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INDEPENDENT EQUITY RESEARCH

Q1-2018 and 12 months since Initiation Updates 27 June, 2018

BIOLINERX is on track with its execution of multiple clinical development programs for the Company's lead product – BL-8040; the company has sufficient cash until H1-2020; target price remains unchanged as company's clinical development is in line with our expectations

Primary Exchange: TASE

Secondary exchange: NASDAQ
(ADS/share 1:1)

Ticker: TLV, NASDAQ: BLRX

Sector: Biotechnology

Industry: Drug Development

Data as at 27 June, 2018
(Source: TASE)

Closing price: NIS 3.3

Market cap: NIS 356.6M

# of shares: 108.0M

Stock performance (12 mos.): 7%

Daily-trading-vol. (12 mos.): NIS 367K

Stock target price: NIS 5.15

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Company Overview

BioLineRx Ltd. (hereinafter: "BioLineRx" or "the Company") is an Israeli clinical-stage biopharmaceutical company focused on oncology and immunology. In 2007, the company was listed on the Tel Aviv Stock Exchange (TLV:BLRX). In July 2011, the company registered American Depositary Shares (ADSs) with the NASDAQ (NASDAQ:BLRX). The Company in-licenses compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

Highlights & Analysis

On June 2018 BioLineRx announced the presentation of new overall survival data from Phase 2a study for BL-8040 in r/r AML patients

New data presented at the 23rd Annual Congress of the European Hematology Association (EHA), held in Stockholm, Sweden, shows that BL-8040, combined with high dose Cytarabine (HiDAC), significantly enhanced overall survival in difficult-to-treat relapsed or refractory AML (r/r AML) patients in a Phase 2a clinical trial.

BioLineRx released its quarterly report on May 22, 2018 detailing the following:

BiolineRx's quarterly progress is in line with our clinical development expectations for its Oncology programs, as per our Annual 2017 report dated 23 March, 2017.

- Partial results from Phase 2a COMBAT study, investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda® (pembrolizumab) in pancreatic cancer were encouraging and top-line results are expected in H2 2018.
- Positive results from Phase 2 study for BL-8040 as novel stem cell mobilization treatment for allogeneic bone-marrow transplantation
- Grant of European patent covering use of BL-8040 with Cytarabine for treating AML; valid through March 2034 with up to five years' patent term extension
- Initiation of Phase 3 study for BL-8040 as novel stem cell mobilization treatment, see below for details.
- A Phase 2b study as an AML consolidation treatment is ongoing with possible interim analysis on this study predicted for second half of 2018 and with top-line results expected in 2020.
- In addition, the company has a collaboration agreement with Genentech, a member of the Roche Group (VTX:ROG), to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML. Genentech commenced a Phase 1b/2 study for the treatment of pancreatic cancer in July 2017, Phase 1b/2 study in gastric cancer in October 2017. An additional Phase 1b/2 study in lung cancer will be initiated in 2018. In September 2017, BioLineRx initiated as well a Phase 1b/2 study under this collaboration in acute myeloid leukemia..

AGI-134 near-clinical therapeutic candidate's advancements:

- Presentation at ASCO-SITC positive pre-clinical data showing direct regression of established primary tumors in mice after injection with AGI-134
- Notice of Allowance issued by the United States Patent and Trademark Office (USPTO) for a patent application claiming the use of AGI-134 for the treatment of solid cancer tumors (when issued, will be valid until May 2035) with a possibility of up to five years patent term extension)
- Planned initiation of Phase 1/2a immuno-oncology study for AGI-134 in several solid tumor indications is expected in mid-2018

We update BioLineRx's equity value to $156.1M / NIS 557M, which remains within a target price ranging between NIS 5.01 and NIS 5.30; a mean of NIS 5.15. This corresponds to a mean value of $1.44 per ADS (representing one ordinary share).

- BioLineRx has a strong balance with adequate cash ($44.2M as of 31 March, 2018) to further support its clinical and regulatory strategy until early H1-2020 without additional capital raising.
- Pending achievements, several major clinical milestones forecasted for 2018 may increase the commercial market value of the company's stock.

Updates for Q1-2018

Q1-2018 Financial Results

Research and development expenses for the three months ending March 31, 2018 were $5.1 million, an increase of $1.5 million, or 41.2%, compared to $3.6 million for the three months ending March 31, 2017. The increase resulted primarily from higher expenses associated with new BL-8040 clinical studies commenced during 2017, spending on the new AGI-134 near-clinical project, and higher expenses related to the BL-1230 project.

Sales and marketing expenses for the three months ending March 31, 2018 were $0.5 million, a decrease of $0.2 million, or 28.9%, compared to $0.7 million for the three months ending March 31, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 incurred in the 2017 period.

General and administrative expenses for the three months ending March 31, 2018 were $1.1 million, similar to the comparable period in 2017.

Operating loss for the quarter ending March 31, 2018 amounted to $6.6 million, compared with an operating loss of $5.3 million for the quarter ending March 31, 2017.

Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of warrant liabilities. These fair-value adjustments were highly influenced by the Company's share price at each period end (revaluation date).

Net financial expenses for the 2018 period primarily relate to investment income earned on bank deposits, offset by losses recorded on foreign currency hedging transactions. The Company recorded an immaterial amount of net financial expenses for the three months ending March 31, 2018 compared to net financial income of $0.5 million for the three months ending March 31, 2017. Net financial income for the 2017 period relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits.

Net loss for the three months ending March 31, 2018 amounted to $6.2 million, compared with a net loss of $4.9 million for the corresponding period.

Cash and cash equivalents totaled $44.2 million as of March 31, 2018.

Net cash used in operating activities was $6.8 million for the three months ending March 31, 2018, compared with net cash used in operating activities of $3.8 million for the three months ending March 31, 2017. The $3.0 million increase in 2018, compared to the corresponding period in 2017, was the result of increased research and development expenses and a decrease in accounts payable.

Net Equity totaled $49 million for the company at 31 March, 2018 compared to $52.9 million at the corresponding date in 2017. The decrease in equity was partially offset by the increase in value of the company's shares and in capital reserves.

R&D highlights

BioLineRx Ltd. announced on June 2018, that it had presented at the 23rd Annual Congress of the European Hematology Association (EHA), held in Stockholm, Sweden, results showing that BL-8040, combined with

high dose cytarabine (HiDAC), significantly enhanced overall survival in difficult-to-treat relapsed or refractory AML (r/r AML) patients in a Phase 2a clinical trial.

In addition, an important new finding shows a statistically significant correlation between patient response and the mobilization of AML blasts. Responding patients demonstrated a clear and significant increase in the number of AML blasts in the peripheral blood following BL-8040 treatment, whereas non-responding patients were largely unaffected.

