# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of August 2013

# **BioLineRx** Ltd.

(Translation of Registrant's name into English)

P.O. Box 45158 19 Hartum Street Jerusalem 91450, Israel (Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

| Form 20-F 🗹 | Form 40-F o |
|-------------|-------------|
|             |             |

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes o No 🗹

On August 6, 2013, the Registrant will issue a press release announcing its financial results for the three months and six months ended June 30, 2013. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of June 30, 2013, and for the three months and six months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated August 6, 2013;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of June 30, 2013, and for the three months and six months then ended;

Exhibit 3 - Registrant's operating and financial review as of June 30, 2013, and for the three months and six months then ended.

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

# BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin Chief Financial and Operating Officer

Dated: August 6, 2013

# **BioLineRx Reports Second Quarter 2013 Results**

JERUSALEM – August 6, 2013 - BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, today reported its results for the quarter ended June 30, 2013.

# **Recent Highlights:**

- **BL-1040 (ventricular remodeling)** The PRESERVATION I clinical trial, a CE-Mark registration trial, is proceeding as scheduled there are currently 36 active sites in 9 countries, including 7 leading sites in the U.S.
- **BL-5010 (skin lesions)** The necessary regulatory submissions to commence a pivotal, CE-Mark registration trial in Europe have been filed; the CRO and three sites in Germany have been selected.
- BL-8040 (AML) The ongoing Phase 2 clinical trial is progressing as planned, and currently has 6 active sites recruiting (out of 8 sites in total); the first patient was enrolled in the study at the MD Anderson Cancer Center in Houston; Northwestern Memorial Hospital in Chicago was recently initiated into the trial and is expected to commence recruitment in the coming weeks; enrollment has been initiated at several leading sites in Israel following approval from the Israeli Ministry of Health;
- BL-7010 (celiac disease) Advanced GLP toxicology studies have begun and the CRO and sites in Europe have been selected for the upcoming Phase 1/2 clinical trial, expected to commence in Q4 2013; results of pre-clinical studies were presented and received with enthusiasm at two leading international meetings - the U.S. Celiac Disease Foundation's annual conference and the Digestive Disease Week conference.

Commenting on the ongoing progress within the Company's pipeline, Kinneret Savitsky, Ph.D., Chief Executive Officer of BioLineRx, remarked, "The second quarter of 2013 has been a period of meaningful achievement for BioLineRx, in which several of our advanced products met important scientific and clinical milestones. Over the next few quarters, we will move forward on multiple exciting near-term opportunities across a number of therapeutic areas with significant unmet medical needs."

"We are eagerly awaiting completion of the CE-Mark registration trial for BL-1040 by our partner, Ikaria, which is expected to occur in 2014. We have high hopes that this unique product will become a breakthrough treatment for AMI and part of the standard of care," stated Dr. Savitsky. "For BL-5010, the CE-Mark registration trial is now slated to begin enrollment later this year, setting a clear pathway for entering the European market by the second half of 2014. The estimated worldwide market for the treatment of conditions such as seborrheic and actinic keratosis is over \$500 million worldwide. We estimate that BL-5010's ease of use and low cost will allow for swift commercial acceptance, and are currently engaged in discussions with potential partners." "We are also very pleased with the progress of the Phase 2 clinical trial for BL-8040, a best-in-class CXCR4 antagonist for the treatment of hematological cancers such as AML. We are on track to deliver partial results from the trial in the fourth quarter of 2013, with final results expected to be available by the second half of 2014."

"Another exciting opportunity for us is BL-7010, a unique product for celiac disease, a market that is projected to reach \$8 billion by 2019. Despite the huge size of this market, there are no pharmacological agents approved for the treatment of celiac disease and the only treatment option is a lifelong gluten-free diet, which is extremely difficult to maintain. There are currently only four clinical-stage projects in the world in the celiac disease development pipeline, one of which is BL-7010. We expect to initiate a Phase 1/2 safety study by the end of 2013 – we have already selected the CRO and treatment sites for the study, and are in the process of preparing the necessary regulatory submissions," concluded Dr. Savitsky.

### **Financial Results:**

During the three-month and six-month periods ended June 30, 2013 and 2012, no revenues were recorded.

Research and development expenses for the three months ended June 30, 2013 were NIS 12.1 million (\$3.3 million), a decrease of NIS 3.9 million (\$1.1 million), or 24%, compared to NIS 16.0 million (\$4.4 million) for the three months ended June 30, 2012. The decrease resulted primarily from lower expenses in 2013 associated with the CLARITY clinical trial in respect of BL-1020, due to termination of the trial in March 2013, offset by a ramp-up in spending on other clinical-stage projects introduced during 2012. Research and development expenses for the six months ended June 30, 2013 were NIS 31.5 million (\$8.7 million), an increase of NIS 0.9 million (\$0.2 million), or 3%, compared to NIS 30.7 million (\$8.5 million) for the comparable 2012 period. Without regard to the NIS 6.0 million one-time reversal of amounts previously accrued to the OCS in respect of BL-1020, research and development expenses increased by NIS 6.8 million). The increase resulted primarily from significantly higher expenses in the 2013 period associated with the CLARITY clinical trial, as well as a ramp-up in spending on other clinical-stage projects introduced during 2012.

Sales and marketing expenses for the three months ended June 30, 2013 were NIS 1.1 million (\$0.3 million), an insignificant increase compared to NIS 0.9 million (\$0.3 million) for the three months ended June 30, 2012. The small increase relates to professional fees and other expenses stemming from an increase in our business development efforts, compared to the second quarter of last year. Sales and marketing expenses for the six months ended June 30, 2013 were NIS 1.8 million (\$0.5 million), an insignificant increase compared to NIS 1.7 million (\$0.5 million) for the comparable period in 2012. The reason for the increase is similar to the one discussed above in the three-month comparison.

General and administrative expenses for the three months ended June 30, 2013 were NIS 3.6 million (\$1.0 million), an increase of NIS 0.6 million (\$0.2 million), or 22%, compared to NIS 3.0 million (\$0.8 million) for the three months ended June 30, 2012. The increase resulted primarily from a one-time expense for professional services incurred in the 2013 period. General and administrative expenses for the six months ended June 30, 2013 were NIS 7.1 million (\$2.0 million), an increase of NIS 0.6 million (\$0.2 million), or 10%, compared to NIS 6.5 million (\$1.8 million) for the comparable 2012 period. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company's operating loss for the three months ended June 30, 2013 amounted to NIS 16.8 million (\$4.6 million), compared with an operating loss of NIS 19.9 million (\$5.5 million) for the comparable period in 2012. The Company's operating loss for the six months ended June 30, 2013 amounted to NIS 40.5 million (\$11.2 million), compared with an operating loss of NIS 38.9 million (\$10.7 million) for the comparable period in 2012.

The Company's net non-operating income amounted to NIS 1.6 million (\$0.4 million) for the three months ended June 30, 2013, a decrease of NIS 1.1 million (\$0.3 million), compared to NIS 2.7 million (\$0.8 million) for the three months ended June 30, 2012. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements conducted in February 2012 and 2013. Net non-operating income amounted to NIS 1.8 million (\$3.8 million) for the six months ended June 30, 2013, an increase of NIS 8.3 million (\$2.3 million), compared to net non-operating income of NIS 5.5 million (\$1.5 million) for the comparable 2012 period. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company recorded net financial expense of NIS 0.4 million (\$0.1 million) for the three months ended June 30, 2013, a change of NIS 6.3 million (\$1.7 million), compared to net financial income of NIS 5.9 million (\$1.6 million) for the three months ended June 30, 2012. Net financial income and expense result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on the Company's net assets denominated in dollars. Net financial expense amounted to NIS 1.8 million (\$0.5 million) for the six months ended June 30, 2012, a change of NIS 5.9 million, compared to net financial income of NIS 4.1 million (\$1.1 million) for the comparable 2012 period. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company's net loss for the three months ended June 30, 2013 amounted to NIS 15.6 million (\$4.3 million), compared with a net loss of NIS 11.3 million (\$3.1 million) for the comparable period in 2012. The Company's net loss for the six months ended June 30, 2013 amounted to NIS 28.4 million (\$7.9 million), compared with a net loss of NIS 29.2 million (\$8.1 million) for the comparable period in 2012.

The Company held NIS 83.5 million (\$23.1 million) in cash, cash equivalents and short-term bank deposits as of June 30, 2013.

