions during Mr. Gavish's term as CEO, including the legal validity granted to the license agreement of October 2011 signed between InterCure and a company controlled by Dr. Benjamin Gavish, Mr. Gavish's father and an interested party in InterCure at the time). InterCure's Board appointed a committee which includes an external attorney hired for this purpose and another director in InterCure in order to investigate the issue and provide the Board conclusions.

On February 21, 2013 and after the reporting date, the Company's special general meeting of shareholders and the general meeting of holders of warrants (series 2) of the Company decided to extend the exercise period of said warrants from February 27, 2013 to December 31, 2013. This decision is subject to the approval of the District Court pursuant to Section 350 to the Israeli Companies Law, 1999. On March 12, 2013 the Court approved the decision to extend the exercise price of the warrants.

On March 3, 2013, the Company notified a subsidiary, InterCure, that if the Company decides not to convert the loan granted to InterCure into shares, it will provide InterCure another six months to repay the loan ("the repayment date"), provided that if any funds are received from InterCure of any source, excluding receipts from operating income, by the repayment date, InterCure will be required to repay the outstanding loan amount, or any part thereof, in installments of at least \$50,000 each.

In keeping with the negotiations held between the Company and Kitov, on March 5, 2013, the parties to the transaction decided to cease the negotiations as they failed to yield any binding agreement.

On March 21, 2013, Prof. Reuven Tzimlichman was appointed to InterCure's medical director. In the consulting agreement of Prof. Tzimlichman it was stated that he will provide InterCure consulting services in the field of research

and development, intellectual property management and medical regulation. The agreement provides the grant of 130,000 share options to Prof. Tzimlichman, exercisable into 130,000 ordinary shares at an exercise price of NIS 0.54 per share. The vesting period of the shares was set to three years when 1/12 of the options shall vest at the end of each quarter. Alternately, if as a result of the signing between InterCure and a medical institution (such as HMO) for the sale of its products through the medical institution, InterCure's products will be sold in excess of \$ 175,000, than 30% of the unvested options at that time shall vest.

After the statement of financial position date through the date of approval of the financial statements, holders of the Company's stock options (series 2) exercised 31,410 stock options (series 2) into 31,410 Ordinary shares of NIS 0.1 par value each for an average exercise increment of NIS 1.02 per stock option. The overall proceeds from the exercise of the stock options (series 2) totaled approximately \$9,000 (approximately NIS 32,000).

## ITEM 9. THE OFFER AND LISTING

### Markets and Share Price History

Since July 12, 2005 our shares have been traded on Tel Aviv Stock Exchange (TASE) under the symbol “XTL”. As of April 17, 2009, when we were delisted from Nasdaq, then our primary trading market, our dual-listing provisions ceased and since then TASE has become our primary trading market for our securities, and our ADRs are quoted on the Pink Sheets under the symbol “XTLBY.PK”. In June 1, 2012, we filed an application for the listing our ADRs on the Nasdaq Stock Exchange, subject to the Company's compliance with the required criteria, which includes, among others, a minimum bid ADR price criterion. In order to facilitate the Company's qualification for listing on The NASDAQ Capital Market, our Board of Directors approved a change in the ratio of our ADRs to ordinary shares and effective October 4, 2012, our ADRs' ratio changed from 1:2 (one ADR representing two NIS 0.1 par value ordinary shares) to 1:20 (one ADR representing twenty NIS 0.1 par value ordinary shares).

On January 27, 2009, we received a Staff Determination Letter from The Nasdaq Stock Market notifying us that the staff of Nasdaq's Listing Qualifications Department determined, using its discretionary authority under Nasdaq Marketplace Rule 4300, that our ADRs would be delisted from Nasdaq. The letter further stated that Nasdaq would suspend trading on our ADRs at the opening of trading on February 5, 2009, unless we appealed Nasdaq's delisting determination. Nasdaq's determination to delist our ADRs was due to the fact we do not meet the stockholders' equity requirement, or any of its alternatives, and that we had failed to comply with Nasdaq's listing criteria. On February 3, 2009, we appealed the determination by the Nasdaq Listing Qualification Staff to delist our ADRs from the Nasdaq Capital Market. The Nasdaq Office of the General Counsel assigned a date of March 19, 2009, for an oral hearing before the Nasdaq Hearings Panel. Nasdaq's delisting action has been stayed, pending a final written determination by the Panel following the hearing. At the hearing, we presented our opposition to Nasdaq's arguments and our business plan that among others enabled compliance with all other applicable Nasdaq listing requirements. In April 2009, we received a letter from the NASDAQ Stock Market informing us of their final decision to delist our ADRs from NASDAQ Capital Markets as of April 17, 2009, which has become final and unappealable as of July 2009.

Following the delisting in April 2009, our ADRs are quoted on the Pink Sheets under the symbol XTLBY.PK). Since September 1, 2005 until April 2009 our primary trading market was NASDAQ Capital Markets. Our ADRs have been traded on the NASDAQ Stock Market under the symbol “XTLB,” with each ADR representing ten NIS 0.02 par value ordinary shares (prior to the 1:5 share consolidation, which was resolved on March 18, 2009, and effected in June 2009).

In the past, our primary trading market was the London Stock Exchange, or LSE, where our shares were listed and traded under the symbol “XTL” since our initial public offering in September of 2000. On October 31, 2007, our ordinary shares were delisted from the LSE, pursuant to the October 2, 2007 vote at our extraordinary general meeting of shareholders.

## American Depositary Shares

The following table presents, for the periods indicated, the high and low market prices for our ADRs as reported on the NASDAQ Stock Market<sup>1</sup> since September 1, 2005 and on the Pink Sheets since April 17, 2009, the date on which our ADRs were initially quoted. For convenience of the readers of this report, the data below was adjusted so that all the quotes of our ADRs price would represent the current ADR-NIS 0.1 par value ordinary share ratio, meaning 1:20.

	US Dollar	
	High	Low
Last Six Calendar Months		
April 2013 (until April 23, 2013)	6.35	4.95
March 2013	6.90	6.35
February 2013	6.92	5.93
January 2013	7.42	5.80
December 2012	7.80	6.72
November 2012	7.00	5.66
October 2012	7.50	5.70
Financial Quarters During the Past Two Full Fiscal Years		
Second Quarter of 2013 (until April 23, 2013)	6.35	4.95
First Quarter of 2013	7.42	5.80
Fourth Quarter of 2012	7.80	5.66
Third Quarter of 2012	8.70	5.10
Second Quarter of 2012	6.90	3.80
First Quarter of 2012	7.30	2.70
Fourth Quarter of 2011	4.40	1.50
Third Quarter of 2011	4.30	2.40
Second Quarter of 2011	3.80	2.20
First Quarter of 2011	5.40	2.30
Full Five Financial Years		
2012	8.70	2.70
2011	5.40	1.50
2010	4.80	0.60
2009	3.20	0.50
2008	49.60	0.40

<sup>1</sup> Our ADRs are quoted on the Pink Sheets since April 17, 2009. Our ADRs were quoted on the NASDAQ Capital Market since December 3, 2007 until April 17, 2009 and prior to that were quoted on the NASDAQ Global Market.

The following table sets forth, for the periods indicated, the high and low sales prices of the NIS 0.1 par value ordinary shares (after the 1:5 share consolidation which was resolved on June 22, 2009) on the Tel Aviv Stock Exchange. For comparative purposes only, we have also provided such figures translated into US Dollars at an exchange rate of 3.625 New Israeli Shekel per US Dollar, as of April 23, 2013 according to the Bank of Israel.

	New Israeli Shekel		US Dollar	
	High	Low	High	Low
<b>Last Six Calendar Months</b>				
April 2013 (until April 23, 2013)	1.137	0.902	0.314	0.249
March 2013	1.294	1.121	0.357	0.309
February 2013	1.299	1.080	0.358	0.298
January 2013	1.349	1.065	0.372	0.294
December 2012	1.440	1.247	0.397	0.344
November 2012	1.359	1.105	0.375	0.305
October 2012	1.444	1.202	0.398	0.332
<b>Financial Quarters During the Past Two Full Fiscal Years</b>				
Second Quarter of 2013 (until April 23, 2013)	1.137	0.902	0.314	0.249
First Quarter of 2013	1.349	1.065	0.372	0.294
Fourth Quarter of 2012	1.444	1.105	0.398	0.305
Third Quarter of 2012	1.697	0.920	0.468	0.254
Second Quarter of 2012	1.249	0.816	0.345	0.225
First Quarter of 2012	1.260	0.503	0.348	0.139
Fourth Quarter of 2011	0.580	0.405	0.160	0.112
Third Quarter of 2011	0.780	0.480	0.215	0.132
Second Quarter of 2011	0.679	0.451	0.187	0.124
First Quarter of 2011	0.987	0.400	0.272	0.110
<b>Full Five Financial Years</b>				
2012	1.697	0.503	0.468	0.139
2011	0.987	0.400	0.272	0.110
2010	0.700	0.162	0.193	0.045
2009	1.285	0.095	0.354	0.026
2008	8.700	0.075	2.400	0.021

<sup>2</sup> On June 22, 2009 a 1:5 share consolidation was resolved. All figures prior to the effective date were adjusted accordingly.

## ITEM 10. ADDITIONAL INFORMATION

### Memorandum and Articles of Association

***Objects and Purposes of the Company***

Pursuant to Part B, Section 3 of our Articles of Association, we may undertake any lawful activity.

***Powers and Obligations of the Directors***

Pursuant to the Israeli Companies Law and our Articles of Association, a director is not permitted to vote on a proposal, arrangement or contract in which he or she has a personal interest. Also, the directors may not vote on compensation to themselves or any members of their body, as that term is defined under Israeli law, without the approval of our audit committee and our shareholders at a general meeting. The requirements for approval of certain transactions are set forth below in “Item 10. Additional Information – Memorandum and Articles of Association–Approval of Certain Transactions.” The power of our directors to enter into borrowing arrangements on our behalf is limited to the same extent as any other transaction by us.



The Israeli Companies Law codifies the fiduciary duties that office holders, including directors and executive officers, owe to a company. An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care generally requires an office holder to act with the same level of care as a reasonable office holder in the same position would employ under the same circumstances. The duty of loyalty includes avoiding any conflict of interest between the office holder's position in the company and such person's personal affairs, avoiding any competition with the company, avoiding exploiting any corporate opportunity of the company in order to receive personal advantage for such person or others, and revealing to the company any information or documents relating to the company's affairs which the office holder has received due to his or her position as an office holder.