The Phase 2a study consisted of 42 patients in two cohorts: (i) dose-escalation (range 0.5-2.0 mg/kg) and (ii) dose-expansion at the selected dose of 1.5 mg/kg. Patients with r/r AML were treated daily with BL-8040 monotherapy for two days followed by combined administration of BL-8040 and HiDAC for 5 days, for 1-2 cycles. Efficacy endpoints included response rate (CR/CRi), overall survival, duration of response and event-free survival.

BL-8040 in combination with HiDAC was safe and well tolerated at all BL-8040 dose levels (range 0.5-2.0 mg/kg). The response rate for all dosing levels was 29% and median overall survival was 9.1 months, compared with historical data on overall survival of 6.1 months for HiDAC alone. In patients receiving the 1.5 mg/kg dose selected for expansion (n=23), the response rate was 39% and median overall survival was 10.7 months with 1-year, 2-year and 3-year survival rates of 38.1%, 23.8% and 23.8%, respectively.

Furthermore, median overall survival for responding patients at the 1.5 mg/kg dose (n=9) was 21.8 months, with 1-year, 2-year and 3-year survival rates of 66.7%, 44.4% and 44.4%, respectively. Responding patients also demonstrated a statistically significant mean 6.3-fold increase (p=0.003) in the number of AML blasts in the peripheral blood following BL-8040 monotherapy treatment, whereas in non-responding patients the mean-fold increase was minor and non-significant (1.66-fold; p=0.21).

In Q1-2018, BioLineRx has operated according to schedule and in line with its strategy executing multiple clinical trials for the Company's lead oncology program, BL-8040:

Partial monotherapy results from Phase 2a COMBAT study, investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda® (pembrolizumab), in pancreatic cancer, showed significantly increased infiltration of T cells into liver metastases in almost half of the pancreatic cancer patients who underwent a biopsy, as well as an increase in the number of total immune cells in the peripheral blood, alongside a decrease in the frequency of peripheral blood regulatory T cells (Tregs) – all of which support the mechanism of action proposed by pre-clinical studies. Study enrollment has been completed, with top-line results expected in H2-2018.

Results from Phase 2 study for BL-8040 as novel stem cell mobilization treatment for allogeneic bone-marrow transplantation support BL-8040 as a one-day dosing regimen for rapid mobilization of stem cells. Primary endpoint of collection of ≥2 million CD34 cells/kg recipient weight after up to 2 leukapheresis (LP) sessions was reached in over 90% of patients (100% of patients at optimal BL-8040 dose of 1.25 mg/kg); all 19 transplanted recipients were successfully engrafted with BL-8040-mobilized grafts, and preliminary graft-versus-host disease (GVHD) data are in line with current standard-of-care incidence rates.

Overall long-term survival results in Phase 2a trial in relapsed/refractory AML demonstrated that the combination of BL-8040 with high-dose Ara-C (HiDAC) significantly improved overall survival, compared with historical data of HiDAC monotherapy. In the BL-8040 dose selected for expansion (1.5 mg/kg), the overall response rate was 39% (N=23) and median overall survival for this cohort was 9.2 months with 1-year and 2-year survival rates of 31.6% and 21.1%, respectively.

Grant of European patent covering use of BL-8040 with Cytarabine for treating AML; valid through March 2034 with up to five years' patent term extension, thus providing significant additional patent protection in AML, one of BL-8040's key indications.

The Company also announced advancements made in its second immuno-oncology compound, AGI-134:

Pre-clinical data presented at ASCO-SITC showed direct regression of established primary tumors after injection with AGI-134 in the majority of mice treated, and that this regression is associated with activation of the innate immune system;

Notice of Allowance issued by the United States Patent and Trademark Office (USPTO) for a patent application claiming the use of AGI-134 for the treatment of solid cancer tumors; this patent, when issued, will be valid until May 2035 with a possibility of up to five years patent term extension. Additional corresponding patent applications for AGI-134 are pending in Europe, Japan, China, Canada, Australia and Israel.

In light of the company's progress this quarter with regard to the AGI-134 project, it is rather apparent that the company will most likely move forward with this asset towards clinical trials in pursuit of eventual market approval. In consequence, we have now incorporated this project into our valuation.

The company expects to achieve a number of key milestones in 2018.

- Partial results from the lead-in part of the Phase 3 GENESIS study in stem-cell mobilization for autologous transplantation are due mid-year 2018;
- Top-line results in immuno-oncology Phase 2a COMBAT study in pancreatic cancer for BL-8040 in combination with KEYTRUDA, under collaboration with Merck, expected in H2 2018;
- Initiation of Phase 1/2a immuno-oncology study for AGI-134 in several solid tumor indications expected in mid-2018;
- Additional overall long-term survival data from Phase 2a trial in relapsed/refractory AML to be presented at EHA in June 2018;
- Full top-line results of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation to be presented at the 23rd Congress of European Hematology Association (EHA) in June 2018.

Analysis

With respect to the Company's clinical development of its Oncology programs, BioLineRx has progressed in line with our expectations as per our **Q4-2017 and Annual analysis report** (published 23 March, 2018). The Company has initiated several clinical studies for its lead asset, BL-8040; including a first pivotal Phase 3 study in autologous stem-cell mobilization, as well as a number of studies under the Company's immunotherapy collaborations with Genentech, MSD and MD Anderson Cancer Center.

BioLineRx has one Phase 3 and several Phase 2 or 1b/2 clinical trials underway. The company is also planning to commence a first-in-man study with their AGI-134 product in patients with solid tumors in mid-2018. Furthermore, the Company has announced partial results of its Phase 2 study in pancreatic cancer, under its immunotherapy collaboration with Merck. **Thus, clinical development is on track with the company's strategy being to continuously execute multiple clinical development programs for its lead asset, BL-8040** and new asset AGI-134.

On the financial side, BioLineRx has a strong cash balance with adequate funds ($44.2M as of 31 March, 2018) to **support clinical and regulatory strategy till H1-2020, without the need to raise additional capital**.

We update BioLineRx's equity value to $156.1M / NIS 557M, which remains within a target price ranging between NIS 5.01 and NIS 5.30; a mean of NIS 5.15. Thus, 1 ADS (representing 1 ordinary share) is equal to $1.44.[1]

Valuation of AGI-134 for the Treatment of Solid Cancer Tumors

Establishing the pipeline value of BioLineRx's AGI-134 pre-clinical asset for the treatment of solid cancer tumors is rather complicated, for a number of reasons. Firstly, the product is in pre-clinical phases, and although results to date have been relatively positive, the product hasn't even begun the prolonged approval process. Secondly, the company has to date not indicated which specific indications the asset will target, merely describing them under the umbrella term 'solid cancer tumors'. Finally, very few companies have adopted a similar clinical development program to a degree of similarity acceptable for use in evaluating BioLineRx's program.