Net cash used in operating activities was NIS 41.5 million (\$11.5 million) for the six months ended June 30, 2013, compared with net cash used in operating activities of NIS 36.4 million (\$10.1 million) for the six months ended June 30, 2012. The NIS 5.1 million (\$1.4 million) increase in net cash used in operating activities during the six-month period in 2013, versus the 2012 period, was primarily the result of increased research and development spending.

Net cash used in investing activities for the six months ended June 30, 2013 was NIS 21.4 million (\$5.9 million), compared to net cash provided by investing activities of NIS 9.9 million (\$2.7 million) for the six months ended June 2012. The cash flows related to investing activities primarily stem from investments in, and maturities of, short-term bank deposits during the respective periods.

Net cash provided by financing activities for the six months ended June 30, 2013 was NIS 46.0 million (\$12.7 million), compared to net cash provided by financing activities of NIS 52.3 million (\$14.5 million) for the six months ended June 2012. The cash flows from financing activities primarily reflect the direct and private placements completed in February 2013 and 2012.

#### **Conference Call and Webcast Information**

BioLineRx will hold a conference call to discuss its second quarter 2013 results today, August 6, 2013, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-668-9141 from the U.S. or +972-3-918-0609 internationally. The call will also be available via live webcast through BioLineRx's website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-782-4291 from the U.S. or +972-3-925-5927 internationally. The replay will be available through August 9, 2013.

#### (Tables follow)

#### About BioLineRx

BioLineRx is a publicly-traded biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of seven clinical stage candidates: BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, and which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions has completed a Phase 1/2 study; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers has commenced a Phase 2 study; BL-7040 for treating inflammatory bowel disease (IBD) has completed a Phase 2a trial; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; BL-1021 for neuropathic pain is in Phase 1 development; and BL-1020 for schizophrenia. In addition, BioLineRx has four products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase 3) and commercialization. For more information on BioLineRx, please visit <u>www.biolinerx.com</u>, the content of which does not form a part of this press release.

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 12, 2013. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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# **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

|   |                     |           | Convenience<br>translation<br>into USD |
|---|---------------------|-----------|--|
|   | December 31,        | June 30,  | June 30,                               |
|   | 2012                | 2013      | 2013                                   |
|   | NIS in the          | usands    | In thousands                           |
| Assets  |                     |           |  |
| CURRENT ASSETS                                |                     |           |  |
| Cash and cash equivalents                     | 68,339              | 50,232    | 13,884                                 |
| Short-term bank deposits                      | 11,459              | 33,238    | 9,187                                  |
| Prepaid expenses                              | 804                 | 561       | 155                                    |
| Other receivables                             | 2,254               | 1,092     | 302                                    |
| Total current assets                          | 82,856              | 85,123    | 23,528                                 |
| NON-CURRENT ASSETS                            |                     |           |  |
| Restricted deposits                           | 3,513               | 1,946     | 538                                    |
| Long-term prepaid expenses                    | 204                 | 170       | 47                                     |
| Property and equipment, net                   | 3,172               | 2,871     | 793                                    |
| Intangible assets, net                        | 1,063               | 932       | 258                                    |
| Total non-current assets                      | 7,952               | 5,919     | 1,636                                  |
| Total assets                                  | 90,808              | 91,042    | 25,164                                 |
| Liabilities and equity<br>CURRENT LIABILITIES |                     |           |  |
| Current maturities of long-term bank loan     | 137                 | _         | _                                      |
| Accounts payable and accruals:                | 107                 |           |  |
| Trade   | 12,283              | 15,084    | 4,169                                  |
| OCS   | 6,148               | -         | .,100                                  |
| Other   | 5,443               | 3,870     | 1,070                                  |
| Total current liabilities                     | 24,011              | 18,954    | 5,239                                  |
| NON-CURRENT LIABILITIES                       |                     |           |  |
| Retirement benefit obligations                | 143                 | 143       | 40                                     |
| Warrants                                      | 10,725              | 8,858     | 2,448                                  |
| Total non-current liabilities                 | 10,868              | 9,001     | 2,488                                  |
| COMMITMENTS AND CONTINGENT LIABILITIES        | 10,000              | 5,001     | 2,400                                  |
| Total liabilities                             | 34,879              | 27,955    | 7,727                                  |
|   |                     |           |  |
| EQUITY  | 1.005               | 0.004     | 62.4                                   |
| Ordinary shares                               | 1,837               | 2,294     | 634                                    |
| Share premium                                 | 464,629             | 498,910   | 137,897                                |
| Capital reserve<br>Accumulated deficit        | 33,802<br>(444,339) | 34,630    | 9,572                                  |
|   |                     | (472,747) | (130,666)                              |
| Total equity                                  | 55,929              | 63,087    | 17,437                                 |
| Total liabilities and equity                  | 90,808              | 91,042    | 25,164                                 |

# **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

|                              |                        |              |                       |          | Convenience<br>into U             |                                 |
|------------------------------|------------------------|--------------|-----------------------|----------|-----------------------------------|---------------------------------|
|                              | Three month<br>June 30 |              | Six months<br>June 30 |          | Three months<br>ended<br>June 30, | Six months<br>ended<br>June 30, |
|                              | 2012                   | 2013         | 2012                  | 2013     | 2013                              | 2013                            |
|                              |                        | NIS in thous | ands                  |          | In thou                           | sands                           |
| RESEARCH AND DEVELOPMENT     |                        |              |                       |          |                                   |                                 |
| EXPENSES, NET                | (16,000)               | (12,087)     | (30,675)              | (31,530) | (3,341)                           | (8,715)                         |
| SALES AND MARKETING EXPENSES | (948)                  | (1,063)      | (1,714)               | (1,834)  | (294)                             | (507)                           |
| GENERAL AND ADMINISTRATIVE   |                        |              |                       |          |                                   |                                 |
| EXPENSES                     | (2,956)                | (3,604)      | (6,481)               | (7,126)  | (996)                             | (1,970)                         |
| OPERATING LOSS               | (19,904)               | (16,754)     | (38,870)              | (40,490) | (4,631)                           | (11,192)                        |
| NON-OPERATING INCOME, NET    | 2,712                  | 1,579        | 5,531                 | 13,841   | 436                               | 3,825                           |
| FINANCIAL INCOME             | 6,050                  | 1,320        | 6,496                 | 1,983    | 365                               | 548                             |
| FINANCIAL EXPENSES           | (172)                  | (1,713)      | (2,403)               | (3,742)  | (473)                             | (1,034)                         |
| COMPREHENSIVE LOSS FOR THE   |                        |              |                       |          |                                   |                                 |
| PERIOD                       | (11,314)               | (15,568)     | (29,246)              | (28,408) | (4,303)                           | (7,853)                         |
| -                            |                        |              |                       |          |                                   |                                 |
|                              |                        | NIS          |                       |          | US                                | D                               |
| LOSS PER ORDINARY SHARE -    |                        |              |                       |          |                                   |                                 |
| BASIC AND DILUTED            | (0.06)                 | (0.07)       | (0.18)                | (0.13)   | (0.02)                            | (0.04)                          |
|                              |                        |              |                       |          |                                   |                                 |

# **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

|  |                  |            | Convenience<br>translation<br>into USD<br>Six months<br>ended |
|--|------------------|------------|---|
|  | Six months ended | l June 30. | June 30,  |
|  | 2012             | 2013       | 2013  |
|  | NIS in thous     |            | In thousands  |
| CASH FLOWS - OPERATING ACTIVITIES  |                  |            |   |
| Comprehensive loss for the period  | (29,246)         | (28,408)   | (7,853)   |
| Adjustments required to reflect net cash used in operating activities (see appendix below) | (7,178)          | (13,133)   | (3,629)   |
| Net cash used in operating activities  | (36,424)         | (41,541)   | (11,482)  |
| iver cash used in operating activities   | (30,424)         | (41,341)   | (11,402)  |
| CASH FLOWS - INVESTING ACTIVITIES  |                  |            |   |
| Investments in short-term deposits   | (54,462)         | (75,008)   | (20,732)  |
| Maturities of short-term deposits  | 64,801           | 52,257     | 14,444  |
| Maturities of restricted deposits  | -                | 1,550      | 428   |
| Purchase of property and equipment   | (431)            | (132)      | (36)  |
| Purchase of intangible assets  | (18)             | (79)       | (22)  |
| Net cash provided by (used in) investing activities  | 9,890            | (21,412)   | (5,918)   |
|  |                  |            |   |
| CASH FLOWS - FINANCING ACTIVITIES  |                  |            |   |
| Repayments of bank loan  | (149)            | (127)      | (35)  |
| Issuance of share capital and warrants, net of issuance expenses                           | 52,453           | 46,101     | 12,742  |
| Proceeds from exercise of employee stock options   | *                | *          | *   |
| Net cash provided by financing activities  | 52,304           | 45,974     | 12,707  |
| INCREASE (DECREASE) IN CASH AND  |                  |            |   |
| INCREASE (DECREASE) IN CASH AND<br>CASH EQUIVALENTS  | 25,770           | (16,979)   | (4,693)   |
| CASH EQUIVALENTS<br>CASH AND CASH EQUIVALENTS – BEGINNING                                  | 23,770           | (10,979)   | (4,093)   |
| OF PERIOD  | 33.061           | 68,339     | 18.889  |
| EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS  | 4,988            | (1,128)    | (312)   |
| CASH AND CASH EQUIVALENTS - END OF PERIOD  | 63,819           | 50,232     | 13,884  |
|  |                  | 00,202     |   |