*Indemnification of Directors and Officers; Limitations on Liability*

Israeli law permits a company to insure an office holder in respect of liabilities incurred by him or her as a result of an act or omission in the capacity of an office holder for:

- a breach of the office holder's duty of care to the company or to another person;
- a breach of the office holder's fiduciary duty to the company, provided that he or she acted in good faith and had reasonable cause to believe that the act would not prejudice the company; and
- a financial liability imposed upon the office holder in favor of another person.

Moreover, a company can indemnify an office holder for any of the following obligations or expenses incurred in connection with the acts or omissions of such person in his or her capacity as an office holder:

· monetary liability imposed upon him or her in favor of a third party by a judgment, including a settlement or an arbitral award confirmed by the court; and

· reasonable litigation expenses, including attorneys' fees, actually incurred by the office holder or imposed upon him or her by a court, in a proceeding brought against him or her by or on behalf of the company or by a third party, or in a criminal action in which he or she was acquitted, or in a criminal action which does not require criminal intent in which he or she was convicted; furthermore, a company can, with a limited exception, exculpate an office holder in advance, in whole or in part, from liability for damages sustained by a breach of duty of care to the company.

Our Articles of Association allow for insurance, exculpation and indemnification of office holders to the fullest extent permitted by law. We have entered into indemnification, insurance and exculpation agreements with our directors and

executive officers, following shareholder approval of these agreements. We have directors' and officers' liability insurance covering our officers and directors for a claim imposed upon them as a result of an action carried out while serving as an officer or director, for (a) the breach of duty of care towards us or towards another person, (b) the breach of fiduciary duty towards us, provided that the officer or director acted in good faith and had reasonable grounds to assume that the action would not harm our interests, and (c) a monetary liability imposed upon him in favor of a third party.

#### Approval of Related Party Transactions under the Israeli Companies Law

##### *Fiduciary duties of the office holders*

The Israeli Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency 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, in light of the circumstances, to obtain:

information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

All other important information pertaining to these actions.

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

refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;

refrain from any activity that is competitive with the business of the company;

refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and

disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act performed in breach of the duty of loyalty of an office holder provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest, as described below.

*Disclosure of personal interests of an office holder and approval of acts and transactions*

The Israeli Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obligated to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

The term personal interest is defined under the Israeli Companies Law to include the personal interest of a person in an action or in the business of a company, including the personal interest of such person's relative or the interest of any

corporation in which the person is an interested party, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Israeli Companies Law, an extraordinary transaction which requires approval is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

Under the Israeli Companies Law, once an office holder has complied with the disclosure requirement described above, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest, or approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder, a transaction with a third party in which the office holder has a personal interest, and an action of an office holder that would otherwise be deemed a breach of duty of loyalty requires approval by the board of directors. Our Articles of Association do not provide otherwise. If the transaction or action considered is (i) an extraordinary transaction, (ii) an action of an office holder that would otherwise be deemed a breach of duty of loyalty and may have a material impact on a company's profitability, assets or liabilities, (iii) an undertaking to indemnify or insure an office holder who is not a director, or (iv) for matters considered an undertaking concerning the terms of compensation of an office holder who is not a director, including, an undertaking to indemnify or insure such office holder, then approval by the audit committee is required prior to approval by the board of directors. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the audit committee, board of directors and shareholders, in that order.

A director who has a personal interest in a matter that is considered at a meeting of the board of directors or the audit committee may generally not be present at the meeting or vote on the matter, unless a majority of the directors or members of the audit committee have a personal interest in the matter or the chairman of the audit committee or board of directors, as applicable, determines that he or she should be present to present the transaction that is subject to approval. If a majority of the directors have a personal interest in the matter, such matter would also require approval of the shareholders of the company.

*Disclosure of personal interests of a controlling shareholder and approval of transactions*

Under the Israeli Companies Law and a recent amendment thereto, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See "Audit Committee" for a definition of controlling shareholder. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, and transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the audit committee, the board of directors and a majority of the shares voted by the shareholders of the company participating and voting on the matter in a shareholders' meeting. In addition, such shareholder approval must fulfill one of the following requirements:

at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

*Duties of shareholders*

Under the Israeli Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, voting at general meetings of shareholders on the following matters:

· an amendment to the articles of association;

· an increase in the company's authorized share capital;

· a merger;

· an increase in the company's authorized share capital; and

· the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above mentioned duties, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The Israeli Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

***Rights Attached to Ordinary Shares***

Through March 18, 2009, our authorized share capital was NIS 10,000,000 consisting of 500,000,000 ordinary shares, par value NIS 0.02 per share. On March 18, 2009, pursuant to a shareholder's meeting, the share capital of our company was consolidated and re-divided so that each five (5) shares of NIS 0.02 nominal value was consolidated into one (1) share of NIS 0.1 nominal value so that following such consolidation and re-division, our authorized share capital consisted of 100,000,000 ordinary shares, par value NIS 0.10 per share. In addition, the authorized share capital of our company was increased from NIS 10,000,000 to NIS 70,000,000 divided into 700,000,000 ordinary shares, NIS 0.10 nominal value. The share consolidation was effected in June 22, 2009.

Holders of ordinary shares have one vote per share, and are entitled to participate equally in the payment of dividends and share distributions and, in the event of our liquidation, in the distribution of assets after satisfaction of liabilities to creditors. No preferred shares are currently authorized. All outstanding ordinary shares are validly issued and fully paid.

### *Transfer of Shares*

Fully paid ordinary shares are issued in registered form and may be freely transferred under our Articles of Association unless the transfer is restricted or prohibited by another instrument or applicable securities laws.



### ***Dividend and Liquidation Rights***

We may declare a dividend to be paid to the holders of ordinary shares according to their rights and interests in our profits. In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the nominal value of their holdings.

This right may be affected by the grant of preferential dividend or distribution rights, to the holders of a class of shares with preferential rights that may be authorized in the future. Under the Israeli Companies Law, the declaration of a dividend does not require the approval of the shareholders of the company, unless the company's articles of association require otherwise. Our Articles provide that the Board of Directors may declare and distribute dividends without the approval of the shareholders.

### ***Annual and Extraordinary General Meetings***

We must hold our annual general meeting of shareholders each year no later than 15 months from the last annual meeting, at a time and place determined by the Board of Directors, upon at least 21 days' prior notice to our shareholders to which we need to add additional three days for notices sent outside of Israel. A special meeting may be convened by request of two directors, 25% of the directors then in office, one or more shareholders holding at least 5% of our issued share capital and at least 1% of our issued voting rights, or one or more shareholders holding at least 5% of our issued voting rights. Notice of a general meeting must set forth the date, time and place of the meeting. Such notice must be given at least 21 days but not more than 45 days prior to the general meeting. The quorum required for a meeting of shareholders consists of at least two shareholders present in person or by proxy who holds or represent between them at least one-third of the voting rights in 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 (with no need for any notice to the shareholders) or until such other later time if such time is specified in the original notice convening the general meeting, or if we serve notice to the shareholders no less than seven days before the date fixed for the adjourned meeting. If at an adjourned meeting there is no quorum present half an hour after the time set for the meeting, any number participating in the meeting shall represent a quorum and shall be entitled to discuss the matters set down on the agenda for the original meeting. All shareholders who are registered in our registrar on the record date, or who will provide us with proof of ownership on that date as applicable to the relevant registered shareholder, are entitled to participate in a general meeting and may vote as described in "Voting Rights" and "Voting by Proxy and in Other Manners," below.

### ***Voting Rights***

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of ordinary shares that represent more than 50% of the voting power represented at a shareholders meeting in which a quorum is present have the power to elect all of our directors, except the external directors whose election requires a special majority as described under the section entitled “Item 6. Directors, Senior Management and Employees – Board Practices – External and Independent Directors.”

Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Shareholders may vote in person or by proxy. 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.

Under the Israeli Companies Law, unless otherwise provided in the Articles of Association or by applicable law, all resolutions of the shareholders require a simple majority. Our Articles of Association provide that all decisions may be made by a simple majority. See “–Approval of Certain Transactions” above for certain duties of shareholders towards the company.

### ***Voting by Proxy and in Other Manners***

Our Articles of Association enable a shareholder to appoint a proxy, who need not be a shareholder, to vote at any shareholders meeting. We require that the appointment of a proxy be in writing signed by the person making the appointment or by an attorney authorized for this purpose, and if the person making the appointment is a corporation, by a person or persons authorized to bind the corporation. In the document appointing a proxy, each shareholder may specify how the proxy should vote on any matter presented at a shareholders meeting. The document appointing the proxy shall be deposited in our offices or at such other address as shall be specified in the notice of the meeting not less than 48 hours before the time of the meeting at which the person specified in the appointment is due to vote.

The Israeli Companies Law and our Articles of Association do not permit resolutions of the shareholders to be adopted by way of written consent, for as long as our ordinary shares are publicly traded.

### ***Limitations on the Rights to Own Securities***

The ownership or voting of ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of the State of Israel, except that nationals of countries which are, or have been, in a state of war with Israel may not be recognized as owners of ordinary shares.

### ***Anti-Takeover Provisions under Israeli Law***

The Israeli Companies Law permits merger transactions with the approval of each party's board of directors and shareholders. In accordance with the Israeli Companies Law, a merger may be approved at a shareholders meeting by a majority of the voting power represented at the meeting, in person or by proxy, and voting on that resolution. In determining whether the required majority has approved the merger, shares held by the other party to the merger, any person holding at least 25% of the outstanding voting shares or means of appointing the board of directors of the other party to the merger, or the relatives or companies controlled by these persons, are excluded from the vote.

Under the Israeli Companies Law, a merging company must inform its creditors of the proposed merger. Any creditor of a party to the merger may seek a court order blocking the merger, if there is a reasonable concern that the surviving company will not be able to satisfy all of the obligations of the parties to the merger. Moreover, a merger may not be completed until at least 30 days have passed from the time the merger was approved in a general meeting of each of the merging companies, and at least 50 days have passed from the time that a merger proposal was filed with the Israeli Registrar of Companies.

Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of such acquisition, the purchaser would become a 25% or greater shareholder of the company. This rule does not apply if there is already another shareholder with 25% or greater shares in the company. Similarly, Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of the acquisition, the purchaser's shareholdings would entitle the purchaser to over 45% of the shares in the company, unless there is a shareholder with 45% or more of the shares in the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received the approval of the company's shareholders; (2) was from a 25% or greater shareholder of the company which resulted in the purchaser becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. These rules do not apply if the acquisition is made by way of a merger. Regulations promulgated under the Israeli Companies Law provide that these tender offer requirements do not apply to companies whose shares are listed for trading external of Israel if, according to the law in the country in which the shares are traded, including the rules and regulations of the stock exchange or which the shares are traded, either:

- there is a limitation on acquisition of any level of control of the company; or
- the acquisition of any level of control requires the purchaser to do so by means of a tender offer to the public.