Valuation Components

According to Paul *et al.* pre-clinical success rates were reported as follows;[2] 51% for discovery research, 69 % for preclinical development, 12.8% for the clinical development phases, 91% for the submission phase - resulting in an overall probability of technical and regulatory success (PTRS) for drug R&D of 4.1%.

We use BioLineRx's BL-8040 for pancreatic cancer and multiple solid tumors (partnership with Genentech) as a future benchmark given that is intended to treat the same general indication of 'multiple solid tumors' and thus appeals to the same patient population.

- The BL-8040 for pancreatic cancer and multiple solid tumors pipeline has an rNPV of $115.1M
- If we bring the success factor for that indication to 100% the asset in treating multiple solid tumors will have an rNPV of $306.2M.[3]

We then apply Paul *et al's* success factor of 4.1% to estimate the AGI-134 asset at approx. **$12.55M** on the eve of initiation of phase 1/2a clinical trials expected to be announced in H2-2018.

- While the roughness of our estimate is a product of the scarcity of information and certainty we can draw a certain degree of confidence from the market.

[1] NIS/$ Calculation: NIS 5.15/3.58 = $1.44
[2] Paul SM, et al. How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nat Rev Drug Discov. 2010; 9:203–214.
[3] Our valuation methodology and parameters are broken down in detail in our **Initiation of Coverage Report (20 July, 2017)**

- Aside from a couple of research groups working on the Intratumoral Injection of α-gal Glycolipids and gal vaccines, there is also a company called Avinity which has similar MoA.

Alphamer technology, proprietary to Centauri Therapeutics and licensed exclusively to Avvinity Therapeutics for oncology applications, is based on chemically synthesized molecules that fuse modified nucleic acid aptamers against proteins overexpressed on the surface of tumor cells with alpha-gal epitopes: a trisaccharide present on the membranes of many organisms, but absent in humans due to the mutation of the GGTA1 gene in evolution.

In March 2016, Horizon Discovery Group (**LSE:HZD**) a leading international gene company announced the formation of an immune-oncology JV with Avvinity and Centauri, in which for a £2.5M immediate investment and an addition £2.8M commitment to be paid pending the success of clinical programs and at the investor's discretion, Horizon would acquire 49.99% of Avvinity's equity.

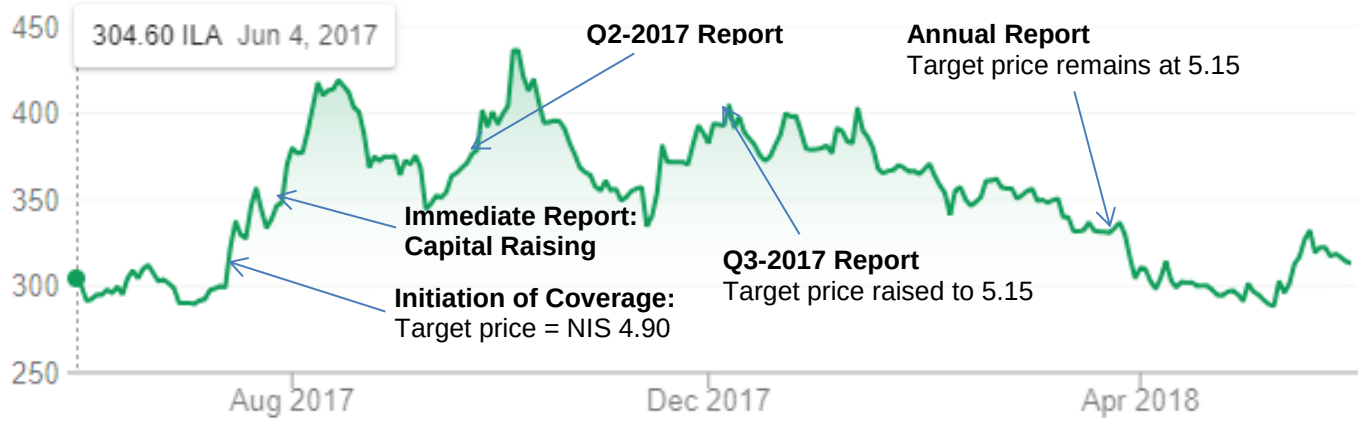
Under the terms of this deal total value of Avvinity at the time of the transaction, and taking into account the GBP=USD exchange rate at the date of its announcement; the company's equity value would have been.

EV = (£2.8M + £2.5M)*2 = £10.6M $EV_{\$}$ = 10.6M*1.41 = **$15M**.

We take the conservative figure from these two calculations and evaluate the AGI-134 asset at $12.55M.

12-Month Stock Movement

Source: Google Finance



Credit to Experts: Dr. Tiran Rothman; Dr. Anna Cirmirakis; Daniel Grunstein

Upcoming Potential Catalysts

Program	Event	Significance	Timeline	Status
BL-8040	Completion of Phase 2 (allogeneic SCM) Top-line results of Phase 2 (allogeneic SCM)	Medium Medium	H1-2018 H1-2018	Achieved Achieved
	Top Line Results Phase 2 study in stem-cell mobilization	Medium	Mid-2018	Achieved
	Initiation of Phase 3 GENESIS study (autologous SCM)	Medium	Q4-2017	Achieved
	Partial results from lead-in part of the Phase 3 GENESIS study (autologous SCM)	High	Mid-2018	On Track
	Top-line results from full study	High	2020	On Track
	Partial results Phase 2 COMBAT (pancreatic cancer, combination with Merck's KEYTRUDA)	Medium	Q1-2018	Achieved
	Top-line results Phase 2 COMBAT (pancreatic cancer, combination with Merck's KEYTRUDA)	High	H2-2018	On Track
	Initiation of Phase 1b/2 with Genentech's atezolizumab (pancreatic cancer)	Low	Q3-2017	Achieved
	Partial results Phase 1b/2 with Genentech	Low	H2 2018	On Track
	Top Line results	High	2019	On Track
	Initiation of Phase 1b/2 Genentech's atezolizumab (gastric cancer)	Low	Q3-2017	Achieved
	Partial results Phase 1b/2 with Genentech	Low	H2 2018	On Track
	Top Line results	High	2019	On Track
	Initiation of Phase 1b/2 Genentech's atezolizumab (non-small cell lung cancer)	Low	2018	On Track
	Initiation of Phase 1b/2 with Genentech's atezolizumab (AML)	Low	Q4-2017	Achieved
	Top Line Results	High	2019	On Track
	Top Line results Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center	High	H2-2018	On Track
	Possible Interim Phase 2b results (AML consolidation)	Medium	H2-2018	Likely
	Top-Line Phase 2b results (AML consolidation)	High	2020	Likely
AGI-134	Initiation of Phase 1/2a (multiple solid tumors)	High	Mid-2018	On Track
BL-5010	Gradual roll out of commercial launch	Low	2020-2021	On track

Sources: Frost & Sullivan Analysis; BioLineRx.