\* Less than 1,000

# BioLineRx Ltd. APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

|  | Six months ende | d June 30, | Convenience<br>translation<br>into USD<br>Six months<br>ended<br>June 30, |
|--|-----------------|------------|---|
|  | 2012            | 2013       | 2013  |
|  | NIS in thou     | sands      | In thousands  |
| Adjustments required to reflect net cash used in operating activities: |                 |            |   |
| Income and expenses not involving cash flows:                          |                 |            |   |
| Depreciation and amortization  | 812             | 578        | 160   |
| Impairment of intangible assets  | -               | 138        | 38  |
| Long-term prepaid expenses   | (7)             | 34         | 9   |
| Exchange differences on cash and cash equivalents                      | (4,988)         | 1,128      | 312   |
| Share-based compensation   | 1,640           | 1,626      | 450   |
| Warrant issuance costs   | 1,204           | 470        | 130   |
| Gain on adjustment of warrants to fair value                           | (6,735)         | (14,498)   | (4,007)   |
| Interest and exchange differences on short-term deposits               | (641)           | 972        | 269   |
| Interest and linkage on bank loan                                      | (14)            | (10)       | (3)   |
| Interest and exchange differences on restricted deposits               | (31)            | 17         | 5   |
|  | (8,760)         | (9,545)    | (2,637)   |
| Changes in operating asset and liability items:                        |                 |            |   |
| Decrease in trade accounts receivable and                              |                 |            |   |
| other receivables  | 1,668           | 1,405      | 388   |
| Decrease in accounts payable and accruals                              | (86)            | (4,993)    | (1,380)   |
| Decrease in accounts payable and accruaits                             | 1,582           | (3,588)    | (992)   |
|  |                 |            |   |
|  | (7,178)         | (13,133)   | (3,629)   |
| Supplementary information on interest received in cash                 | 1,088           | 323        | 89  |

# BioLineRx Ltd. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED) AS OF JUNE 30, 2013

# BioLineRx Ltd. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED) AS OF JUNE 30, 2013

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# **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

|   | December 31, | June 30,  | Convenience<br>translation<br>into USD<br>(Note 1b)<br>June 30, |
|---|--------------|-----------|---|
|   | 2012         | 2013      | 2013  |
|   | NIS in tho   | usands    | In thousands  |
| Assets  |              |           |   |
| CURRENT ASSETS                                |              |           |   |
| Cash and cash equivalents                     | 68,339       | 50,232    | 13,884  |
| Short-term bank deposits                      | 11,459       | 33,238    | 9,187   |
| Prepaid expenses                              | 804          | 561       | 155   |
| Other receivables                             | 2,254        | 1,092     | 302   |
| Total current assets                          | 82,856       | 85,123    | 23,528  |
| NON-CURRENT ASSETS                            |              |           |   |
| Restricted deposits                           | 3,513        | 1,946     | 538   |
| Long-term prepaid expenses                    | 204          | 170       | 47  |
| Property and equipment, net                   | 3,172        | 2,871     | 793   |
| Intangible assets, net                        | 1,063        | 932       | 258   |
| Total non-current assets                      | 7,952        | 5,919     | 1,636   |
| Total assets                                  | 90,808       | 91,042    | 25,164  |
| Liabilities and equity<br>CURRENT LIABILITIES | 105          |           |   |
| Current maturities of long-term bank loan     | 137          | -         | -   |
| Accounts payable and accruals:                | 12 202       | 15 00 4   | 4.100   |
| Trade<br>OCS                                  | 12,283       | 15,084    | 4,169   |
|   | 6,148        | -         | -   |
| Other   | 5,443        | 3,870     | 1,070   |
| Total current liabilities                     | 24,011       | 18,954    | 5,239   |
| NON-CURRENT LIABILITIES                       |              |           |   |
| Retirement benefit obligations                | 143          | 143       | 40  |
| Warrants                                      | 10,725       | 8,858     | 2,448   |
| Total non-current liabilities                 | 10,868       | 9,001     | 2,488   |
| COMMITMENTS AND CONTINGENT LIABILITIES        |              |           |   |
| Total liabilities                             | 34,879       | 27,955    | 7,727   |
| EQUITY  |              |           |   |
| Ordinary shares                               | 1,837        | 2,294     | 634   |
| Share premium                                 | 464,629      | 498,910   | 137,897   |
| Capital reserve                               | 33,802       | 34,630    | 9,572   |
| Accumulated deficit                           | (444,339)    | (472,747) | (130,666)   |
| Total equity                                  | 55,929       | 63,087    | 17,437  |
| Total liabilities and equity                  | 90,808       | 91,042    | 25,164  |
| roun nuonnets une equity                      |              | 51,042    | 20,104  |

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

# **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

|  |                       |             |                       |          | Convenience<br>into U<br>(Note    | SD                              |
|--|-----------------------|-------------|-----------------------|----------|-----------------------------------|---------------------------------|
|  | Three month<br>June 3 |             | Six months<br>June 30 |          | Three months<br>ended<br>June 30, | Six months<br>ended<br>June 30, |
|  | 2012                  | 2013        | 2012                  | 2013     | 2013                              | 2013                            |
|  |                       | NIS in thou | sands                 |          | In thous                          | sands                           |
| RESEARCH AND DEVELOPMENT                       |                       |             |                       |          |                                   |                                 |
| EXPENSES, NET                                  | (16,000)              | (12,087)    | (30,675)              | (31,530) | (3,341)                           | (8,715)                         |
| SALES AND MARKETING EXPENSES                   | (948)                 | (1,063)     | (1,714)               | (1,834)  | (294)                             | (507)                           |
| GENERAL AND ADMINISTRATIVE                     |                       |             |                       |          |                                   |                                 |
| EXPENSES                                       | (2,956)               | (3,604)     | (6,481)               | (7,126)  | (996)                             | (1,970)                         |
| OPERATING LOSS                                 | (19,904)              | (16,754)    | (38,870)              | (40,490) | (4,631)                           | (11,192)                        |
| NON-OPERATING INCOME, NET                      | 2,712                 | 1,579       | 5,531                 | 13,841   | 436                               | 3,825                           |
| FINANCIAL INCOME                               | 6,050                 | 1,320       | 6,496                 | 1,983    | 365                               | 548                             |
| FINANCIAL EXPENSES                             | (172)                 | (1,713)     | (2,403)               | (3,742)  | (473)                             | (1,034)                         |
| COMPREHENSIVE LOSS FOR THE<br>PERIOD           | (11,314)              | (15,568)    | (29,246)              | (28,408) | (4,303)                           | (7,853)                         |
|  |                       | NIS         |                       |          | US                                | D                               |
| LOSS PER ORDINARY SHARE -<br>BASIC AND DILUTED | (0.06)                | (0.07)      | (0.18)                | (0.13)   | (0.02)                            | (0.04)                          |