The Israeli Companies Law provides specific rules and procedures for the acquisition of shares held by minority shareholders, if the majority shareholder holds more than 90% of the outstanding shares. If, as a result of an acquisition of shares, the purchaser will hold more than 90% of a company's outstanding shares, the acquisition must be made by means of a tender offer for all of the outstanding shares. If less than 5% of the outstanding shares are not tendered in the tender offer, all the shares that the purchaser offered to purchase will be transferred to it. The Israeli Companies Law provides for appraisal rights if any shareholder files a request in court within three months following the consummation of a full tender offer. If more than 5% of the outstanding shares are not tendered in the tender offer, then the purchaser may not acquire shares in the tender offer that will cause his shareholding to exceed 90% of the outstanding shares of the company. Israeli tax law treats specified acquisitions, including a stock-for-stock swap between an Israeli company and a foreign company, less favorably than does US tax law. These laws may have the effect of delaying or deterring a change in control of us, thereby limiting the opportunity for shareholders to receive a premium for their shares and possibly affecting the price that some investors are willing to pay for our securities.

### ***Rights of Shareholders***

Under the Israeli Companies Law, our shareholders have the right to inspect certain documents and registers including the minutes of general meetings, the register of shareholders and the register of substantial shareholders, any document held by us that relates to an act or transaction requiring the consent of the general meeting as stated above under “-Approval of Certain Transactions,” our Articles of Association and our financial statements, and any other document which we are required to file under the Israeli Companies Law or under any law with the Registrar of Companies or the Israeli Securities Authority, and is available for public inspection at the Registrar of Companies or the Securities Authority, as the case may be.

If the document required for inspection by one of our shareholders relates to an act or transaction requiring the consent of the general meeting as stated above, we may refuse the request of the shareholder if in our opinion the request was not made in good faith, the documents requested contain a commercial secret or a patent, or disclosure of the documents could prejudice our good in some other way.

The Israeli Companies Law provides that with the approval of the court any of our shareholders or directors may file a derivative action on our behalf if the court finds the action is a priori, to our benefit, and the person demanding the action is acting in good faith. The demand to take action can be filed with the court only after it is serviced to us, and we decline or omit to act in accordance to this demand.

### ***Enforceability of Civil Liabilities***

We are incorporated in Israel and most of our directors and officers and the Israeli experts named in this report reside outside the US. Service of process upon them may be difficult to effect within the US. Furthermore, because substantially all of our assets, and those of our non-US directors and officers and the Israeli experts named herein, are located outside the US, any judgment obtained in the US against us or any of these persons may not be collectible within the US.

We have been informed by our legal counsel in Israel, Kantor & Co., that there is doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act, pursuant to original actions instituted in Israel. However, subject to particular time limitations, executory judgments of a US court for monetary damages in civil matters may be enforced by an Israeli court, provided that:

the judgment was obtained after due process before a court of competent jurisdiction, that recognizes and enforces similar judgments of Israeli courts, and the court had authority according to the rules of private international law currently prevailing in Israel;

- adequate service of process was effected and the defendant had a reasonable opportunity to be heard;

the judgment is not contrary to the law, public policy, security or sovereignty of the State of Israel and its enforcement is not contrary to the laws governing enforcement of judgments;

the judgment was not obtained by fraud and does not conflict with any other valid judgment in the same matter between the same parties;

the judgment is no longer appealable; and

an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court.

We have irrevocably appointed XTL Biopharmaceuticals, Inc., our US subsidiary, as our agent to receive service of process in any action against us in any US federal court or the courts of the State of New York.

Foreign judgments enforced by Israeli courts generally will be payable in Israeli currency. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to render judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment. Under existing Israeli law, a foreign judgment payable in foreign currency may be paid in Israeli currency at the rate of exchange for the foreign currency published on the day before date of payment. Current Israeli exchange control regulations also permit a judgment debtor to make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily may be linked to Israel's consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at that time. Judgment creditors must bear the risk of unfavorable exchange rates.

## **Material Contracts**

### ***VivoQuest Inc.***

In August 2005, we entered into an asset purchase agreement with VivoQuest, a privately held biotechnology company based in the US, pursuant to which we agreed to purchase from VivoQuest certain assets, including VivoQuest's laboratory equipment, and to assume VivoQuest's lease of its laboratory space. In consideration, we paid \$450,000 to VivoQuest, which payment was satisfied by the issuance of ordinary shares having a fair market value in the same amount as of the closing date. The asset purchase was completed in September 2005. In addition, we entered into a license agreement with VivoQuest pursuant to which we acquired exclusive worldwide, perpetual, irrevocable and non-terminable rights to VivoQuest's patents, intellectual property and technology. The license covers a proprietary compound library, including VivoQuest's lead HCV compounds, that was developed through the use of

Diversity Oriented Synthesis, or DOS, technology. The terms of the license agreement include an initial upfront license fee of approximately \$941,000 that was paid in our ordinary shares. The license agreement also provides for additional milestone payments triggered by certain regulatory and sales targets. The milestone payments amount to an aggregate of \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our election. In addition, the license agreement requires that we make royalty payments in the range of 2% to 8%, depending on net product sales. Commercialization of the DOS program has been out-licensed to Presidio Pharmaceuticals, Inc. (see “Presidio Pharmaceuticals, Inc.” below).



***Presidio Pharmaceuticals, Inc.***

In March 2008, and as revised August 2008, we signed an agreement to out-license the DOS program to Presidio Pharmaceuticals, Inc., or Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio was granted a license for patent rights and technology relating to the DOS program, and became responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a \$5.94 million, non-refundable, upfront payment in cash from Presidio and we were eligible to receive up to an additional aggregate amount of \$59 million upon reaching certain development and commercialization milestones. In addition, we were eligible to receive a royalty payment in the range of 1% to 10% on direct product sales by Presidio, and a percentage of Presidio's income if the DOS program was sublicensed by Presidio to a third party. Presidio was responsible for all further development and commercialization activities relating to the DOS program. On August 22, 2012, Presidio requested to terminate its engagement with the Company effective as of August 24, 2012. Following a notice of the termination of the agreement, Presidio's entire DOS technology (including all the patents maintained by Presidio) was reverted back to the Company after 90 days from the date of said notice in accordance with the provisions of the agreement.

***Bio-Gal Ltd.***

On March 18, 2009, we announced that we had entered into an asset purchase agreement with Bio-Gal Ltd. ("Bio-Gal"), a Gibraltar private company, for the rights to a use patent on Recombinant Erythropoietin ("rHuEPO") for the prolongation of multiple myeloma patients' survival and improvement of their quality of life. On December 31, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL could acquire XTEPO Ltd., a special purpose company that was established by Bio-Gal's shareholders who received from Bio-Gal all of Bio-Gal's rights on rHuEPO and raised approximately \$1.5 million. We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. In accordance with the terms of the amended asset purchase agreement, we issued to XTEPO's shareholders ordinary shares representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful completion of Phase 2. Such payment of \$350,000 mentioned above shall be made to Yeda Research and Development Company Ltd. ("Yeda") upon the earlier of (i) six months from the Successful Completion of Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO at any time after the completion of the Phase 2 of an amount of minimum \$2 million. On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the prerequisites had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to article 104 and 103 to the Israeli tax ordinance (Revised), 1961. (See note 14c to the consolidated financial statements: Intangible Asset).



***MinoGuard Ltd.***

On March 24, 2011, the Company entered into a term sheet to acquire the assets of MinoGuard by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without any other payments. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia. The transaction was subject, among others, to completion of due diligence studies, examination of the regulatory track for the continued development of the drug and the approval of the Company's Board. On November 30, 2011, the agreement with MinoGuard was completed after all prerequisites abovementioned had fully met. In accordance with the terms of the license agreement we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of its net sales and/or percentage from the Company third-party out-license receipts in the range of 7.5%-20% according to the clinical phase of the drug at the time of an out-license transaction. It should be noted that the Company has the sole discretion to pay any of the above amounts in cash or by way of issuing of its shares to MinoGuard. In addition to the above payments, if we shall not commence a phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of \$45,000 for the initial year, which will increase by \$90,000 per year and up to \$675,000 for the eighth year of license. The agreement states that receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter.

The term of the license commenced upon the signing of the license agreement and be effective for unlimited time. Upon the expiration of the last payment obligation of XTL the license will be considered perpetual and fully paid up.

The license may be terminated in by either XTL without cause upon 30 days notice, or by the licensor for no commercial progress in the event that by the date of June 30th, 2013 neither commencement of phase II Clinical Trial with respect to the licensed product has occurred, nor XTL has entered into a Sublicense Agreement with a substantial third party.

***InterCure Ltd.***

On June 13, 2012, we entered into an agreement with InterCure according to which, subject to carrying out the Debt Settlement before the transaction, InterCure will convert all of its debts into Ordinary shares of InterCure based on the distribution mechanism determined with all of its debtors (including its employees). The Company will acquire control over InterCure in consideration for investing in InterCure an aggregate amount of approximately \$ 2.7 million, subject to adjustments, as detailed below. Also, in addition to the Company's investment in InterCure, Medica Fund will invest approximately \$ 630,000 in InterCure (subject to adjustments).

InterCure is a public company whose shares are traded on the TASE and which develops a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension.

The transaction was consummated on July 25, 2012. The Company acquired 16,839,532 Ordinary shares of InterCure with no par value in consideration of a private placement of 7,165,662 Ordinary shares of the Company of NIS 0.1 par value each whose value on the date of signing the agreement, measured based on the quoted market price of the Company's shares on the TASE, approximated \$2.2 million (the market value of such shares on the InterCure Closing date was approximately \$2.47 million), which represented a pre-money valuation of InterCure of \$1.75 million, after all of InterCure's debts were converted as described above ("InterCure's adjusted value").

In addition, the Company provided InterCure an amount of approximately \$150,000 in cash on the basis of InterCure's adjusted value. After effecting the above allocation, the Company held about 50.79% of the issued and outstanding share capital of InterCure. The investment of Medica Fund on the date of closing on the basis of InterCure's adjusted value amounted to approximately \$ 460,000.