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Investment Thesis

BioLineRx Ltd. is an Israeli publicly-traded, specialty biopharmaceutical company focused on the in-licensing and clinical development of therapeutics for oncology and immunology. BioLineRx, headquartered in Modi`in, Israel, was incorporated and commenced operations in April 2003. In 2007, the company was listed on the Tel Aviv Stock Exchange (TASE). In July 2011, the company registered American Depositary (ADSs) in the NASDAQ Capital Market. Investors can view the company as a large clinical "lab" that licenses advanced candidates in pre-clinical phases and transforms them into commercially-ready drugs.

BioLineRx is currently advancing a lead clinical program, BL-8040, in multiple clinical studies: Phase 3 study for autologous bone-marrow transplantation (BMT), completed Phase 2 for allogeneic BMT, Phase 2b for consolidation AML, Phase 1b/2 study, in combination with Atezolizumab, for maintenance AML, Phase 2a for pancreatic cancer in combination with MSD's KEYTRUDA® (pembrolizumab), and multiple Phase 1b/2 studies for gastric cancer and pancreatic cancer in combination with Genentech TECENTRIQ® (atezolizumab). It also plans a Phase 1b/2 study for non-small lung cancer in combination with Genentech TECENTRIQ® to be initiated in 2018. The Company has two pre-clinical ongoing studies: one with AGI-134: an immunotherapy treatment for multiple solid tumors, with clinical studies expected to commence in mid-2018; and one program with Novartis for dry eye syndrome. In addition, the Company out-licensed their BL-5010 drug for treatment of skin lesions to Perrigo (**NYSE/TLV:Perrigo**).

BioLineRx has an experienced management team, Board of Directors and Oncology Scientific Advisory Board with a successful track record at big and small pharma of bringing patented drugs to the market, as well as extensive managerial, financial, and transactional expertise to support its clinical and business progress. Furthermore, the company pipeline is generated by systematically identifying, validating and in-licensing therapeutic candidates. Over 2,000 compounds have already been systematically screened and evaluated, of which over forty commenced development.

However, after a decade of working in the "classic" business model used by many small drug development companies, of in-licensing pre-clinical compounds and out-licensing them during late clinical stages, the company has not yet launched a significant drug into the market.

We see the company as a long-term investment opportunity in the field of Immuno-Oncology for cancer treatment. In the coming year, several significant events are expected that will impact the company significantly. While Immuno-Oncology is a promising domain, there are significant clinical, regulatory and commercialization associated risk. In our view, BioLineRx's market capitalization is less than the true value, of the multiple clinical indications under development, the company's recent acquisition, and cash to fund clinical development until H1-2020.

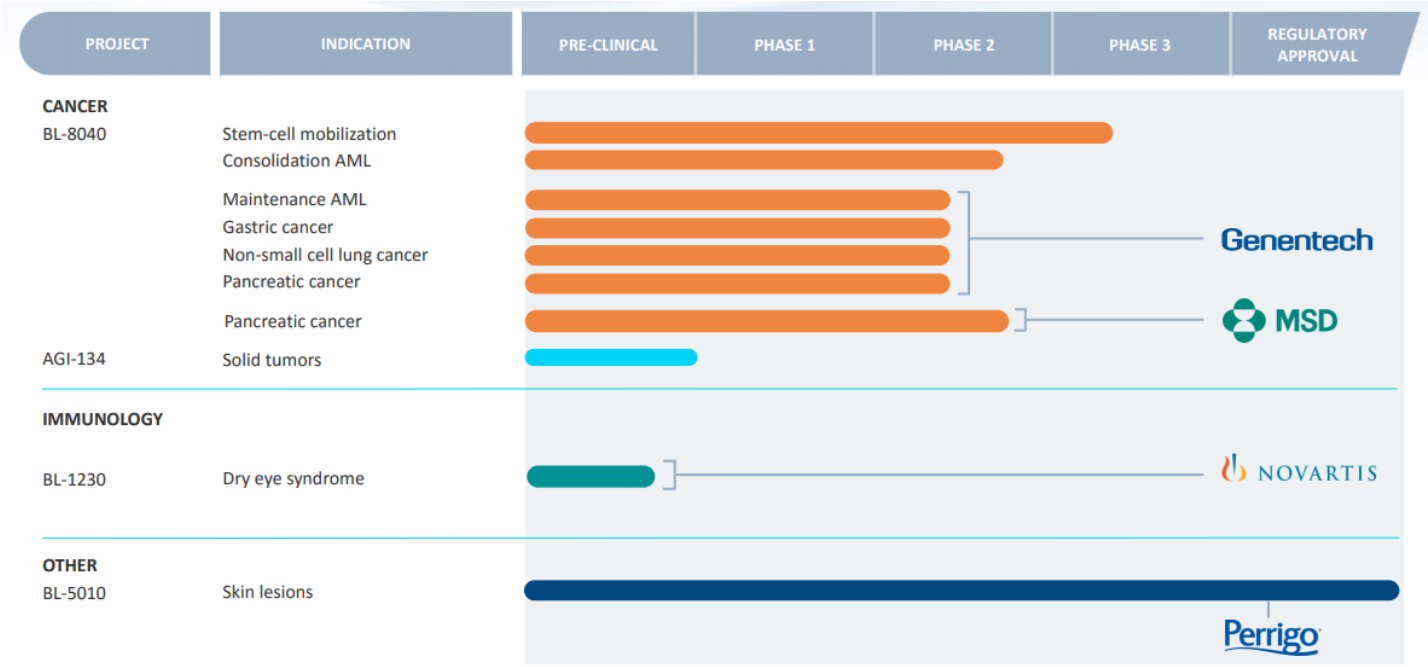
Pipeline Summary

BioLineRx is currently advancing multiple clinical programs. Key programs are:

BL-8040 -a short cyclic peptide for: SCM (initiated Phase 3 study in Q4 2017 for autologous bone-marrow transplantation (BMT) and completed Phase 2 for allogeneic BMT), AML (consolidation AML Phase 2b study ongoing and maintenance AML Phase 1b/2 study, in combination with Atezolizumab ongoing), pancreatic cancer in combination with MSD's KEYTRUDA® (pembrolizumab), (Phase 2a study ongoing), and gastric cancer, non-small cell lung cancer and pancreatic cancer in combination with Genentech TECENTRIQ® (atezolizumab) (Phase 1b/2 studies ongoing and for non-small lung cancer planned for 2018)

BL-5010 -a proprietary, pen-like applicator containing a novel, acidic, aqueous solution for treatment of skin lesions. The rights to the product in Europe, and a few additional regions, were out-licensed to Perrigo. The BL-5010 received a CE Mark in Q2 2016, and is being commercialized as a medical device in Europe; however, it is not a major driver for the Company.