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

# **BioLineRx Ltd.** CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

|  | Ordinary<br>shares          | Share<br>premium                           | Capital<br>reserve                                      | Accumulated<br>deficit | Total                                      |
|--|-----------------------------|--|---|------------------------|--|
|  |                             | N  | IS in thousands   |                        |  |
| BALANCE AT JANUARY 1, 2012   | 1,236                       | 421,274                                    | 31,317  | (368,069)              | 85,758                                     |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2012:  |                             |  |   |                        |  |
| Issuance of share capital , net  | 524                         | 35,143                                     | -   | -                      | 35,667                                     |
| Employee stock options exercised   | -                           | 42   | (42)  | -                      | -  |
| Employee stock options forfeited and expired   | -                           | 315  | (315)   | -                      | -  |
| Share-based compensation   | -                           | -  | 1,640   | -                      | 1,640                                      |
| Comprehensive loss for the period  |                             |  | -   | (29,246)               | (29,246)                                   |
| BALANCE AT JUNE 30, 2012   | 1,760                       | 456,774                                    | 32,600  | (397,315)              | 93,819                                     |
|  |                             |  |   |                        |  |
|  |                             |  |   |                        |  |
|  | Ordinary                    | Share                                      | Capital   | Accumulated            |  |
|  | Ordinary<br>shares          | Share<br>premium                           | Capital reserve   | Accumulated<br>deficit | Total                                      |
|  | 5                           | premium                                    | -   |                        | Total                                      |
| BALANCE AT JANUARY 1, 2013   | 5                           | premium                                    | reserve   |                        | <b>Total</b><br>55,929                     |
| BALANCE AT JANUARY 1, 2013<br>CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:  | shares                      | premium<br>N                               | reserve<br>IS in thousands                              | deficit                |  |
| -  | shares                      | premium<br>N                               | reserve<br>IS in thousands                              | deficit                |  |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:  | shares 1,837                | premium<br>N<br>464,629                    | reserve<br>IS in thousands                              | deficit                | 55,929                                     |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:<br>Issuance of share capital , net   | shares 1,837<br>455         | premium N<br>464,629<br>33,225             | reserve<br>IS in thousands<br>33,802                    | deficit                | 55,929                                     |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:<br>Issuance of share capital, net<br>Employee stock options exercised  | shares<br>1,837<br>455<br>* | premium<br>464,629<br>33,225<br>224        | reserve<br>IS in thousands<br>33,802                    | deficit                | 55,929<br>33,680                           |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:<br>Issuance of share capital , net<br>Employee stock options exercised<br>Warrants exercised   | shares<br>1,837<br>455<br>* | premium<br>464,629<br>33,225<br>224<br>258 | reserve<br>(S in thousands<br>33,802<br>-<br>(224)<br>- | deficit                | 55,929<br>33,680<br>-<br>260<br>-<br>1,626 |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:<br>Issuance of share capital , net<br>Employee stock options exercised<br>Warrants exercised<br>Employee stock options forfeited and expired | shares<br>1,837<br>455<br>* | premium<br>464,629<br>33,225<br>224<br>258 | reserve<br>(S in thousands<br>33,802<br>(224)<br>(574)  | deficit                | 55,929<br>33,680<br>-<br>260               |

\* Represents an amount less than 1,000

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

# **BioLineRx Ltd.** CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

|  | Ordinary<br>shares | Share<br>premium    | Capital reserve     | Accumulated deficit | Total   |
|--|--------------------|---------------------|---------------------|---------------------|---------|
|  | Co                 | onvenience translat | tion into USD in th | ousands (Note 1b)   |         |
| BALANCE AT JANUARY 1, 2013                   | 508                | 128,422             | 9,343               | (122,813)           | 15,460  |
| CHANGES FOR SIX MONTHS ENDED JUNE 30, 2013:  |                    |                     |                     |                     |         |
| Issuance of share capital, net               | 126                | 9,183               | -                   | -                   | 9,309   |
| Employee stock options exercised             | *                  | 62                  | (62)                | -                   | -       |
| Warrants exercised                           | *                  | 71                  | -                   | -                   | 71      |
| Employee stock options forfeited and expired | -                  | 159                 | (159)               | -                   | -       |
| Share-based compensation                     | -                  | -                   | 450                 | -                   | 450     |
| Comprehensive loss for the period            |                    | -                   |                     | (7,853)             | (7,853) |
| BALANCE AT JUNE 30, 2013                     | 634                | 137,897             | 9,572               | (130,666)           | 17,437  |

\* Represents an amount less than 1,000

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

# BioLineRx Ltd. CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

|  |                  |            | Convenience<br>translation<br>into USD<br>(Note 1b)<br>Six months<br>ended |
|--|------------------|------------|--|
|  | Six months endeo | l June 30, | June 30,   |
|  | 2012             | 2013       | 2013   |
|  | NIS in thous     | ands       | In thousands   |
| CASH FLOWS - OPERATING ACTIVITIES  |                  |            |  |
| Comprehensive loss for the period  | (29,246)         | (28,408)   | (7,853)  |
| Adjustments required to reflect net cash used in operating activities (see appendix below) | (7,178)          | (13,133)   | (3,629)  |
| Net cash used in operating activities  | (36,424)         | (41,541)   | (11,482)   |
| CASH FLOWS - INVESTING ACTIVITIES  |                  |            |  |
| Investments in short-term deposits   | (54,462)         | (75,008)   | (20,732)   |
| Maturities of short-term deposits  | 64,801           | 52,257     | 14,444   |
| Maturities of restricted deposits  | -                | 1,550      | 428  |
| Purchase of property and equipment   | (431)            | (132)      | (36)   |
| Purchase of intangible assets  | (18)             | (79)       | (22)   |
| Net cash provided by (used in) investing activities  | 9,890            | (21,412)   | (5,918)  |
|  |                  |            |  |
| CASH FLOWS - FINANCING ACTIVITIES  |                  |            |  |
| Repayments of bank loan  | (149)            | (127)      | (35)   |
| Issuance of share capital and warrants, net of issuance expenses                           | 52,453           | 46,101     | 12,742   |
| Proceeds from exercise of employee stock options   | *                | *          | *  |
| Net cash provided by financing activities  | 52,304           | 45,974     | 12,707   |
| INCREASE (DECREASE) IN CASH AND  |                  |            |  |
| CASH EQUIVALENTS   | 25,770           | (16,979)   | (4,693)  |
| CASH AND CASH EQUIVALENTS – BEGINNING<br>OF PERIOD   | 33,061           | 68,339     | 18,889   |
| EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS  | 4,988            | (1,128)    | (312)  |
| CASH AND CASH EQUIVALENTS - END OF PERIOD  | 63,819           | 50,232     | 13,884   |
|  |                  |            |  |

\* Less than 1,000

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

# **BioLineRx Ltd.** APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

|  | Six months end |          | Convenience<br>translation<br>into USD<br>(Note 1b)<br>Six months<br>ended<br>June 30, |
|--|----------------|----------|--|
|  | 2012           | 2013     | 2013   |
|  | NIS in tho     | Isands   | In thousands   |
| Adjustments required to reflect net cash used in operating activities: |                |          |  |
| Income and expenses not involving cash flows:                          |                |          |  |
| Depreciation and amortization  | 812            | 578      | 160  |
| Impairment of intangible assets  |                | 138      | 38   |
| Long-term prepaid expenses   | (7)            | 34       | 9  |
| Exchange differences on cash and cash equivalents                      | (4,988)        | 1,128    | 312  |
| Share-based compensation   | 1,640          | 1,626    | 450  |
| Warrant issuance costs   | 1,204          | 470      | 130  |
| Gain on adjustment of warrants to fair value                           | (6,735)        | (14,498) | (4,007)  |
| Interest and exchange differences on short-term deposits               | (641)          | 972      | 269  |
| Interest and linkage on bank loan                                      | (14)           | (10)     | (3)  |
| Interest and exchange differences on restricted deposits               | (31)           | 17       | 5  |
|  | (8,760)        | (9,545)  | (2,637)  |
| Changes in operating asset and liability items:                        |                |          |  |
| Decrease in trade accounts receivable and                              |                |          |  |
| other receivables  | 1,668          | 1,405    | 388  |
| Decrease in accounts payable and accruals                              | (86)           | (4,993)  | (1,380)  |
|  | 1,582          | (3,588)  | (1,500)  |
|  | (7,178)        | (13,133) | (3,629)  |
|  | 1.000          | 222      |  |
| Supplementary information on interest received in cash                 | 1,088          | 323      | 89   |

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

# NOTE 1 – GENERAL INFORMATION

# a. General

BioLineRx Ltd. ("BioLineRx") was incorporated and commenced operations in April 2003.

Since incorporation, BioLineRx has been engaged, both independently and through its consolidated entities (collectively, the "Company"), in the development of therapeutics, from early-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, BioLineRx registered a limited partnership, BioLine Innovations Jerusalem L.P. ("BIJ LP"), which commenced operations in January 2005. BioLineRx holds a 99% interest in BIJ LP, with the remaining 1% held by a wholly owned subsidiary of BioLineRx, BioLine Innovations Ltd. BIJ LP was established to operate a biotechnology incubator located in Jerusalem under an agreement with the State of Israel.

In February 2007, BioLineRx listed its securities on the Tel Aviv Stock Exchange ("TASE") and they have been traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") are also traded on the NASDAQ Capital Market.