Further, the Company and Medica Fund provided InterCure a loan of \$ 500,000 (the Company's share is \$ 330,000) for a period of up to ten months at an overall interest rate of 15%. The Company and Medica Fund have the right to convert the loan into an additional 11,546,507 shares of InterCure (the Company's share is 7,620,695 shares) which will constitute, upon conversion and assuming full dilution on the date of closing, approximately 24.47% of the issued and outstanding share capital of InterCure (the Company's share in the convertible loan is 16.15% of the issued and outstanding share capital of InterCure). On August 6, 2012, Medica Fund converted the loan it provided InterCure into shares and its stake in InterCure rose to approximately 23.69% of the issued and outstanding share capital of InterCure (about 18.61% on a fully diluted basis, as of the date of the loan's conversion). On March 3, 2013, the Company notified InterCure that if the Company decides not to convert the loan granted to InterCure into shares, it will provide InterCure another six months to repay the loan ("the repayment date"), provided that if any funds are received from InterCure from any source, excluding receipts from operating income, by the repayment date, InterCure will be required to repay the outstanding loan amount, or any part thereof, in installments of at least \$ 50,000 each.

As of the date of the approval of the financial statements, our stake in InterCure is approximately 45.41% of the issued and outstanding share capital of InterCure. However, if we convert the loan extended to InterCure into shares, our stake in InterCure will be approximately 54.72%. Assuming that all of the options granted to employees and directors in InterCure are exercised, and assuming the above loan is converted, our stake in InterCure will be approximately 52.63%.

In October 2012, InterCure granted 20,185,184 performance contingent options (exercisable into 20,185,184 Ordinary shares with no par value) to Giboov (see details below). If all of the performance contingent options granted to Giboov are exercised, and assuming the conversion of said loan and the exercise of the entire options granted to directors and employees, our stake in InterCure will be approximately 36.69% of the issued and outstanding share capital of InterCure.

***Agreement with Giboov Ltd., a Provider of Online Marketing and Sales Services***

On September 24, 2012, InterCure announced the signing of a three-year non-exclusive strategic service agreement with Giboov, a private company wholly-owned by Messrs. Shay Ben-Yitzhak and Avner Yassur, for the provision of online marketing and sales services of InterCure's products.

According to the strategic agreement, which is territorially unlimited, Giboov will provide InterCure online sales services in return for a monthly fee of \$ 40,000 plus VAT in return for the services ("the consideration") whereby in the first four months of the strategic agreement period, no consideration will be paid and will later be paid provided that revenues are derived from online sales in an amount of at least \$50,000. In addition, InterCure will provide monthly online advertising budgets for the online sale activity performed by Giboov, which will not be less than \$130,000, and all under the mechanism as described in the agreement.

In the context of the strategic agreement, Giboov will be allocated up to 20,185,184 unlisted stock options that are exercisable into shares of InterCure for an exercise price (dividend adjusted) of NIS 0.54 per stock option which will vest according to Giboov's compliance with annual sales targets. In the context of the strategic agreement, Giboov's shareholders were given a put option to sell to InterCure Giboov's entire share capital for a period of 18 months from the effective date of the strategic agreement. On the date of signing the strategic agreement, InterCure was granted a call option to purchase Giboov's entire share capital for a period of one year from the effective date of the strategic agreement. The agreement's allocation items were approved by the general meeting of InterCure's shareholders on October 28, 2012. InterCure will be able to cancel the agreement if Giboov fails to meet the sales targets prescribed in the strategic agreement effective from March 2014 or in the event of material breach of the agreement, fraud, damage etc. For further details regarding the agreement with Giboov, see note 18(a) to the consolidated financial statements.

***Manufacturing agreement with a subcontractor***

As of the date of this report, the Chinese manufacturer of the device is the exclusive supplier of the Ultra versions. The Chinese manufacturer is a company registered in Hong Kong which holds manufacturing plants in Shenzhen, China. According to the turnkey manufacturing agreement, the entire manufacturing process is performed by the Chinese manufacturer, including the purchase of raw materials and components from suppliers, and the supply of a finished product to InterCure. The Chinese manufacturer is restricted to entering into engagements with suppliers approved by InterCure only and is in charge of supervising the quality of the raw materials and components supplied by it in accordance with InterCure's specifications. The Chinese manufacturer manufactures according to order forecasts delivered by InterCure from time to time and is committed to provide InterCure reasonable advance notice if any shortage of raw materials and/or components is expected in the market or in a specific supplier. The timeframe in which the Chinese manufacturer can respond to increased device demands and increased manufacturing is derived from the rate of the change in demand.

***License agreement and line of credit***

On October 6, 2011, InterCure's audit committee and Board approved an agreement for the receipt of a line of credit from Yazmonit Ltd. (a company controlled by Dr. Benjamin Gavish, a director and interested party in InterCure at the time, "the LC agreement" and "Yazmonit", respectively) as a qualifying transaction for InterCure owing to InterCure's credit crisis and low inventory levels and as a means of allowing InterCure's continued operating activities. According to the LC agreement, Yazmonit extended a third party which is InterCure's product manufacturer a credit line in a total of approximately US\$ 72 thousand for a period of 40 days ("the LC term"). At the end of the LC term, InterCure shall pay the third party an amount of \$ 72,120 or provide it an alternative credit line. As collateral in favor of Yazmonit and should the third party exercise all or part of the credit line, then the products (or part thereof, based on the payment made by InterCure) will be delivered from the third party to the exclusive ownership of Yazmonit and the latter will be able to sell them.

According to the LC agreement, extending the LC term by up to 90 days requires the approval of InterCure's license agreement with Yazmonit ("the license agreement") whereby, subject to obtaining the Israeli Chief Scientist's approval (if indeed required), InterCure will provide Yazmonit an exclusive license to use the technology and patent rights of an unutilized portion of its IP ("the license") and the right to use InterCure's RESPeRATE trademark for an indefinite period in consideration of an overall amount of US\$ 25,000. The license includes any future product and applications that require an external computer unit (and a smartphone) and are not in the field of treating hypertension. According to the license agreement, the license will not include products and/or applications for treating hypertension in any form whatsoever nor will it include any stand-alone product in any field of future indication developed by InterCure. In addition, according to the license agreement, if Yazmonit needs components manufactured by or for InterCure, InterCure will sell them to Yazmonit at cost + 5%. According to the LC agreement, InterCure was able to repurchase the license from Yazmonit for a sum of US\$ 75,000 over a four-month period from the effective date of the agreement (which has elapsed as of the date of this report).

On October 25, 2011, the meeting of holders of debentures (series A) of InterCure decided not to object to InterCure's engagement in the license agreement. On November 7, 2011, InterCure announced that it had obtained the approval of the holders of debentures (series B) of InterCure for the license agreement. On the same date, InterCure's audit committee and Board approved its engagement in the license agreement. To the best of the Company's knowledge, on October 12, 2011, Yazmonit opened the line of credit discussed above and on November 13, 2011 it delivered the consideration for the license agreement. The LC agreement was extended twice (to May 30, 2012 and December 31, 2012) under the same terms.

On January 21, 2013, InterCure announced that it was examining several issues regarding the license agreement, including its legal validity.

### *Proteologics*

On November 21, 2012, in an off-market transaction, we purchased from Teva 4,620,356 Ordinary shares of NIS 1.0 par value each of Proteologics, representing Teva's entire stake in Proteologics and approximately 31.35% of Proteologics' issued and outstanding share capital, in consideration of approximately NIS 6.5 million (approximately \$ 1.7 million), which were paid in cash. Proteologics is a public company whose shares are listed on the TASE and is engaged in the discovery and development of drugs comprised of various components of the UBIQUITIN system, which was discovered by Dr. Avram Hershko and Dr. Aaron Ciechanover, both 2004 Nobel Prize laureates in Chemistry for the discovery of the UBIQUITIN system.

***Clalit Health Services - Clalit Research Institute Ltd. Collaboration framework agreement***

On March 14, 2012, we signed a strategic collaboration framework agreement with Clalit Health Services - Clalit Research Institute Ltd. ("the Institute") and Mor Research Applications Ltd. according to which the Institute provides the Company with the right to receive contents which are based on the Institute's database in connection with technologies that stem from inventions and patents of Clalit Health Services' physicians, in projects whose content shall be agreed upon by us, the Institute and Mor in advance and in writing. In consideration for the above, we shall pay the Institute the cost basis related to the Institute's activity in the framework of any project plus an additional 10% of the total royalties Mor is entitled pursuant to its agreements with the Company in connection with each technology where rights were granted to the Company. This agreement may be terminated by giving a written and advance notice of 180 days by any of the parties on condition that all joint active projects have reached their end.

***Bicifadine License***

In November 2008, we announced that the Phase 2b clinical trial failed to meet its primary and secondary endpoints, and as a result we ceased development of Bicifadine for diabetic neuropathic pain in 2008. In January 2007, XTL Development had signed an agreement with DOV to in-license the worldwide rights for Bicifadine. XTL Development was developing Bicifadine for the treatment of diabetic neuropathic pain. In accordance with the terms of the license agreement, XTL Development paid an initial up-front license fee of \$7.5 million in cash in 2007. In addition, XTL Development would have been required to make milestone payments of up to \$126.5 million over the life of the license. These milestone payments would have been made in either cash and/or our ordinary shares, at our election, with the exception of \$5 million in cash, due upon or after regulatory approval of the product. XTL Development was also obligated to pay royalties to DOV on net sales of Bicifadine. Following our announcement of the failure of the phase 2b clinical trial, we ceased development of Bicifadine for diabetic neuropathic pain in 2008 and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, both XTL Development and DOV ceased the prosecution and maintenance of those patents relating to Bicifadine. In March 2010, the agreement was formally terminated.

In addition, XTL Development was committed to pay a transaction advisory fee to certain third party intermediaries in connection with the in-license of Bicifadine from DOV. Once the Bicifadine license agreement was terminated, the commitment to pay a further transaction advisory fee ceased. In March 2010, we formally terminated the license agreement and therefore all unvested SARs have automatically expired. See "Item 5 – Operating and Financial Review and Prospects – Obligations and Commitments."

**Exchange Controls**



Under Israeli Law, Israeli non-residents who purchase ordinary shares with certain non-Israeli currencies (including dollars) may freely repatriate in such non-Israeli currencies all amounts received in Israeli currency in respect of the ordinary shares, whether as a dividend, as a liquidating distribution, or as proceeds from any sale in Israel of the ordinary shares, provided in each case that any applicable Israeli income tax is paid or withheld on such amounts. The conversion into the non-Israeli currency must be made at the rate of exchange prevailing at the time of conversion.