The diagram below represents the estimated timeline per indication in the pipeline. This is subject to changes in development plans and regulatory requirements/clarifications, including complementary /additional studies.



Source: BiolineRx Corporate Presentation, June 2018

Note the company advised in their quarterly report that though they continue to actively source, rigorously evaluate and in-license selected therapeutic candidates, during the reporting period the company terminated BL-9020 in light of scientific, regulatory and commercial considerations. BL-9020 was being investigated as a treatment of Type 1 diabetes. The company has also terminated BL-1210/BL1220 investigated for the treatment of liver fibrosis and for the treatment of numerous liver failure conditions such as end-stage liver disease (ESLD) and for conditions potentially leading to liver failure such as NASH respectively.

Market, Standard of Care and Unmet Needs

The three key indications for BL-8040 are **acute myeloid leukaemia, stem cell mobilization and pancreatic cancer**, which we will elaborate on in the following sections:

Acute Myeloid Leukaemia

Acute myeloid leukaemia (AML) is an aggressive form of a blood cancer with an unknown aetiology. It begins in the bone marrow when stem cells overproduce immature white blood cells. Those immature white blood cells are called blast cells and they quickly spread into the bloodstream from where they can often metastasize to other organs and tissues.

AML is the most common type of leukaemia in adults (uncommon before the age of 45) and if left untreated it progresses quickly and aggressively and can be fatal. AML continues to have the lowest survival rate of all leukaemias. Some key environmental factors such as chemical and radiation exposure have been shown to increase the risk for AML.

The highest rates of AML are observed in the United States, Australia and Europe. AML predominantly affects elderly people, and it has been estimated by the American Cancer Society that there will be approximately 19,520 new cases and 10,670 deaths from AML in the United States in 2018.[4] The annual incidence rate of AML in Europe is estimated to be 1/33,000 - 1/25,000.[5] The 2018 global AML disease therapeutics market was estimated at $1,014 million. Over the coming years, this market is predicted to expand at a CAGR of 28.4% and reach $1.67 billion by 2020.[6]

Treatment for AML is primarily determined by a patient's age, performance status and cytogenetics. The current standard of care for AML includes intensive chemotherapy, radiation therapy, and stem cell transplant.

After receiving remission induction chemotherapy, over 90% of patients will have a recurrence of the disease. To prevent this from happening, consolidation therapy follows immediately after a patient recovers from the remission induction therapy. Not all patients would be eligible for the intensive therapy due to debilitating side effects of this treatment. In most cases, only patients younger than 60 years old qualify for this therapy. According to BioLineRx management, the majority of patients achieving complete remission at the induction treatment will continue to consolidation treatment. CR rates at induction are estimated at 60%-70%.

The most commonly used chemotherapy drugs for treating AML are cytarabine (cytosine arabinoside or ara-C) and the anthracycline drugs (such as daunorubicin (daunomycin), idarubicin, and mitoxantrone). Other chemotherapy drugs used are: Cladribine (Leustatin®, 2-CdA) Fludarabine (Fludara®); Topotecan; Etoposide (VP-16); 6-thioguanine (6-TG), Hydroxyurea (Hydrea®); corticosteroid drugs, such as prednisone or dexamethasone (Decadron®), methotrexate (MTX), 6-mercaptopurine (6-MP, Azacitidine (Vidaza®); and Decitabine (Dacogen®) to name a few.

Current treatment guidelines of AML have not changed dramatically over the past years.[7] With increased knowledge about the underlying causes of the AML, one would expect to observe new viable treatments to enter the market. It has been observed that one in three people diagnosed with AML has a mutation in the *FLT3* gene. There were no new drugs approved during the last 25 years, until April 2017, when Novartis

[4] https://www.cancer.org/content/dam/CRC/PDF/Public/8674.00.pdf Accessed on 5th of May 2018
[5] OrphaNet (2014). "Acute myeloid leukemia." http://www.orpha.net/consor4.01/www/cgi-bin/OC_Exp.php?lng=EN&Expert=519 Accessed January 27, 2016.
[6] https://www.thepharmaletter.com/article/acute-myeloid-leukemia-market-to-be-worth-1-67-billion-by-2020
[7] T. M. Kadia, F. Ravandi, J. Cortes, H. Kantarjian; New drugs in acute myeloid leukemia. Ann Oncol 2016; 27 (5): 770-778. doi: 10.1093/annonc/mdw015

announced FDA approval of their Rydapt® for newly diagnosed patients who are FMS-like tyrosine kinase 3 mutation-positive (FLT3+), hence opening new treatment options for approximately 30% of diagnosed patients. There are some AML cases that can be explained by changes in the c-KIT gene. Alternative treatments that are being evaluated in clinical trials for the treatment of AML are categorized as targeted therapies, such as small molecule inhibitors of serine-threonine proteins kinases, immunological agents against tumor-associated antigens/genes, and antagonists against cell-surface receptors as well as monoclonal antibodies.

The pipeline is very extensive (100+ drug candidates) and only several promising drug candidates in late clinical trials are shown below.