In January 2008, BioLineRx established a wholly owned subsidiary, BioLineRx USA Inc. ("BioLineRx USA"), which served as the Company's business development arm in the United States. During 2011, the Company transferred its business development activities to Israel, and BioLineRx USA is no longer active.

The Company has been engaged in drug development since its incorporation. Although the Company has generated revenues from two outlicensing transactions, the Company cannot determine with reasonable certainty if and when the Company will have sustainable profits.

## b. Convenience translation into U.S. dollars ("dollars", "USD" or "\$")

For the convenience of the reader, the reported New Israeli Shekel ("NIS") amounts as of June 30, 2013 have been translated into dollars, at the representative rate of exchange on June 30, 2013 (\$1 = NIS 3.618). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

c. The condensed consolidated interim financial statements of the Company as of June 30, 2013, and for the three and six months then ended were approved by the Board of Directors on August 6, 2013, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.



#### NOTE 2 – BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of June 30, 2013, and for the three and six months then ended (hereinafter – the interim financial statements) have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" (hereinafter – IAS 34). These interim financial statements, which are unaudited, do not include all disclosures necessary for a complete presentation of financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements as of December 31, 2012 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The results of operations for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

#### NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2012 and for the year then ended.

#### NOTE 4 - ISSUANCES OF SHARE CAPITAL AND WARRANTS

#### a. Private placement of share capital and warrants to Orbimed

In February 2013, the Company completed a direct placement to leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC. The placement consisted of 2,666,667 ADSs and 1,600,000 warrants to purchase an additional 1,600,000 ADSs, at a unit price of \$3.00. The warrants have an exercise price of \$3.94 per ADS and are exercisable for a term of five years. The offering raised a total of \$8,000,000, with net proceeds of approximately \$7,700,000, after deducting fees and expenses.

The warrants are exercisable over a period of five years from the date of their issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current derivative financial liability. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

The amount of the direct placement consideration allocated to the warrants was approximately \$3,400,000, as calculated on the basis of the Black-Scholes model, which reflects their fair value as of the issuance date. The portion of total issuance costs allocable to the warrants, in the amount of approximately \$130,000, was recorded as non-operating expense on the statement of comprehensive loss. The change in fair value from the date of issuance through June 30, 2013, amounting to approximately \$2,350,000, has been recorded as non-operating income on the statement of comprehensive loss.

# NOTE 4 - ISSUANCES OF SHARE CAPITAL AND WARRANTS (cont.)

### b. Share purchase agreement with Lincoln Park Capital

In September 2012, BioLineRx and Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"), entered into a \$15 million purchase agreement (the "Purchase Agreement"), together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to \$15 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the Purchase Agreement.

During the six months ended June 30, 2013, BioLineRx sold a total of 1,844,136 ADSs to LPC for aggregate gross proceeds of \$4,830,000. In connection with these issuances, a total of 46,105 ADSs was issued to LPC as a commitment fee and a total of \$97,000 was paid to Oberon Securities as a finder's fee.

On a cumulative basis, from the effective date of the Purchase Agreement through the approval date of these financial statements, BioLineRx has sold a total of 2,490,503 ADSs to LPC for aggregate gross proceeds of \$6,630,000. In connection with these issuances, a total of 62,264 ADSs was issued to LPC as a commitment fee and a total of \$133,000 was paid to Oberon Securities as a finder's fee.

#### NOTE 5 - AT-THE-MARKET EQUITY OFFERING SALES AGREEMENT

In May 2013, BioLineRx and Stifel, Nicolaus & Company, Incorporated ("Stifel") entered into an at-the-market equity offering sales agreement, pursuant to which Stifel, may, at BioLineRx's discretion and at such times as BioLineRx shall determine from time to time, sell up to a maximum of \$20,000,000 of its ADSs through an "at-the-market" program (the "ATM Program").

The ATM Program allows BioLineRx, subject to the terms of the agreement, to raise capital at times and in amounts deemed suitable by it to support its business plans. BioLineRx is not required to sell any ADSs at any time during the term of the ATM Program.

BioLineRx will pay Stifel a commission equal to 3.00% of the gross sales price of the ADSs for amounts of ADSs sold pursuant to the agreement. BioLineRx agreed to reimburse Stifel for its out-of-pocket expenses, including reasonable fees and expenses of counsel, in connection with the ATM Program.

# NOTE 6 - SHAREHOLDERS' EQUITY

As of June 30, 2013 and December 31, 2012, share capital is composed of ordinary shares, as follows:

|                                  | Number of or                    | dinary shares           |
|----------------------------------|---------------------------------|-------------------------|
|                                  | December<br>31,<br>2012         | June 30,<br>2013        |
| Authorized share capital         | 750,000,000                     | 750,000,000             |
| Issued and paid-up share capital | 183,713,197                     | 229,475,578             |
|                                  |                                 |                         |
|                                  | In N                            | NIS                     |
|                                  | In M<br>December<br>31,<br>2012 | NIS<br>June 30,<br>2013 |
| Authorized share capital         | December<br>31,                 | June 30,                |

# NOTE 7 - RESEARCH AND DEVELOPMENT

- **a.** In March 2013, the Company decided to terminate the CLARITY study in connection with its BL-1020 therapeutic candidate for schizophrenia. As a result of the study termination, the Company reversed the remaining liability to repay grants previously received from the OCS in respect of BL-1020, amounting to NIS 6,148,000, since it became more likely than not that such liability would not be repaid.
- **b.** Trade accounts payable and accruals as of June 30, 2013 reflect an accrual of NIS 5,900,000 related to activities in respect of the CLARITY study, including study termination costs. Such amounts are reflected in research and development expenses.
- c. Research and development expenses are reflected net of research grants received from an interested (related) party of the Company, pursuant to a research funding arrangement for early development stage projects, as follows:

|  | Six months<br>June 3 |        |
|--|----------------------|--------|
|  | 2012                 | 2013   |
|  | NIS in tho           | usands |
| ants received from an interested party, offset against research and development expenses | 1,693                | 1,691  |

# NOTE 8 - NON-OPERATING INCOME, NET

|                                   | Six months en | ded June 30, |  |
|-----------------------------------|---------------|--------------|--|
|                                   | 2012          | 2013         |  |
|                                   | NIS in the    | ousands      |  |
| uance costs                       | 1,204         | 657          |  |
| Changes in fair value of warrants | (6,735)       | (14,498)     |  |
|                                   | 5,531         | 13,841       |  |

# NOTE 9 – AGREEMENT WITH CTTQ

In June 2013, the Company signed an out-licensing agreement with Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd. ("CTTQ"), the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV in the pre-clinical stages of development. Under the terms of the agreement, the Company granted CTTQ exclusive rights to develop, manufacture and commercialization milestones, for a total potential deal value of approximately \$30 million. In addition, the Company has the right to receive high single-digit royalties on future sales of the drug. The Company has retained the right to develop and commercialize BL-8030 in other parts of the world. As the technology transfer activities required under the agreement had not yet been completed as of June 30, 2013, no revenues were recorded during the quarter.

#### **OPERATING AND FINANCIAL REVIEW**

You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this 6-K, as well as in our Annual Report on Form 20-F filed on March 12, 2013 (the "Annual Report").

U.S. dollar amounts presented herein (other than amounts that were originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of June 30, 2013 (\$1 = NIS 3.618). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

#### **Forward Looking Statements**

The following discussion contains "forward-looking statements", including statements regarding expectations, beliefs, intentions or strategies for the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions, and are subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those listed below as well as those discussed in the Annual Report (particularly those in "Item 3. Key Information – Risk Factors"). Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our preclinical studies, clinical trials, and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- · competitive companies, technologies and our industry; and
- · statements as to the impact of the political and security situation in Israel on our business.