## **Taxation**

On August 3, 2010 we issued XTEPO's shareholders ordinary shares representing approximately 69.44% of our then issued and outstanding ordinary share capital as part of the Bio-Gal transaction (see also Israeli Tax Considerations below). As a result of the shifts of ownership, the Company's US carry back losses are subject to significant certain limitations and/or reductions. See "Item 3- Key Information – Risk Related to our Financial Condition."

The following discussion of Israeli and US tax consequences material to our shareholders is not intended and should not be construed as legal or professional tax advice and does not exhaust all possible tax considerations. To the extent that the discussion is based on new tax legislation, which has not been subject to judicial or administrative interpretation, the views expressed in the discussion might not be accepted by the tax authorities in question. This summary does not purport to be a complete analysis of all potential tax consequences of owning ordinary shares or ADRs. In particular, this discussion does not take into account the specific circumstances of any particular shareholder (such as tax-exempt entities, certain financial companies, broker-dealers, shareholders subject to Alternative Minimum Tax, shareholders that actually or constructively own 10% or more of our voting securities, shareholders that hold ordinary shares or ADRs as part of straddle or hedging or conversion transaction, traders in securities that elect mark to market, banks and other financial institutions or shareholders whose functional currency is not the US dollar), some of which may be subject to special rules.

*We urge shareholders to consult their own tax advisors as to the US, Israeli, or other tax consequences of the purchase, ownership and disposition of ordinary shares and ADRs, including, in particular, the effect of any foreign, state or local taxes. For purposes of the entire Taxation discussion, we refer to ordinary shares and ADRs collectively as ordinary shares.*

### ***Israeli Tax Considerations***

The following discussion refers to the current tax law applicable to companies in Israel, with special reference to its effect on us. This discussion also includes specified Israeli tax consequences to holders of our ordinary shares and Israeli Government programs benefiting us.

### **Corporate Tax Rate**

The income of the Company is subject to corporate tax at the regular rate; the guidance of the amendment to the Income Tax Ordinance, 2005 from August 2008 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2008 are as follows: 2008 - 27%, 2009 - 26% and 2010 and thereafter - 25%.

On July 14, 2009, the “Knesset” (Israeli Parliament) passed the Law for Economic Efficiency (Amended Legislation for Implementing the Economic Plan for 2009 and 2010), 2009, which prescribes, among others, an additional gradual reduction in the corporate tax rates starting 2011 to the following tax rates: 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 - 20%, 2016 and thereafter - 18%.

In December 2011, following the enactment of the Law for the Changing the Tax Burden (Legislative Amendments), 2011 (hereafter - "Tax Burden Distribution Law"), the phased reduction in the corporate tax was eliminated, and corporate tax rate in 2012 and thereafter was set to 25%.

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

Israeli tax law allows, under specific conditions, a tax deduction in the year incurred for expenditures, including capital expenditures, relating to scientific research and development projects, if the expenditures are approved by the relevant Israeli government ministry, determined by the field of research, and the research and development is for the promotion of the company and is carried out by or on behalf of the company seeking the deduction. Expenditures not so approved are deductible over a three-year period. In the past, expenditures that were made out of proceeds made available to us through government grants were automatically deducted during a one year period.

### **Israeli Estate and Gift Taxes**

Generally, Israel does not currently impose taxes on inheritance or bona fide gifts. For transfer of assets by inheritance or gift that would normally be subject to capital gains tax or land appreciation tax, the recipient's tax cost basis and date of purchase are generally deemed to be the same as those for the transferor of the property.

**Capital Gains Tax on Sale of our Ordinary Shares by Both Residents and Non-Residents of Israel**

Israeli law generally imposes a capital gains tax on the sale of capital assets located in Israel, including shares in Israeli resident companies, by both residents and non-residents of Israel, unless a specific exemption is available or unless a treaty between Israel and the country of the non-resident provides otherwise. The law distinguishes between the inflationary surplus and the real gain. The inflationary surplus is the portion of the total capital gain, which is equivalent to the increase of the relevant asset's purchase price attributable to the increase in the Israeli consumer price index from the date of purchase to the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus. A non resident that invests in taxable assets with foreign currency may elect to calculate the inflationary amount by using such foreign currency.

Non-Israeli residents will be exempt from Israeli capital gains tax on any gains derived from the sale of shares publicly traded on a stock exchange recognized by the Israeli Ministry of Finance (including the Tel-Aviv Stock Exchange and NASDAQ), provided such shareholders did not acquire their shares prior to an initial public offering and that such capital gains are not derived by a permanent establishment of the foreign resident in Israel. Notwithstanding the foregoing, dealers in securities in Israel are taxed at the regular tax rates applicable to business income. However, Non-Israeli corporations will not be entitled to such exemption if an Israeli resident (1) has a controlling interest of 25% or more in such non-Israeli corporation, or (2) is the beneficiary of, or is entitled to, 25% or more of the revenue or profits of such non-Israeli corporation, whether directly or indirectly. In any event, the provisions of the tax reform shall not affect the exemption from capital gains tax for gains accrued before January 1, 2003, as described in the previous paragraph.

The capital gains tax imposed on Israeli tax resident individuals on the sale of securities was 20%. With respect to an Israeli tax resident individual who is a "substantial shareholder" on the date of sale of the securities or at any time during the 12 months preceding such sale, the capital gains tax rate was increased to 25%. In December 2011, following the enactment of the Tax Burden Distribution Law, the tax rates mentioned above were increased to 25% and 30%, respectively, from 2012 and thereafter. A "substantial shareholder" is defined as someone who alone, or together with another person, holds, directly or indirectly, at least 10% in one or all of any of the means of control in the corporation. With respect to Israeli tax resident corporate investors, capital gains tax at the regular corporate rate will be imposed on such taxpayers on the sale of traded shares.

In addition, pursuant to the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended (the "United States- Israel Tax Treaty"), the sale, exchange or disposition of ordinary shares by a person who qualifies as a resident of the US within the meaning of the United States-Israel Tax Treaty and who is entitled to claim the benefits afforded to such person by the United States-Israel Tax Treaty (a "Treaty United States Resident") generally will not be subject to the Israeli capital gains tax unless such "Treaty United States Resident" holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the twelve- month period preceding such sale, exchange or disposition, subject to certain conditions or if the capital gains from such sale are considered as business income attributable to a permanent establishment of the US resident in Israel. However, under the United States-Israel Tax Treaty, such "Treaty United States Resident"

would be permitted to claim a credit for such taxes against the US federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations in US laws applicable to foreign tax credits.

**Taxation of Dividends**

Non-residents of Israel are subject to income tax on income accrued or derived from sources in Israel.

The tax rate imposed on dividends distributed by an Israeli company to Israeli tax resident individuals or to non-Israeli residents was set at a rate of 20%. With respect to “substantial shareholders,” as defined above, the applicable tax rate was 25%. In December 2011, following the enactment of the Tax Burden Distribution Law, the tax rates mentioned above were increased to 25% and 30%, respectively, from 2012 and thereafter. The taxation of dividends distributed by an Israeli company to another Israeli corporate tax resident is generally exempt from tax.

In any case, dividends distributed from the taxable income attributable to an Approved Enterprise, to both Israeli tax residents and non-Israeli residents remains subject to a 15% tax rate.

Notwithstanding, dividends distributed by an Israeli company to Israeli tax resident individuals or to non-Israeli residents was subject to a 20% withholding tax, which was increased to 25% from 2012 and thereafter, following the enactment of the Tax Burden Distribution Law (15% in the case of dividends distributed from the taxable income attributable to an Approved Enterprise), unless a lower rate is provided in a treaty between Israel and the shareholder’s country of residence. Dividends distributed by an Israeli company to another Israeli tax resident company are generally exempt, unless such dividends are distributed from taxable income attributable to an Approved Enterprise, in which case such dividends are taxed at a rate of 15%, or unless such dividends are distributed from income that was not sourced in Israel, in which case such dividends are taxed at a rate of 25%.

Under the US-Israel Tax Treaty, the maximum Israeli tax and withholding tax on dividends paid to a holder of ordinary shares who is a resident of the US is generally 25%, but is reduced to 12.5% if the dividends are paid to a corporation that holds in excess of 10% of the voting rights of company during the company’s taxable year preceding the distribution of the Dividend and the portion of the company’s taxable year in which the dividend was distributed. Dividends of an Israeli company derived from the income of an Approved Enterprise will still be subject to a 15% dividend withholding tax; if the dividend is attributable partly to income derived from an Approved Enterprise, and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. A non-resident of Israel who has dividend income derived from or accrued in Israel, from which tax was withheld at the source, is generally exempt from the duty to file tax returns in Israel in respect of such income, provided such income was not derived from a business conducted in Israel by the taxpayer.

### ***US Federal Income Tax Considerations***

The following discusses the material US federal income tax consequences to a holder of our ordinary shares, who qualifies as a US holder, which is defined as:

a citizen or resident of the US;

- a corporation created or organized under the laws of the US, the District of Columbia, or any state; or
- a trust or estate, treated, for US federal income tax purposes, as a domestic trust or estate.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, which we refer to as the Code, current and proposed Treasury regulations promulgated under the Code, and administrative and judicial decisions as of the date of this report, all of which are subject to change, possibly on a retroactive basis. This discussion does not address any aspect of state, local or non-US tax laws. Except where noted, this discussion addresses only those holders who hold our shares as capital assets. This discussion does not purport to be a comprehensive description of all of the tax considerations that may be relevant to US holders entitled to special treatment under US federal income tax laws, for example, financial institutions, insurance companies, tax-exempt organizations and broker/dealers, and it does not address all aspects of US federal income taxation that may be relevant to any particular shareholder based on the shareholder's individual circumstances. In particular, this discussion does not address the potential application of the alternative minimum tax, or the special US federal income tax rules applicable in special circumstances, including to US holders who:

- have elected mark-to-market accounting;

- hold our ordinary shares as part of a straddle, hedge or conversion transaction with other investments;
  - own directly, indirectly or by attribution at least 10% of our voting power;
    - are tax exempt entities;
- are persons who acquire shares in connection with employment or other performance of services; and
  - have a functional currency that is not the US dollar.

Additionally, this discussion does not consider the tax treatment of partnerships or persons who hold ordinary shares through a partnership or other pass-through entity or the possible application of US federal gift or estate taxes. Material aspects of US federal income tax relevant to a holder other than a US holder are also described below.