Drug Pipeline for AML (adapted from new drugs in acute myeloid leukemia[8,9]

Agent	Company	Mode of action	Clinical trial	Notes
Bisantre	Race Oncology (ASX:RAC)	RNA synthesis inhibitor/DNA inhibitor	Registered	Anthracycline-related cytostatic
Vyxeos (CPX-351)	Jazz Pharmaceuticals (NASDAQ:JAZZ)	Cytotoxic; liposomal formulation of cytarabine and daunorubicin in 5:1 molar ratio	Market approval[10]	CPX-351 versus 7 + 3 exhibited improved outcomes in patients with secondary AML
Volasertib	Boehringer Ingelheim	Polo-like kinase 1 inhibitor/Protein kinase inhibitor/Apoptosis stimulant/Cell cycle inhibitor	Phase 3 Study	2nd-generation dihydropteridinone polo-like kinase 1 inhibitor. Volasertib combined with LDAC demonstrated improved outcomes over LDAC.
Sapacitabine	Sankyo	Cytotoxic; orally bioavailable novel nucleoside analog	Phase 3 Study – Failed[11]	Sapacitabine had outcomes similar to low-dose cytarabine (LDAC), but sequential combination study with decitabine showed promising results.
SGI-110	Astex Pharmaceuticals	Cytotoxic; longer acting hypomethylating agent	Phase 3 Study	Single-agent activity in AML and myelodysplastic syndrome seems promising.
AG-221	Agios Pharmaceuticals (NASDAQ: AGIO)	Small-molecule inhibitor of isocitrate dehydrogenase (IDH)-2 enzyme	Market Approval[12]	Single-agent studies demonstrated significant activity in patients with IDH2-mutated AML. Combination studies with conventional chemotherapy have been planned.
Gilteritinib ASP-2215	Kotobuki Pharmaceutical (TYO:7809) in collaboration with Astellas (TYO:4503)	Small molecule both FLT3 and AXL kinases	Phase 3 Study	Single-agent studies are just underway, with preliminary data anticipated.
Midostaurin		Small-molecule multikinase inhibitor with activity against	FDA approved	7 + 3 with our without midostaurin in newly diagnosed patients with FLT3-mutated AML demonstrated

[8] T. M. Kadia, F. Ravandi, J. Cortes, H. Kantarjian; New drugs in acute myeloid leukemia. Ann Oncol 2016; 27 (5): 770-778. doi: 10.1093/annonc/mdw015
[9] Evaluate Pharma
[10] https://www.onclive.com/web-exclusives/fda-approves-cpx351-for-two-types-of-aml
[11] https://www.genengnews.com/gen-news-highlights/cyclacel-phase-iii-sapacitabine-aml-study-fails-to-meet-primary-endpoint/81253923
[12] http://www.pmlive.com/pharma_news/celgene,_agios_get_fda_ok_for_leukaemia_drug_idhifa_1200158

		mutant FLT (FLT-ITD) in AML		significant improvement in event-free- and overall survival among younger patients (median age 48 years) in the midostaurin treated arm.
Quizartinib	Ambit Biosciences (Acquired by Daiichi-Sankyo (**TYO:4568**))	Small-molecule multikinase inhibitor with potent activity against FLT3-ITD	Phase 3 Study - Complete[13]	Single-agent dose-finding studies have demonstrated efficacy, but DLT is QT prolongation. Lower doses of quizartinib have demonstrated similar activity but less toxicity. These are now being studied in combination studies.
SGN-CD33A	Seattle Genetics (**NASDAQ:SGEN**)	Monoclonal antibody-drug conjugate directed at CD33, carrying a pyrrolobenzodiazepine dimer (toxin)	Phase 3 Study	Single-agent and combination studies are underway in several clinical settings. Preliminary experience is positive, demonstrating good safety profile and efficacy in clearing bone marrow blasts.
Idasanutlin	Roche	MDM2 inhibitor	Phase 3 Study	Small molecule that activates the p53 pathway by preventing the binding between the p53 and its inhibitor MDM2

The major unmet needs in current AML disease management include treatment of older patients. The 5-year overall survival (OS) among patients over the age of 60 years is in the range of 10%–20%, highlighting the clear need for newer therapies to address those patients.

AML has the lowest survival rates and, as previously mentioned, while one in nine patients require intensive therapy, they will not necessarily qualify for it. Companies are looking at alternative treatments that are less invasive and have fewer side effects. Based on the company`s understanding, physicians are very concerned about remission durations and rates. The understanding in this field is that minimal-residual disease (MRD) is a critical factor in determining the duration of response, and this specifically where we assume BL-8040 can contribute.

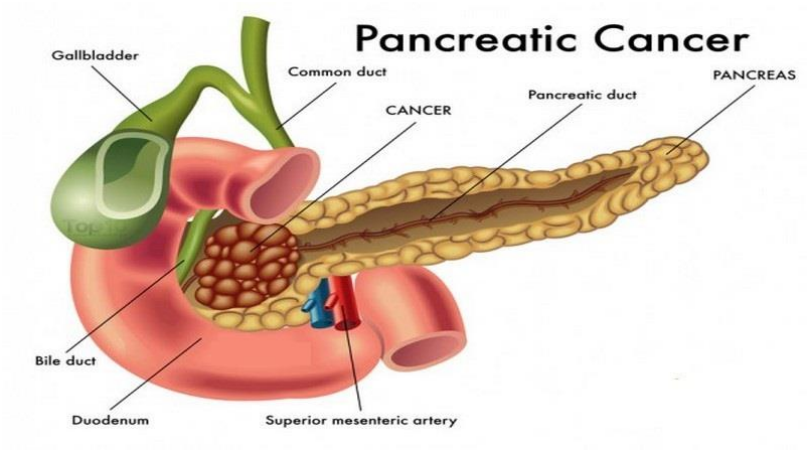
Pancreatic Cancer

Pancreatic cancer is caused by the uncontrolled and abnormal growth of cells in the pancreas. Depending on the origin of the cancerous cells it can be classified as:

- Ductal adenocarcinoma, which starts from cells in the lining of the pancreatic ducts (95% of all cases);
- Ampullary cancer, which starts from cells in the hepatopancreatic duct;
- Cystic tumors, with cancerous cells being found in the cysts in the pancreas;
- Acinar cell carcinomas, which starts from the cells that make pancreatic juice;
- Neuroendocrine tumors, which starts from the endocrine cells;
- Lymphoma, which starts from the lymphatic tissue in the pancreas.

[13] https://www.prnewswire.com/news-releases/daiichi-sankyo-announces-single-agent-quizartinib-significantly-prolongs-overall-survival-compared-with-chemotherapy-in-patients-with-relapsedrefractory-aml-with-flt3-itd-mutations-quantum-r-study-300643962.html

Diagram of the pancreas and pancreatic cancer[14]