#### Overview

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of seven clinical therapeutic candidates: BL-1040, BL-5010, BL-8040, BL-7040, BL-8020, BL-1021 and BL-1020. In addition, we have four therapeutic candidates in pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. We also operate, with financial support of the Office of the Chief Scientist of the Israeli Ministry of Trade and Industry (OCS), a biotechnology incubator to evaluate therapeutic candidates. As of June 30, 2013, we have received approximately NIS 53.7 million (\$14.8 million) in funding from the OCS to operate the incubator, which does not include NIS 22.3 million (\$6.2 million) in funding we have received from the OCS outside of the incubator agreement as of that date. Such amounts include aggregate funding of approximately NIS 36.5 million (\$10.1 million) for terminated programs. We are not required to repay funds received for terminated programs. The incubator agreement with the OCS will terminate on December 31, 2013; we do not expect to receive significant future funding from this arrangement. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

The following is a description of our seven clinical therapeutic candidates:

- BL-1040 is a novel resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. BL-1040 is being developed as a medical device. In March 2010, we announced encouraging results from a phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing arrangement with Ikaria, Inc., or Ikaria, with respect to the development, manufacture and commercialization of BL-1040. In December 2011, Ikaria commenced PRESERVATION I, a CE Mark registration clinical trial of BL-1040 (initially called IK-5001, and now called the "Bioabsorbable Cardiac Matrix" device, or BCM device, by Ikaria).
- BL-5010 comprises a customized, proprietary pen-like applicator (BL-5010P) containing a novel formulation of two acids, which is being developed for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a phase 1/2 clinical trial of BL-5010. We have received European confirmation from the British Standards Institution Notified Body in the UK of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We are planning to commence a pivotal CE-Mark registration trial for European approval in the second half of 2013.
- BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for acute myeloid leukemia, or AML, and other hematological cancers. In June 2013, we announced the enrollment of the first patient in a phase 2 trial in the United States and receipt of regulatory approval from the Israeli Ministry of Health to conduct the trial in Israel.
- BL-7040 is an orally available synthetic oligonucleotide which we are developing for the treatment of inflammatory bowel disease, or IBD. In April 2013, we announced positive results from a phase 2a proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel.
- BL-8020 is an orally available treatment for the hepatitis C virus, or HCV, with a unique mechanism of action involving the inhibition of HCVinduced autophagy in host cells. We have recently commenced a phase 1/2 clinical trial to evaluate the safety, tolerability and effectiveness of BL-8020 at two sites in France.



- BL-1021 is a new chemical entity in development for the treatment of neuropathic pain. We are currently evaluating potential development collaborations with other parties in order to continue development of this compound.
- BL-1020 is an orally available drug in development for the treatment of schizophrenia. In March 2013, we announced that results from an interim analysis of the phase 2/3 CLARITY trial indicated that the trial would not meet its pre-specified primary efficacy endpoint. Based on these results, we discontinued the study, and are currently in the process of reviewing and cleaning the study data. We expect to receive a full analysis of the unblinded study data on all study patients in the third quarter of 2013, at which point we will make a decision about the future of this therapeutic candidate.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Ikaria. Under the agreement, we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart following AMI. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment of \$7.0 million upon the execution of the license agreement. Upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment of \$10.0 million in April 2010, and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the effectiveness of the agreement. In May 2011, following the acquisition of Cypress Bioscience by Royalty Pharma earlier in the year, we reacquired all of the rights to develop and commercialize BL-1020 from Cypress Bioscience and currently hold full global rights to the product. We commenced the phase 2/3 CLARITY trial in June 2011 and in March 2013, we announced that results from an interim analysis of the phase 2/3 CLARITY trial indicated that the trial would not meet its pre-specified primary efficacy endpoint. Based on these results, we discontinued the study, and are currently in the process of reviewing and cleaning the study data. We expect to receive a full analysis of the un-blinded study data on all study patients in the third quarter of 2013, at which point we will make a decision about the future of BL-1020.

In June 2013, we signed an out-licensing agreement with Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd., or CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV – see "Recent Company Developments."

We have funded our operations primarily through the sale of equity securities (both in direct and private placements and in three public offerings on the TASE), funding received from the OCS, payments received under the licensing arrangements with Ikaria and Cypress Bioscience, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone payments that we expect to receive from Ikaria and CTTQ, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of June 30, 2013, we held \$23.1 million of cash, cash equivalents and short-term bank deposits, based on the exchange rate reported by the Bank of Israel as of June 30, 2013.

### **Recent Company Developments**

#### Clinical and Pre-Clinical Development

In April 2013, we announced positive phase 2a results for BL-7040. The study showed that BL-7040 is safe and effective in treating ulcerative colitis, a form of IBD. The phase 2a trial was an open-label, proof-of-concept study to evaluate the efficacy, safety and tolerability of BL-7040 in patients with moderately active ulcerative colitis. Patients who completed the study were treated for five weeks with BL-7040: 12 mg/day for up to three weeks, followed by 40 mg/day for two additional weeks. The clinical trial was carried out at five leading medical centers in Israel.

In April 2013, we announced enrollment of the first patient in a phase 1/2 trial for BL-8020, an orally available, interferon-free treatment for HCV. The study is an open-label trial to evaluate the efficacy, safety and tolerability of BL-8020 in patients infected with HCV. It is being conducted at two clinical sites in France and will include HCV-infected patients of any genotype who have previously failed or relapsed following treatment with the standard-of-care.

In June 2013, we announced enrollment of the first patient in a phase 2 trial for BL-8040, for the treatment of acute myeloid leukemia (AML). The patient was enrolled at the MD Anderson Cancer Center in Houston. We also announced receipt of regulatory approval from the Israeli Ministry of Health to conduct the trial in Israel. The Israeli sites have all been initiated, and have commenced recruitment. In addition, we recently completed initiation of an additional premier US site – Northwestern University Memorial Hospital in Chicago – which is expected to commence recruitment in the next few weeks. The study is a multicenter, open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in adult subjects with relapsed or refractory AML. The primary endpoints of the study are the safety and tolerability of BL-8040. Secondary endpoints include the pharmacokinetic profile of the drug and an efficacy evaluation, as assessed by various parameters, such as the response rate by bone marrow biopsy. The study is also designed in a way that will enable the investigators to evaluate the capabilities of BL-8040 in mobilizing cancer cells from the bone marrow to the peripheral blood, and in inducing their cell death. Up to 50 patients are expected to be enrolled in the study, which is expected to be conducted at 8 sites in the U.S. and Israel.

In July 2013, we announced that we have filed the necessary regulatory submissions to commence a pivotal, CE-Mark registration trial for BL-5010P - for the non-surgical removal of skin lesions - with the German Federal Institute for Drugs and Medical Devices (BfArM), as well as with the relevant ethics committees. The pivotal study is a single-arm, open-label, bridging study of BL-5010P, a pen-like applicator containing BL-5010, a novel aqueous solution. The primary objective of the study is to assess the efficacy of a single application of BL-5010P for the removal of seborrheic keratosis (SK) lesions. Secondary objectives include safety and tolerability assessments of the cosmetic outcomes as evaluated by both patients and investigators, and the ability to preserve the treated SK lesions for histopathological diagnosis. Up to 20 patients are expected to be enrolled at three leading sites in Germany. The CRO and the sites have already been selected for the trial.

#### Addition and Termination of Therapeutic Candidates

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. In July 2013, we terminated our BL-5040 project for scientific considerations in light of experimental results. BL-5040 was intended to treat cachexia. Until its termination, BL-5040 was conducted by our incubator.

#### **Business Development**

In June 2013, we signed an out-licensing agreement with CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV. Under the terms of the agreement, we granted CTTQ exclusive rights to develop, manufacture and commercialize BL-8030 in China and Hong Kong. CTTQ will pay us an upfront license fee, plus future development, regulatory and commercialization milestones, for a total potential deal value of approximately \$30 million. In addition, we have the right to receive high single-digit royalties on future sales of the drug. We have retained the right to develop and commercialize BL-8030 in other parts of the world.

In May 2013, we entered into an at-the-market equity offering sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, whereby Stifel may, from time to time and as we may determine at our discretion, sell on our behalf up to \$20 million of our ADSs throughout the period during which the sales agreement remains in effect. In addition, we may also sell ADSs to Stifel as principal, in accordance with a separate terms agreement to be entered into between Stifel and us. As of the date of this report, we have not sold any ADSs through or to Stifel.

In September 2012, we entered into a \$15 million purchase agreement with Lincoln Park Capital Fund, LLC, or LPC, whereby LPC agreed to purchase, from time to time, up to \$15 million of our ADSs, subject to certain limitations, during the 36-month term of the purchase agreement. During the six months ended June 30, 2013, we sold a total of 1,844,136 ADSs to LPC for aggregate gross proceeds of \$4,830,000. In connection with these issuances, a total of 46,105 ADSs was issued to LPC as a commitment fee and a total of \$97,000 was paid to Oberon Securities as a finder's fee. On a cumulative basis, from the effective date of the purchase agreement through the approval date of these financial statements, we have sold a total of 2,490,503 ADSs to LPC for aggregate gross proceeds of \$6,630,000. In connection with these issuances, a total of 62,264 ADSs was issued to LPC as a commitment fee and a total of \$133,000 was paid to Oberon Securities as a finder's fee.