Each shareholder should consult its tax advisor regarding the particular tax consequences to such holder of ownership and disposition of our shares, as well as any tax consequences that may arise under the laws of any other relevant foreign, state, local, or other taxing jurisdiction.

### **Taxation of Dividends Paid on Ordinary Shares**

Subject to the description of the passive foreign investment company rules below, a US holder will be required to include in gross income as ordinary income the amount of any distribution paid on ordinary shares, including any Israeli taxes withheld from the amount paid, to the extent the distribution is paid out of our current or accumulated earnings and profits as determined for US federal income tax purposes. Distributions in excess of these earnings and profits will be applied against and will reduce the US holder's basis in the ordinary shares and, to the extent in excess of this basis, will be treated as gain from the sale or exchange of ordinary shares.

Certain dividend income may be eligible for a reduced rate of taxation. Dividend income will be taxed to a non-corporate holder at the applicable long-term capital gains rate if the dividend is received from a "qualified foreign corporation," and the shareholder of such foreign corporation holds such stock for more than 60 days during the 121 day period that begins on the date that is 60 days before the ex-dividend date for the stock. The holding period is tolled for any days on which the shareholder has reduced his risk of loss. A "qualified foreign corporation" is either a corporation that is eligible for the benefits of a comprehensive income tax treaty with the US or a corporation whose stock, the shares of which are with respect to any dividend paid by such corporation, is readily tradable on an established securities market in the United States. However, a foreign corporation will not be treated as qualified if it



is a passive foreign investment company (as discussed below) for the year in which the dividend was paid or the preceding year. Distributions of current or accumulated earnings and profits paid in foreign currency to a US holder will be includible in the income of a US holder in a US dollar amount calculated by reference to the exchange rate on the day the distribution is received. A US holder that receives a foreign currency distribution and converts the foreign currency into US dollars subsequent to receipt will have foreign exchange gain or loss based on any appreciation or depreciation in the value of the foreign currency against the US dollar, which will generally be US source ordinary income or loss.

As described above, we will generally be required to withhold Israeli income tax from any dividends paid to holders who are not resident in Israel. See “- Israeli Tax Considerations—Taxation of Dividends” above. If a US holder receives a dividend from us that is subject to Israeli withholding, the following would apply:

You must include the gross amount of the dividend, not reduced by the amount of Israeli tax withheld, in your US taxable income.

You may be able to claim the Israeli tax withheld as a foreign tax credit against your US income tax liability. However, to the extent that 25% or more of our gross income from all sources was effectively connected with the conduct of a trade or business in the US (or treated as effectively connected, with limited exceptions) for a three-year period ending with the close of the taxable year preceding the year in which the dividends are declared, a portion of this dividend will be treated as US source income, possibly reducing the allowable foreign tax.

The foreign tax credit is subject to significant and complex limitations. Generally, the credit can offset only the part of your US tax attributable to your net foreign source passive income. Additionally, if we pay dividends at a time when 50% or more of our stock is owned by US persons, you may be required to treat the part of the dividend attributable to US source earnings and profits as US source income, possibly reducing the allowable credit.

A US holder will be denied a foreign tax credit with respect to Israeli income tax withheld from dividends received on the ordinary shares to the extent the US holder has not held the ordinary shares for at least 16 days of the 31-day period beginning on the date which is 15 days before the ex-dividend date or, alternatively, to the extent the US holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a US holder has substantially diminished its risk of loss on the ordinary shares are not counted toward meeting the 16-day holding period required by the statute.

If you do not elect to claim foreign taxes as a credit, you will be entitled to deduct the Israeli income tax withheld from your XTL dividends in determining your taxable income.

Individuals who do not claim itemized deductions, but instead utilize the standard deduction, may not claim a deduction for the amount of the Israeli income taxes withheld.

If you are a US corporation holding our stock, the general rule is that you cannot claim the dividends-received deduction with respect to our dividends. There is an exception to this rule if you own at least 10% of our ordinary shares (by vote) and certain conditions are met.

Special rules, described below, apply if we are a passive foreign investment company.

### **Taxation of the Disposition of Ordinary Shares**

Subject to the description of the passive foreign investment company rules below, upon the sale, exchange or other disposition of our ordinary shares, a US holder will recognize capital gain or loss in an amount equal to the difference between the US holder's basis in the ordinary shares, which is usually the cost of these shares, and the amount realized on the disposition. Capital gain from the sale, exchange or other disposition of ordinary shares held more than one year is long-term capital gain and is eligible for a reduced rate of taxation for non-corporate holders. In general, gain realized by a US holder on a sale, exchange or other disposition of ordinary shares generally will be treated as US source income for US foreign tax credit purposes. A loss realized by a US holder on the sale, exchange or other disposition of ordinary shares is generally allocated to US source income. However, regulations require the loss to be

allocated to foreign source income to the extent certain dividends were received by the taxpayer within the 24-month period preceding the date on which the taxpayer recognized the loss. The deductibility of a loss realized on the sale, exchange or other disposition of ordinary shares is subject to limitations for both corporate and individual shareholders.

A US holder that uses the cash method of accounting calculates the US dollar value of the proceeds received from a sale of ordinary shares as of the date that the sale settles, and will generally have no additional foreign currency gain or loss on the sale, while a US holder that uses the accrual method of accounting is required to calculate the value of the proceeds of the sale as of the trade date and may therefore realize foreign currency gain or loss, unless the US holder has elected to use the settlement date to determine its proceeds of sale for purposes of calculating this foreign currency gain or loss. In addition, a US holder that receives foreign currency upon disposition of our ordinary shares and converts the foreign currency into US dollars subsequent to receipt will have foreign exchange gain or loss based on any appreciation or depreciation in the value of the foreign currency against the US dollar, which will generally be US source ordinary income or loss.

### **Tax Consequences If We Are A Passive Foreign Investment Company**

Special tax rules apply to the timing and character of income received by a US holder of a PFIC. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The IRS has indicated that cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income, and the relative values of passive and non-passive assets, including goodwill. Furthermore, because the goodwill of a publicly-traded corporation such as us is largely a function of the trading price of its shares, the valuation of that goodwill is subject to significant change throughout each year. A determination as to a corporation's status as a PFIC must be made annually. We believe that we were likely not a PFIC for the taxable years ended December 31, 2011, 2010, 2009 and 2008. Although such a determination is fundamentally factual in nature and generally cannot be made until the close of the applicable taxable year, based on our current operations, we believe that we were likely not classified as a PFIC for the taxable year ended December 31, 2012. Notwithstanding the above, we may be a PFIC in subsequent years. In addition, even though we may not be a PFIC in any one particular year, the PFIC taint remains, and the special PFIC tax regime will continue to apply.

If we are classified as a PFIC, a special tax regime would apply to both (a) any "excess distribution" by us (generally, the US holder's ratable share of distributions in any year that are greater than 125% of the average annual distributions received by such US holder in the three preceding years or its holding period, if shorter) and (b) any gain recognized on the sale or other disposition of your ordinary shares. Under this special regime, any excess distribution and recognized gain would be treated as ordinary income and the federal income tax on such ordinary income is determined under the following steps: (i) the amount of the excess distribution or gain is allocated ratably over the US holder's holding period for our ordinary shares; (ii) tax is determined for amounts allocated to the first year in the holding period in which we were classified as a PFIC and all subsequent years (except the year in which the excess distribution was received or the sale occurred) by applying the highest applicable tax rate in effect in the year to which the income was allocated; (iii) an interest charge is added to this tax calculated by applying the underpayment interest rate to the tax for each year determined under the preceding sentence from the due date of the income tax return for such year to the due date of the return for the year in which the excess distribution or sale occurs; and (iv) amounts allocated to a year prior to the first year in the US holder's holding period in which we were classified as a PFIC or to the year in which the excess distribution or the disposition occurred are taxed as ordinary income and no interest charge applies.

A US holder may generally avoid the PFIC regime by electing to treat his PFIC shares as a “qualified electing fund.” If a US holder elects to treat PFIC shares as a qualified electing fund, also known as a “QEF Election,” the US holder must include annually in gross income (for each year in which PFIC status is met) his *pro rata* share of the PFIC’s ordinary earnings and net capital gains, whether or not such amounts are actually distributed to the US holder. A US holder may make a QEF Election with respect to a PFIC for any taxable year in which he was a shareholder. A QEF Election is effective for the year in which the election is made and all subsequent taxable years of the US holder. Procedures exist for both retroactive elections and the filing of protective statements. A US holder making the QEF Election must make the election on or before the due date, as extended, for the filing of the US holder's income tax return for the first taxable year to which the election will apply.

A QEF Election is made on a shareholder-by-shareholder basis. A US holder must make a QEF Election by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder's timely filed US federal income tax return. We have complied with the record-keeping and reporting requirements that are a prerequisite for US holders to make a QEF Election for the 2007 and 2006 tax years. While we plan to continue to comply with such requirements, if, in the future, meeting those record-keeping and reporting requirements becomes onerous, we may decide, in our sole discretion, that such compliance is impractical and will so notify US holders.

Alternatively, a US holder may also generally avoid the PFIC regime by making a so-called "mark-to-market" election. Such an election may be made by a US holder with respect to ordinary shares owned at the close of such holder's taxable year, provided that we are a PFIC and the ordinary shares are considered "marketable stock." The ordinary shares will be marketable stock if they are regularly traded on a national securities exchange that is registered with the Securities and Exchange Commission, or the national market system established pursuant to section 11A of the Securities and Exchange Act of 1934, or an equivalent regulated and supervised foreign securities exchange.

If a US holder were to make a mark-to-market election with respect to ordinary shares, such holder generally will be required to include in its annual gross income the excess of the fair market value of the PFIC shares at year-end over such shareholder's adjusted tax basis in the ordinary shares. Such amounts will be taxable to the US holder as ordinary income, and will increase the holder's tax basis in the ordinary shares. Alternatively, if in any year, a United States holder's tax basis exceeds the fair market value of the ordinary shares at year-end, then the US holder generally may take an ordinary loss deduction to the extent of the aggregate amount of ordinary income inclusions for prior years not previously recovered through loss deductions and any loss deductions taken will reduce the shareholder's tax basis in the ordinary shares. Gains from an actual sale or other disposition of the ordinary shares with a "mark-to-market" election will be treated as ordinary income, and any losses incurred on an actual sale or other disposition of the ordinary shares will be treated as an ordinary loss to the extent of any prior "unreversed inclusions" as defined in Section 1296(d) of the Code.