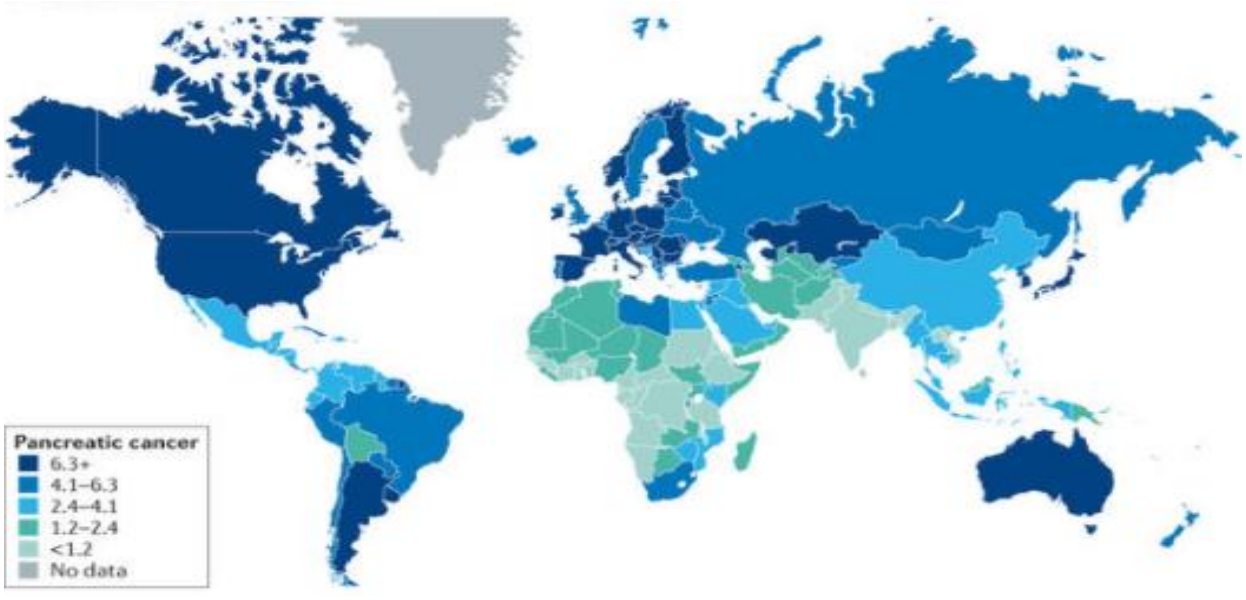


Pancreatic cancer is a major cause of cancer-associated mortality and it is the 10th most common cancer, excluding non-melanoma skin cancer. The highest rates of pancreatic cancer are observed in the United States, Australia and Europe.[15]

Pancreatic cancer is more common in older people, with 50% of all new cases diagnosed in people aged 75 or over. Statistics show that 1 in 71 people will be diagnosed with pancreatic cancer during their lifetime.[16] It has been estimated by the American Cancer Society that there will be approximately 55,440 new cases and 44,330 deaths from pancreatic cancer in the United States in 2018.[17]

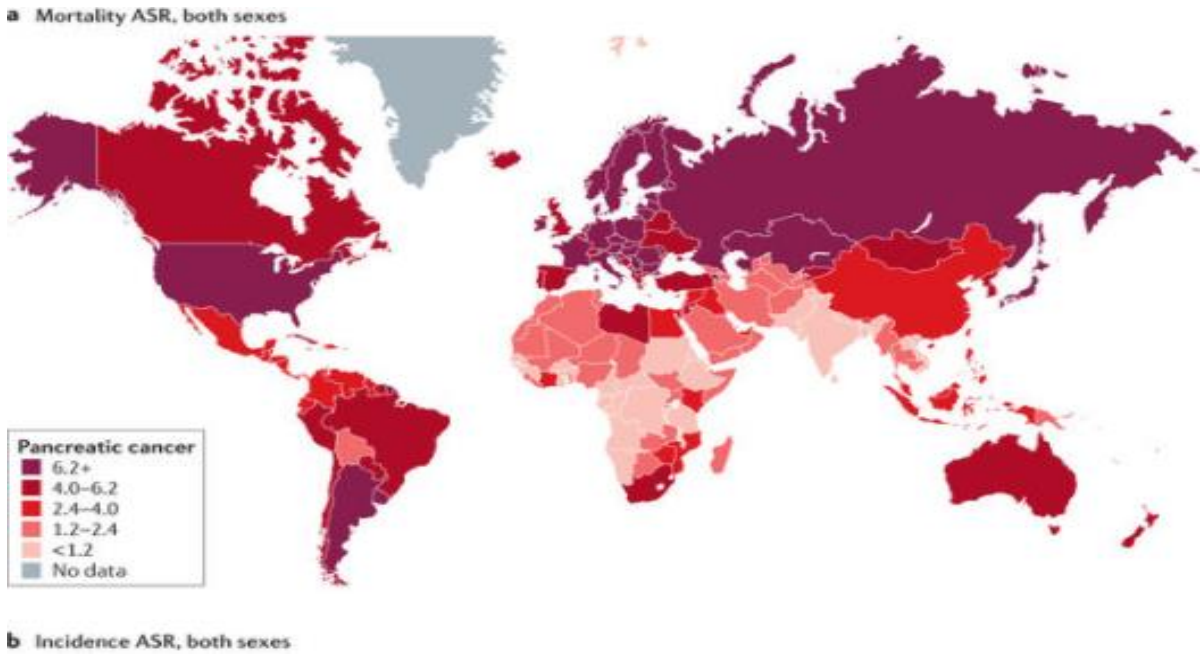
Some risk factors can increase the chance of getting pancreatic cancer. Smoking was shown to increase that chance by 50%, with approximately 20-30% of all cases being caused solely by cigarette smoking. Obesity is additional risk factor, with overweight people being 20% more likely to develop that form of cancer. In addition, age, gender, race, family history as well as pre-existing conditions may also increase the likelihood of developing this disease.

Global incidence rates of pancreatic cancer.[18]



[14] http://surgicalgastro.com/. Accessed on 22nd of May 2017.
[15] Kleeff, J, Korc, M, Apte, M et al. Pancreatic cancer. Nat Rev Dis Primers. 2016; 2: 16022
[16] http://www.macmillan.org.uk
[17] https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html Accessed on 5th of June 2018
[18] Kleeff, J, et al. Pancreatic cancer. Nat Rev Dis Primers. 2016

Global mortality rates of pancreatic cancer.[19]



Pancreatic cancer survival rates have been improving from decade to decade. However, this type of cancer is still considered to be largely incurable, due to the fact that there are no symptoms at the early stages of the disease, and hence it is often not detected until the cancer has advanced. It is also highly difficult to diagnose early, as pancreatic cancer does not display sensitive and specific markers to aid detection.