#### Revenues

Our revenues to date have been generated primarily from milestone payments under our licensing arrangements with Ikaria and the amounts we received from Cypress Bioscience. We entered into a license and collaboration agreement with Ikaria in 2009, in respect of which Ikaria paid us an up-front payment of \$7.0 million. In addition, upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment of \$10.0 million, which was subject to a 15% withholding tax in the United States. We received a full refund of the tax withheld from the U.S. Internal Revenue Service in the third quarter of 2011. In June 2010, we entered into a license agreement with Cypress Bioscience. Under the terms of the license agreement, we received an upfront fee of \$30.0 million. The license agreement with Cypress Bioscience was terminated, effective as of May 31, 2011.

Under the terms of our agreement with Ikaria, in addition to the payments mentioned above, the maximum future development-related payments to which we are entitled is \$115.5 million. We are also entitled to maximum commercialization milestone payments of \$150.0 million, subject to the terms and conditions of the license agreement. Certain payments we have received from Ikaria have been subject to a 15% withholding tax in the United States, and certain payments we may receive in the future, if at all, may also be subject to a 15% withholding tax in the United States. Receipt of any milestone payment under the Ikaria agreement depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments. We believe that we may be entitled to a refund of withholding taxes paid in connection with future payments from the U.S. government but there can be no assurance that we will be able to obtain such a refund. In addition, we may be able to use U.S. taxes withheld from future payments to us as credits against Israeli corporate income tax when we have income, if at all, but there can be no assurance that we will be able to realize the credits. Our payments to our in-licensors are to be made from the net consideration received from our out-licensees.

We expect our revenues for the next several years to be derived primarily from payments under our current agreements with Ikaria with regard to BL-1040, as well as additional collaborations that we may enter into in the future, including with regard to BL-5010, BL-8040, BL-7040, BL-8020, BL-1021, BL-1020 or other therapeutic candidates. Furthermore, we may receive future royalties on product sales, if any, under our agreements with Ikaria and CTTQ, as well as under any future agreement relating to BL-5010, BL-8040, BL-7040, BL-8020, BL-1021, BL-1020 or other compounds.

# **Research and Development**

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

| Project | Status   | Expected or Recent Near Term Milestone   |
|---------|--|--|
| BL-1040 | CE registration pivotal trial (conducted by Ikaria)  | PRESERVATION 1 study results expected in 2014  |
| BL-5010 | Completed phase 1/2 pilot study; regulatory<br>documents submitted for pivotal CE Mark<br>registration trial | Commencement of pivotal CE Mark registration trial in second half of 2013  |
| BL-8040 | Commenced phase 2  | Partial study results by end of 2013; commencement of clinical study for additional therapeutic indication in first half of 2014                             |
| BL-7040 | Phase 2 trial completed  | Clinical and business evaluation, including examination of potential additional indications; potential co-development collaboration or licensing transaction |
| BL-8020 | Commenced phase 1/2  | Partial study results expected by end of 2013/beginning of 2014  |
| BL-1021 | Completed phase 1a   | Potential co-development collaboration   |
| BL-1020 | Phase 2/3 CLARITY trial terminated   | Completion of full analysis of un-blinded study data on all study patients; final decision about future of therapeutic candidate                             |

In addition to the projects set forth above, the following table identifies our current portfolio of projects that are in the preclinical stages of development. Such projects have significantly lower costs due to their stage of development.

| Project        | Description          | Indication              | Status                       |
|----------------|----------------------|-------------------------|------------------------------|
| BL-7010        | Polymer              | Celiac disease          | Advanced preclinical studies |
| BL-8030        | Small molecule       | Hepatitis C             | Preclinical studies          |
| BL-7060/EDP 29 | Peptide              | Inflammatory diseases   | Preclinical studies          |
| BL-9010        | Bi-specific antibody | Severe allergies/Asthma | Preclinical studies          |

Set forth below is a summary of the gross direct costs allocated to our main projects on an individual basis, as well as the gross direct costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2010, 2011 and 2012; for the six months ended June 30, 2013; and on an aggregate basis since project inception. Certain of such costs are covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

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|   | Yea   | r Ended December | 31,                | Six Months<br>Ended June 30, | Since Project |
|---|-------|------------------|--------------------|------------------------------|---------------|
|   | 2010  | 2011             | 2012               | 2013                         | Inception     |
|   |       | (in the          | usands of U.S. dol | lars)                        |               |
| BL-1040   | 167   | 3                | -                  | -                            | 10,227        |
| BL-5010   | 384   | 94               | 132                | 64                           | 2,200         |
| BL-8040   | -     | -                | 723                | 1,894                        | 2,617         |
| BL-7040   | -     | 465              | 500                | 312                          | 1,277         |
| BL-8020   | -     | -                | 794                | 425                          | 1,219         |
| BL-1021   | 924   | 466              | 68                 | 7                            | 7,134         |
| BL-1020   | 450   | 2,765            | 7,448              | 4,440                        | 55,998        |
| Other projects                                  | 1,704 | 3,262            | 3,061              | 652                          | 25,597        |
| Total gross direct project costs <sup>(1)</sup> | 3,629 | 7,055            | 12,726             | 7,794                        | 106,269       |

(1) Does not include indirect project costs and overhead, including payroll and related expenses (including stock-based compensation), facilities, depreciation and impairment of intellectual property, which are included in total research and development expenses in our financial statements. Certain of such costs are also covered by OCS funding.

As indicated in the above table, a significant portion of our research and development costs have been incurred in connection with our BL-1020 project. As a result of the CLARITY study termination, it is likely that we will no longer incur significant additional costs in connection with the project.

From our inception through June 30, 2013, we have incurred research and development expense of approximately NIS 545.6 million (\$150.8 million). We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to remain our most significant cost as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Because of the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

#### Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

# **General and Administrative Expenses**

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

### **Non-Operating Expense and Income**

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the placements related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder's fees, as well as other one-time expenses, associated with the initial set-up of the Lincoln Park Capital share purchase agreement.

#### **Financial Expense and Income**

Financial expense and income consists of interest earned on our cash, cash equivalents and short-term bank deposits; bank fees and other transactional costs; and expense or income resulting from fluctuations of the dollar and other currencies, in which a portion of our assets and liabilities are denominated, against the NIS (our functional currency).

#### **Significant Accounting Policies and Estimates**

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2012.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

### **Results of Operations – Overview**

#### Revenues

We did not record any revenues during each of the three-month or six-month periods ended June 30, 2013 and 2012.

#### Cost of revenues

We did not record any cost of revenues during each of the three-month or six-month periods ended June 30, 2013 and 2012.

#### **Research and development expenses**

At December 31, 2011, our drug development pipeline consisted of 15 therapeutic candidates. During 2012, we added four new compounds to our pipeline and discontinued the development of five compounds from the pipeline, so that our drug development pipeline as of December 31, 2012 consisted of 14 therapeutic candidates. During the first six months of 2013, we added one new compound to our pipeline and discontinued the development of four additional compounds from the pipeline, so that our drug development of 11 therapeutic candidates.

# **Operating Results Comparison between Periods**

# Revenues and cost of revenues

See discussion under "Results of Operations - Overview" above.

# Research and development expenses

|   | Three months ended June 30, |        |                 | Six mo      | onths ended June 3 | 30,        |
|---|-----------------------------|--------|-----------------|-------------|--------------------|------------|
|   | Increase                    |        |                 |             | Increase           |            |
|   | 2012                        | 2013   | (decrease)      | 2012        | 2013               | (decrease) |
|   |                             |        | (in thousands o | of NIS)     |                    |            |
| Research and development expenses, net  | 16,000                      | 12,087 | (3,913)         | 30,675      | 31,530             | 855        |
| One-time reversal of liability to the OCS in  |                             |        |                 |             |                    |            |
| respect of BL-1020  | -                           | -      | -               | -           | 5,993              | 5,993      |
| "Normalized" research and development   |                             |        |                 |             |                    |            |
| expenses, net   | 16,000                      | 12,087 | (3,913)         | 30,675      | 37,523             | 6,848      |
| One-time reversal of liability to the OCS in<br>respect of BL-1020<br>"Normalized" research and development |                             |        | (3,913)         | -<br>30,675 | -,                 |            |

#### Comparison of three-month periods ending June 30, 2013 and 2012

Research and development expenses for the three months ended June 30, 2013 were NIS 12.1 million (\$3.3 million), a decrease of NIS 3.9 million (\$1.1 million), or 24%, compared to NIS 16.0 million (\$4.4 million) for the three months ended June 30, 2012. The decrease resulted primarily from lower expenses in 2013 associated with the CLARITY clinical trial in respect of BL-1020, due to termination of the trial in March 2013, offset by a ramp-up in spending on other clinical-stage projects introduced during 2012.