The mark-to-market election is made on a shareholder-by-shareholder basis. The mark-to-market election is made by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder's timely filed US federal income tax return for the year of election. Such election is effective for the taxable year for which made and all subsequent years until either (a) the ordinary shares cease to be marketable stock or (b) the election is revoked with the consent of the IRS.

A US holder who did not make an election either to (i) treat us as a "qualified electing fund," or (ii) mark our ordinary shares to market, will be subject to the following:

gain recognized by the US holder upon the disposition of, as well as income recognized upon receiving certain excess distributions on the ordinary shares would be taxable as ordinary income;

the US holder would be required to allocate the excess distribution and/or disposition gain ratably over such US holder's entire holding period for such ordinary shares;

the amount allocated to each year other than the year of the excess distribution or disposition and pre-PFIC years would be subject to tax at the highest applicable tax rate, and an interest charge would be imposed with respect to the resulting tax liability;

the US holder would be required to file an annual return on IRS Form 8621 for the years in which distributions were received on and gain was recognized on dispositions of, our ordinary shares; and

any US holder who acquired the ordinary shares upon the death of the shareholder would not receive a step-up to market value of his income tax basis for such ordinary shares. Instead such US holder beneficiary would have a tax basis equal to the decedent's basis, if lower.

*In view of the complexity of the issues regarding our treatment as a PFIC, US shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC.*

### **US Federal Income Tax Consequences for Non-US holders of Ordinary Shares**

Except as described in “Information Reporting and Back-up Withholding” below, a Non-US holder of ordinary shares will not be subject to US federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, ordinary shares, unless:

the item is effectively connected with the conduct by the Non-US holder of a trade or business in the US and, in the case of a resident of a country which has a tax treaty with the US, the item is attributable to a permanent establishment in the US;

the Non-US holder is subject to tax under the provisions of US tax law applicable to US expatriates; or

the individual non-US holder is present in the US for 183 days or more in the taxable year of the disposition and certain other conditions are met.

### **Information Reporting and Back-Up Withholding**

US holders generally are subject to information reporting requirements with respect to dividends paid in the US on ordinary shares. Existing regulations impose back-up withholding on dividends paid in the US on ordinary shares unless the US holder provides IRS Form W-9 or otherwise establishes an exemption. US holders are subject to information reporting and back-up withholding on proceeds paid from the disposition of ordinary shares unless the US holder provides IRS Form W-9 or otherwise establishes an exemption.

Non-US holders generally are not subject to information reporting or back-up withholding with respect to dividends paid on, or upon the disposition of, ordinary shares, provided that the non-US holder provides a taxpayer identification number, certifies to its foreign status, or otherwise establishes an exemption to the US financial institution holding the ordinary shares.



Prospective investors should consult their tax advisors concerning the effect, if any, of these Treasury regulations on an investment in ordinary shares. Back-up withholding is not an additional tax. The amount of any back-up withholding will be allowed as a credit against a holder's US federal income tax liability and may entitle the holder to a refund, provided that specified required information is furnished to the IRS on a timely basis.

### **US Federal Income Tax Consequences for XTL**

As of April 7, 2009, we did not have a “permanent establishment” in the US. Our board of directors consists of a majority of Israeli residents and our CEO is domiciled in Israel. However, for the period we did have a “permanent establishment” in the US, any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. The maximum US corporate income tax rate (not including applicable state and local tax rates) is currently at 35%. In addition, if we had income attributable to the permanent establishment in the US, we may be subject to an additional branch profits tax of 30% on our US effectively connected earnings and profits, subject to adjustment, for that taxable year if certain conditions occur, unless we qualified for the reduced 12.5% US branch profits tax rate pursuant to the United States-Israel tax treaty. We would be potentially able to credit any foreign taxes that may become due in the future against its US tax liability in connection with income attributable to its US permanent establishment and subject to both US and foreign income tax.

As of December 31, 2012, we did not earn any taxable income for US federal tax purposes and we do not have a permanent establishment. If we eventually earn taxable income attributable to our US permanent establishment, we would be able to utilize accumulated loss carryforwards to offset such income only to the extent these carryforwards were attributable to our US permanent establishment. As of December 31, 2012, the net operating tax losses (“NOL”) of the US subsidiaries amounted to approximately \$20 million. These losses of the U.S. subsidiaries are limited in use and it is probable that they will be even significantly reduced due to state tax laws that deal in cases of "change of control" which is the outcome of the carrying out the Bio-Gal transaction. (see “Item 10 financial information-material contracts”) and subject to further limitations in case of a future offering or capital raise, resulting in more than 50 percentage point change over a three year look back period, and expiring through 2029. Pursuant to a US tax rule.

*The above comments are intended as a general guide to the current position. Any person who is in any doubt as to his or her taxation position, and who requires more detailed information than the general outline above or who is subject to tax in a jurisdiction other than the United States should consult professional advisers.*

## **Documents on Display**

We voluntarily file reports and other information with the SEC under the Exchange Act and the regulations thereunder applicable to foreign private issuers. You may inspect and copy reports and other information filed by us with the SEC at the SEC’s public reference facilities described below. Although as a foreign private issuer we are not required to file periodic information as frequently or as promptly as US companies, we generally announce publicly our interim and year-end results promptly on a voluntary basis and will file that periodic information with the SEC under cover of Form 6-K. As a foreign private issuer, we are also exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and other provisions in Section 16 of the Exchange Act.

You may review and obtain copies of our filings with the SEC, including any exhibits and schedules, at the SEC’s public reference facilities in Room 1580, 100 F. Street, N.E., Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our periodic filings will also be available on the SEC’s website at [www.sec.gov](http://www.sec.gov). These SEC filings are also available to the public from commercial document retrieval services. Any statement in this annual report about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to this annual report, the contract or document is deemed to modify the description contained in this annual report. We urge you to review the exhibits themselves for a complete description of the contract or document.

## **Item 11. Quantitative and Qualitative Disclosures About Market Risk**

*Interest Rate Risk.* The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in bank deposits in accordance with our investment policy. As of December 31, 2012, our portfolio of financial instruments consists of cash and cash equivalents, short-term bank deposits with multiple institutions. The average duration of all of our investments held as of December 31, 2012, was less than one year. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

*Foreign Currency and Inflation Risk.* We generate most of our revenues and hold most of our cash, cash equivalents and bank deposits in US dollars. While a substantial amount of our operating expenses are in US dollars, we incur a portion of our expenses in New Israeli Shekels. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers, as our head office is located in Israel. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. The Company's treasury's risk management policy, excluding InterCure, is to hold NIS-denominated cash and cash equivalents and short-term deposits in the amount of the anticipated NIS-denominated liabilities for nine-twelve consecutive months from time to time and this in line with the directives of the Company's Board. InterCure is focuses on actions to reduce to minimum the negative effects arising from this risk and therefore holds cash and cash equivalents in currencies in which it operates, in accordance with management's assessments. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel.

As of December 31, 2012, if the Group's functional currency had weakened by 10% against the NIS with all other variables remaining constant, post-tax loss for the year would have been \$ 89 thousand lower (2011 - post-tax loss approximately \$ 30 thousand lower; 2010 - post-tax loss approximately \$ 11 thousand higher), mainly as a result of exchange rate changes on translation of other accounts receivable, net and exchange rate changes on NIS-denominated cash and cash equivalents and short-term deposits. Loss was more sensitive to movement in the exchange rate in relation to the NIS in 2012 than in 2011 mainly because of the increased amount of the NIS-denominated balances in the items of cash, receivables and payables of the Group.

*Credit Risk.* Credit risks are managed at the Group level. The Group has no significant concentrations of credit risk. The Group has a policy to ensure collection through sales of its products to wholesalers with an appropriate credit history and through retail sales in cash or by credit card.

The Group extends a 30-day term to its customers. The Group regularly monitors the credit extended to its customers and their general financial condition but does not require collateral as security for these receivables. The Group provides an allowance for doubtful accounts based on the factors that affect the credit risk of certain customers, past experience and other information. Credit risks arise from cash and cash equivalents, restricted bank deposits as well as outstanding receivables.

The Group, excluding InterCure, engages with banks and financial institutions which are independently rated A at least. As for InterCure, part of its cash is held in a bank with an A- credit rating.

*Liquidity Risk.* Cash flow forecasting is performed by the Group's management both in the entities of the Group and aggregated by the Group. The Group's management monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operations. The Group currently does not use credit facilities. Forecasting takes into consideration several factors such as raising capital to finance operations and certain liquidity ratios that the Group strives to achieve.

Surplus cash held to finance operating activities is invested in interest bearing current accounts, time deposits and other similar channels. These channels were chosen by reference to their appropriate maturities or liquidity to provide sufficient cash balances to the Group as determined by the abovementioned forecasts.

As of December 31, 2012 and 2011, the maturity of the Group's financial liabilities is less than one year from each of the reporting dates.

**Item 12. Description of Securities Other than Equity Securities**

**American Depositary Shares**

*Fees Payable By ADS Holders.* A copy of our Form of Deposit Agreement with The Bank of New York Mellon (the “Depositary”) (including the Form of American Depositary Receipt or “ADR”) was filed with the SEC as an exhibit to our Form F-6 filed on November 28, 2007 (the “Deposit Agreement”). Pursuant to the Deposit Agreement, holders of our ADSs may have to pay to the Depositary, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

<b>Item Associated Fee</b>	<b>Depositary Action</b>
1. Taxes and other governmental charges	As necessary
2. Registration fees in effect for the registration of transfers of shares generally on the share register of XTL or foreign registrar and applicable to transfers of shares to or from the name of the Depositary or its nominee or the custodian or its nominee on the making of deposits or withdrawals	As necessary
3. Expenses incurred by the Depositary	<ul style="list-style-type: none"> <li>• Cable, telex and facsimile transmission (where expressly provided for in the Deposit Agreement)</li> <li>• Foreign currency conversion into US dollars</li> <li>• Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property</li> <li>• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates</li> </ul>
4. \$5.00 or less per 100 ADSs (or portion thereof)	
5. \$0.02 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the Deposit Agreement, including, among other things:

- cash distributions or dividends,
- distributions other than cash, shares or rights,
- distributions in shares, and
- rights of any other nature, including rights to subscribe for additional shares.

- |    |   |   |
|----|---|---|
| 6. | A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs | Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS registered holders |
| 7. | \$.02 (or less) per ADSs per calendar year  | Depositary services   |
| 8. | Any charges incurred by the depositary or its agents for servicing the deposited securities   | As necessary  |

*Fees Paid to XTL by the Depositary.* As of January 1, 2012 through April 24, 2013, the Company has not received any fees, direct payments or indirect payments from The Bank of New York Mellon.