# Comparison of six-month periods ending June 30, 2013 and 2012

Research and development expenses for the six months ended June 30, 2013 were NIS 31.5 million (\$8.7 million), an increase of NIS 0.9 million (\$0.2 million), or 3%, compared to NIS 30.7 million (\$8.5 million) for the six months ended June 30, 2012. Without regard to the NIS 6.0 million one-time reversal of amounts previously accrued to the OCS in respect of BL-1020, research and development expenses increased by NIS 6.8 million (\$1.9 million). The increase resulted primarily from significantly higher expenses in the 2013 period associated with the CLARITY clinical trial, as well as a ramp-up in spending on other clinical-stage projects introduced during 2012.

# Sales and marketing expenses

|                              | Three    | Three months ended June 30, |              |           | onths ended June | 30,        |
|------------------------------|----------|-----------------------------|--------------|-----------|------------------|------------|
|                              | Increase |                             |              |           |                  | Increase   |
|                              | 2012     | 2013                        | (decrease)   | 2012      | 2013             | (decrease) |
|                              |          |                             | (in thousand | s of NIS) |                  |            |
| Sales and marketing expenses | 948      | 1,063                       | 115          | 1,714     | 1,834            | 120        |

# Comparison of three-month periods ending June 30, 2013 and 2012

Sales and marketing expenses for the three months ended June 30, 2013 were NIS 1.1 million (\$0.3 million), an insignificant increase compared to NIS 0.9 million (\$0.3 million) for the three months ended June 30, 2012. The small increase relates to professional fees and other expenses stemming from an increase in our business development efforts, compared to the second quarter of last year.



# Comparison of six-month periods ending June 30, 2013 and 2012

Sales and marketing expenses for the six months ended June 30, 2013 were NIS 1.8 million (\$0.5 million), an insignificant increase compared to NIS 1.7 million (\$0.5 million) for the six months ended June 30, 2012. The reason for the increase is similar to the one discussed above in the three-month comparison.

# General and administrative expenses

|                                     | Three months ended June 30, |       |               | Six m     | onths ended June | 30,        |
|-------------------------------------|-----------------------------|-------|---------------|-----------|------------------|------------|
|                                     | Increase                    |       |               |           |                  | Increase   |
|                                     | 2012                        | 2013  | (decrease)    | 2012      | 2013             | (decrease) |
|                                     |                             |       | (in thousands | s of NIS) |                  |            |
| General and administrative expenses | 2,956                       | 3,604 | 648           | 6,481     | 7,126            | 645        |

# Comparison of three-month periods ending June 30, 2013 and 2012

General and administrative expenses for the three months ended June 30, 2013 were NIS 3.6 million (\$1.0 million), an increase of NIS 0.6 million (\$0.2 million), or 22%, compared to NIS 3.0 million (\$0.8 million) for the three months ended June 30, 2012. The increase resulted primarily from a one-time expense for professional services incurred in the 2013 period.

# Comparison of six-month periods ending June 30, 2013 and 2012

General and administrative expenses for the six months ended June 30, 2013 were NIS 7.1 million (\$2.0 million), an increase of NIS 0.6 million (\$0.2 million), or 10%, compared to NIS 6.5 million (\$1.8 million) for the six months ended June 30, 2012. The reason for the increase is similar to the one discussed above in the three-month comparison.

# Non-operating income, net

|                           | Three months ended June 30, |       |               | Six months ended June 30, |        |            |
|---------------------------|-----------------------------|-------|---------------|---------------------------|--------|------------|
|                           | Increase                    |       |               |                           |        | Increase   |
|                           | 2012                        | 2013  | (decrease)    | 2012                      | 2013   | (decrease) |
|                           |                             |       | (in thousands | of NIS)                   |        |            |
| Non-operating income, net | 2,712                       | 1,579 | (1,133)       | 5,531                     | 13,841 | 8,310      |

# Comparison of three-month periods ending June 30, 2013 and 2012

We recognized net non-operating income of NIS 1.6 million (\$0.4 million) for the three months ended June 30, 2013, a decrease of NIS 1.1 million (\$0.3 million), compared to net non-operating income of NIS 2.7 million (\$0.8 million) for the three months ended June 30, 2012. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

# Comparison of six-month periods ending June 30, 2013 and 2012

We recognized net non-operating income of NIS 13.8 million (\$3.8 million) for the six months ended June 30, 2013, an increase of NIS 8.3 million (\$2.3 million), compared to net non-operating income of NIS 5.5 million (\$1.5 million) for the six months ended June 30, 2012. The reason for the increase is similar to the one discussed above in the three-month comparison.



# Financial income (expense), net

|                                | Three months ended June 30, |         |              | Six months ended June 30, |         |            |
|--------------------------------|-----------------------------|---------|--------------|---------------------------|---------|------------|
|                                | Increase                    |         |              |                           |         | Increase   |
|                                | 2012                        | 2013    | (decrease)   | 2012                      | 2013    | (decrease) |
|                                |                             |         | (in thousand | s of NIS)                 |         |            |
| Financial income               | 6,050                       | 1,320   | (4,730)      | 6,496                     | 1,983   | (4,513)    |
| Financial expenses             | (172)                       | (1,713) | 1,541        | (2,403)                   | (3,742) | 1,339      |
| Net financial income (expense) | 5,878                       | (393)   | (6,271)      | 4,093                     | (1,759) | (5,852)    |

### Comparison of three-month periods ending June 30, 2013 and 2012

We recognized net financial expense of NIS 0.4 million (\$0.1 million) for the three months ended June 30, 2013, a change of NIS 6.3 million (\$1.7 million), compared to net financial income of NIS 5.9 million (\$1.6 million) for the three months ended June 30, 2012. Net financial income and expense result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on our net assets denominated in dollars.

#### Comparison of six-month periods ending June 30, 2013 and 2012

We recognized net financial expense of NIS 1.8 million (\$0.5 million) for the six months ended June 30, 2013, a change of NIS 5.9 million (\$1.6 million), compared to net financial income of NIS 4.1 million (\$1.1 million) for the six months ended June 30, 2012. The reason for the increase is similar to the one discussed above in the three-month comparison.

# Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public (in Israel) and private offerings of our equity securities, grants and loans from the OCS, and payments received under our strategic licensing arrangements. At June 30, 2013, we held NIS 83.5 million (\$23.1 million) in cash, cash equivalents and short-term bank deposits.

In February 2013, we completed a direct placement to OrbiMed. The placement consisted of 2,666,667 ADSs and warrants to purchase an additional 1,600,000 ADSs, at a unit price of \$3.00. The warrants have an exercise price of \$3.94 per ADS and are exercisable for a term of five years. The offering raised a total of \$8.0 million, with net proceeds of approximately \$7.7 million, after deducting fees and expenses.

In May 2013, we entered into an at-the-market equity offering sales agreement with Stifel, whereby Stifel may, from time to time as we may determine at our discretion, sell on our behalf up to \$20 million of our ADSs throughout the period during which the sales agreement remains in effect. In addition, we may also sell ADSs to Stifel as principal, in accordance with a separate terms agreement to be entered into between Stifel and us. As of the date of this report, we have not sold any ADSs through or to Stifel.

Pursuant to the share purchase agreement with LPC signed in September 2012, we may sell, from time to time, and at our discretion, up to \$15 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through the date of this report, we have sold an aggregate of approximately \$6.6 million of our ADSs to LPC, leaving an available balance under the facility of approximately \$8.4 million.

Net cash used in operating activities was NIS 41.5 million (\$11.5 million) for the six months ended June 30, 2013, compared with net cash used in operating activities of NIS 36.4 million (\$10.1 million) for the six months ended June 30, 2012. The NIS 5.1 million (\$1.4 million) increase in net cash used in operating activities during the six-month period in 2013, compared to the six-month period in 2012, was primarily the result of increased research and development spending.

Net cash used in investing activities for the six months ended June 30, 2013 was NIS 21.4 million (\$5.9 million), compared to net cash provided by investing activities of NIS 9.9 million (\$2.7 million) for the six months ended June 2012. The cash flows related to investing activities primarily stem from investments in, and maturities of, our short-term bank deposits during the respective periods.

Net cash provided by financing activities for the six months ended June 30, 2013 was NIS 46.0 million (\$12.7 million), compared to net cash provided by financing activities of NIS 52.3 million (\$14.5 million) for the six months ended June 2012. The cash flows from financing activities primarily reflect the direct and private placements that we completed in February 2013 and 2012.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2015, we will require significant additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- · the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- · payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

#### **Off-Balance Sheet Arrangements**

Since inception, 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.