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**

Not applicable.



## Item 15. Controls and Procedures

(a) *Disclosure controls and procedures.* Our management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rules 13a-15 and 15d-15 of the Securities Exchange Act of 1934. As of December 31, 2012, an evaluation was performed under the supervision and with the participation of our management of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures as of December 31, 2012 were effective.

(b) *Internal controls over financial reporting.* Our management is responsible for establishing and maintaining adequate control over financial reporting, as such term is defined in Rule 13a-15(f) of the exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria established in *Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Also, our evaluation was conducted pursuant to section 9b(c) to the Israeli Securities regulations (Periodic and Immediate Reports), 1970, which came into effect on the reporting for December 31, 2010 for the first time (as we are traded on the TASE). Based on that evaluation, our management believes our internal control over financial reporting was effective as of December 31, 2012. Our management's assessment of, and conclusion on, the effectiveness of internal control over financial reporting did not include the internal controls of Intercure, which was acquired during 2012, and is included in our 2012 consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurances with respect to the preparation and presentation of financial statements.

Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, the independent registered public accounting firm that audited the financial statements included in this annual report, has issued an audit report as of December 31, 2012, and dated March 24, 2013 relating to the financial statements which are incorporated by reference in this annual report on Form 20-F for the year ended December 31, 2012. See "Item 18. Financial Statements."

(c) *Internal controls.* There have been no significant changes in our internal control over financial reporting that occurred during the fiscal year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 16. Reserved**

Not applicable.

**Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that Jaron Diamant, chairperson of our audit committee, is an audit committee financial expert, as defined by applicable SEC regulations, and is independent in accordance with applicable SEC regulations.

**Item 16B. Code of Ethics**

We have adopted a Code of Conduct applicable that applies to all employees, directors and officers of our company, including our principal executive officer, principal financial officer, principal accounting officer or controller and other individuals performing similar functions. A copy of our Code of Conduct can be found on our website ([www.xtlbio.com](http://www.xtlbio.com)) and may also be obtained, without charge, upon a written request addressed to our investor relations department, XTL Biopharmaceuticals Ltd., PO Box 4033, Herzliya 46140, Israel.

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**Item 16C. Principal Accountant Fees and Services**

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

Our audit committee is responsible for the oversight of the independent auditors' work. The audit committee's policy is to pre-approve all audit and non-audit services provided by our independent auditors, Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd. ("PWC"). These services may include audit services, audit-related services and tax services, as further described below.

**Principal Accountant Fees and Services**

We were billed the following fees for professional services rendered by PWC, for the years ended December 31, 2012 and 2011.

	2012	2011
	(in thousands US\$)	
Audit fees	70	51
Audit-related fees	12	-
Tax fees	-	-
All Other fees	5	4
Total	87	55

The audit fees for the years ended December 31, 2012 and 2011, respectively, were for professional services rendered for the audit of our annual consolidated financial statements, review of interim consolidated financial statements and statutory audits, including Israeli tax reports. The audit fees for the year ended December 31, 2012 includes also fees for the audit of InterCure's annual consolidated financial statements.

The audit-related fees for the year ended December 31, 2012 were for the professional services rendered for the audit of Proteologics' statement of financial position as of the acquisition date (November 21, 2012).

Other fees for the year ended December 31, 2012 were for professional services rendered for obtaining ruling from the Israeli Securities Authority.

For the fiscal year ended December 31, 2012 and 2011, all of our audit-related fees, tax fees and other fees were pre-approved by our audit committee.

**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 REGISTERED ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

Not applicable. Our securities are not traded on a national securities exchange. Our ADRs are traded on the Pink Sheets, an inter-dealer electronic quotation and trading system in the over-the-counter (OTC) securities market, under the symbol “XTLBY.PK.” Our ordinary shares are traded on the Tel Aviv Stock Exchange under the symbol “XTL.”

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PART III

**Item 17. Financial Statements**

We have elected to furnish financial statements and related information specified in Item 18.

**Item 18. Financial Statements**

Our audited and consolidated financial statements for the fiscal year ending December 31, 2012, as well as our accountant's report, are incorporated by reference from Form 6-K filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 24, 2013, in chapter 3.

**Item 19. Exhibits**

The following exhibits are filed as part of this annual report:

Exhibit Number	Description
3.1	Articles of Association†
4.1	Form of Share Certificate (including both Hebrew and English translations). *
4.2	Form of American Depositary Receipt (included in Exhibit 4.3). †
4.3	Deposit Agreement, dated as of August 31, 2005, by and between XTL Biopharmaceuticals Ltd., The Bank of New York, as Depositary, and each holder and beneficial owner of American Depositary Receipts issued thereunder. †
4.5	Form of Director and Senior Management Lock-up Letter.
10.16	2001 Share Option Plan dated February 28, 2001. †
10.17	Letter of Understanding, dated August 5, 2005, relating to the License Agreement dated June 2, 2004 between Cubist Pharmaceuticals, Inc. and XTL Biopharmaceuticals Ltd. †
10.26	License Agreement Between XTL Biopharmaceuticals Ltd. and VivoQuest, Inc., dated August 17, 2005†
10.27	Asset Purchase Agreement Between XTL Biopharmaceuticals Ltd. and VivoQuest, Inc., dated August 17, 2005†
10.28	Securities Purchase Agreement, dated March 17, 2006, by and among XTL Biopharmaceuticals Ltd., and the purchasers named therein. #

- 10.29 Registration Rights Agreement, dated March 22, 2006, by and among XTL Biopharmaceuticals Ltd. and the purchasers named therein. #
- 10.30 Form of Ordinary Share Purchase Warrants, dated March 22, 2006, issued to the purchasers under the Securities Purchase Agreement. ^
- 10.32 License Agreement between XTL Development, Inc. and DOV Pharmaceutical, Inc., dated January 15, 2007. \*
- 10.34 Securities Purchase Agreement, dated October 25, 2007, by and among XTL Biopharmaceuticals Ltd., and the purchasers named therein. #
- 10.35 Registration Rights Agreement, dated October 25, 2007, by and among XTL Biopharmaceuticals Ltd. and the purchasers named therein. #
- 10.36 License Agreement By and Between XTL Biopharmaceuticals Ltd. and Presidio Pharmaceuticals, Inc. dated March 19, 2008. #
- 10.37 Amended and Restated License Agreement By and Between XTL Biopharmaceuticals Ltd. and Presidio Pharmaceuticals, Inc. dated August 4, 2008. &>

- 10.38 Services Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., Quoque Bioventures LLC and Antecip Bioventures LLC. +
- 10.39 Stock Appreciation Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.40 Registration Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.41 Stock Appreciation Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Antecip Bioventures LLC. +
- 10.42 Registration Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.43 Asset Purchase Agreement, dated as of March 18, 2009 between XTL Biopharmaceuticals Ltd. and Bio-Gal Ltd. &, >
- 10.44 Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Biogal Ltd. (under its previous name Haverfield Ltd.) and Biogal Advanced Biotechnology Ltd. dated January 7, 2002. &, >
- 10.45 Amendment to Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Haverfield Ltd. and Biogal Advanced Biotechnology Ltd. effective as of April 1, 2008. &, >
- 10.46 Amended Bio-Gal Agreement, entered into December 31, 2009. @
- 10.47 Share Transfer Agreement, entered into December 31, 2009. @
- 10.48 Termination to Bicycladine License, dated March 2010. @
- 10.49 Employment Agreement, dated as of January 18, 2010, between XTL Biopharmaceuticals Ltd. and David Grossman. @
- 10.50 Employment Agreement, dated as of July 29, 2009, between XTL Biopharmaceuticals Ltd. and Ronen Twito. @
- 10.51 Consulting Agreement, dated as of August 27, 2010, between XTL Biopharmaceuticals Ltd. and Moshe Mittelman. ~
- 10.52 Option to License Agreement, dated as of September 1, 2010, between XTL Biopharmaceuticals Ltd. and Yeda Research and Development Company Limited. ~
- 10.53 License Agreement, dated as of November 30, 2011, between XTL Biopharmaceuticals Ltd. and MinoGuard Ltd. >
- 10.54 A translation from Hebrew of strategic collaboration framework agreement, dated as of March 14, 2012, between XTL Biopharmaceuticals Ltd. and Clalit Health Services - Clalit Research Institute Ltd.
- 10.55 Shares Purchase Agreement, dated March 18, 2012, by and among XTL Biopharmaceuticals Ltd., and the purchasers
- 10.56 A translation from Hebrew of term sheet, dated as of June 13, 2012, between XTL Biopharmaceuticals Ltd. and InterCure Ltd.
- 10.57 A translation from Hebrew of strategic service agreement, dated as of September 24, 2012, between InterCure Ltd. and Giboov Ltd.
- 10.58 Share Purchase Agreement, dated as of November 21, 2012, between XTL Biopharmaceuticals Ltd. and Teva Pharmaceutical Industries Ltd.
- 10.59 A translation from Hebrew of employment agreement, dated as of December 12, 2012, between InterCure Ltd. and Omri Batzir



- 10.60 Consulting Agreement, dated as of March 21, 2013, between InterCure Ltd. and Prof. Reuven Zimlichman
- 10.61 Financial statement of Proteologics Ltd. as of December 31, 2012 and for the year then ended, dated March 7, 2013
- 21.1 List of Subsidiaries
- 23.2 Consent of BDO Ziv Haft Consulting and Management Ltd, dated April 25, 2013.
- 23.3 Consent of Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd, for Proteologics Ltd., dated April 25, 2013.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated April 25, 2013.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated April 25, 2013.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated April 25, 2013

† Incorporated by reference from the registration statement on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on July 14, 2005, as it may be amended or restated.

^ Incorporated by reference from the registration statement on Form F-1 filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 20, 2006, as it may be amended or restated.

\* Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007.

# Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 27, 2008.

+ Incorporated by reference from the current annual report on Form 6-K filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on October 24, 2008.

& Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 6, 2009.

@ Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on June 30, 2010.

~ Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on May 30, 2011.

Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 29, 2012.

> Confidential treatment has been requested with respect to the omitted portions of this exhibit.

**SIGNATURES**

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

**XTL  
BIOPHARMACEUTICALS  
LTD.**  
*(Registrant)*

Signature: /s/ David Grossman  
David Grossman  
Chief Executive Officer

Date: April 25, 2013