The 2016 global pancreatic cancer therapeutics market was estimated at $2.41 billion. Over the coming years, this market is predicted to expand at a CAGR of 7.54% and reach $2.99 billion by 2021.[20]

The treatment for pancreatic cancer is mostly determined by type and location of cancer, as well as how advanced it is and whether it has metastasized. The current standard of care for pancreatic cancer includes surgery that aims at complete removal of the tumor and any other cancerous cells. Approximately 17% of patients will have an operable form of cancer; however for the remaining 83% of the patients, the cancer is unresectable and their prognosis is extremely poor. Chemotherapy or chemoradiotherapy for non-operable patients are two available treatment options that aim at slowing down the growth of cancer and relieving symptoms. It may also be used before the surgery to shrink the cancerous mass and hence facilitate removal. For chemotherapy, the most commonly used first-line treatment is Gemcitabine (Gemzar®), FOLFIRINOX, Tarceva, Nab-paclitaxel (Abraxane®), Fluorouracil (5-FU) and Gemcitabine given with Capecitabine (GemCap). A patient often becomes resistant to chemotherapy treatment; thus, second-line chemotherapy is prescribed to extend the patient's life. ONIVYDE has been recently approved and can be used for patients with metastatic pancreatic cancer that have been previously treated with Gemcitabine.

Current treatment guidelines for pancreatic cancer have not changed dramatically in the past years and progress in drug development is hindered due to the complex genomic, epigenetic and metabolic underlying causes of the disease.[21] Alternative treatments being evaluated in clinical trials for the treatment of pancreatic cancer primarily focus on testing out new combinations of existing drugs or adding new drugs to standard chemotherapy treatments. There are several promising therapeutic targets in Phase 3 clinical trials however single-agent use of checkpoint inhibitors has not yielded any efficacy in this indication.

[19] Kleeff, J, et al. Pancreatic cancer. Nat Rev Dis Primers. 2016
[20] Market Data Forecast: "Pancreatic Cancer Therapeutics Market By Treatment Type (Surgery, Chemotherapy, Radiation Therapy, Others), By Type (Exocrine Pancreas Cancer, Endocrine Pancreas Cancer), By End Users (Hospitals, Clinics, Research Institutes, Others), by Region – Global Industry Analysis, Size, Share, Growth, Trends, and Forecasts (2016–2021)"
[21] Kleeff, J, Korc, M, Apte, M et al. Pancreatic cancer. Nat Rev Dis Primers. 2016; 2: 16022

Drug pipeline for pancreatic cancer[22,23]

Agent	Company	Mode of action	Notes
TS-1 + leucovorin	Taiho	Thymidylate synthase inhibitor/ Orotate phosphoribosyl transferase inhibitor	Fixed-dose combination of TS-1 (tegafur + CDHP + oxonic acid) and calcium folinate (leucovorin)
Trabedersen	Autotelic	Transforming growth factor beta 2 antagonist	An antisense therapy targeted to transforming growth factor (TGF)-ß2
Rigosertib	Onconova (NASDAQ:ONTX)	Polo-like kinase 1 inhibitor/ Cell cycle inhibitor/ Mcl-1 antagonist	Novel, small molecule, tumor specific PI-3K (phosphoinositide-3 kinase) and PLK (Polo-like kinase) inhibitor targeting the Ras binding domain
Pegylated interleukin-10	ARMO Biosciences	Interleukin 10 agonist	PEGylated form of recombinant human interleukin-10 (IL-10)
PEGPH20	Halozyme (NASDAQ:HALO)	Hyaluronidase stimulant	Pegylated recombinant human hyaluronidase for use in combination with chemotherapeutics as an anticancer agent
Novaferon	Genova Biotech	Angiogenesis inhibitor/ Apoptosis stimulant/ Immunostimulant	Interferon-like protein. It inhibits tumor cell proliferation and revascularization, induces apoptosis and stimulates antitumor activity of the immune system
Napabucasin	Boston Biomedical	STAT transcription factor 3 inhibitor/ Apoptosis stimulant	Orally-administered agent targeting STAT3
Glufosfamide	Baxter Oncology	DNA inhibitor	Alkylating agent with a structure similar to that of the oxazaphosphorines
Gastrimmune	Cancer Advances	Gastrin inhibitor/ Immunostimulant/ Apoptosis stimulant	Synthetic version of the 9 amino acid residues from the N-terminus of gastrin-17 (G17) linked to a diphtheria toxoid (DT) via a peptide spacer
Dendritic cell vaccine	Tella (TYO:2191)	Immunostimulant	Dendritic cells are extracted from the blood of patients and pulsed with cancer associated antigens such as WT1 or MUC1 peptides before being re-administered to the patient, where they stimulate a specific immune response to the cancer antigen
Cisplatin	Nano Carrier	DNA inhibitor	Medicelle formulation of cisplatin
Algenpantucel-L	NewLink Genetics (NASDAQ:NLNK)	Immunostimulant	Polyvalent Hyper Acute-Pancreatic cancer vaccine

Pancreatic cancer still remains one of the most difficult cancers to treat and, in fact, to date the only curative therapy is a surgical resection. Only 17% of pancreatic cancers are operable (median survival for patients is 24 months) and 83% of patients do not qualify for operation (median survival of 6 months) and hence require alternative therapies.

Currently available chemotherapies are not curative but primarily aimed at improving the quality of life and easing symptoms. There are no targeted therapies or immune-oncology therapies being developed for pancreatic cancer. There is still a clear need to identify new therapeutic targets, as the four key genes identified to be involved in pancreatic cancer, namely TP53, KRAS, SMAD4 and CDKN2A, do not have

[22] EvaluatePharma
[23] Frost & Sullivan Analysis

developed targets against them. Therefore, there is a clear need for newer therapies to improve the survival rate for pancreatic cancer patients.

According to BioLineRx management, evidence of efficacy in this tumor will lead to rapid expansion of studies in other tumor types such as NSCLC, gastric, ovarian and others (in combination with checkpoint inhibitors).

Stem Cell Mobilization (SCM)

Bone marrow contains hematopoietic stem cells that mature into white blood cells (leukocytes), red blood cells (erythrocytes), and platelets (thrombocytes). Limited amounts of those hematopoietic stem cells are naturally released from the bone marrow into the bloodstream and are called peripheral blood stem cells (PBSCs).

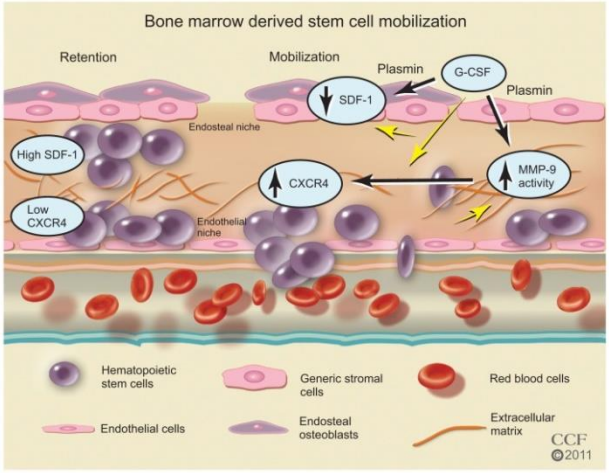
Patients with malignant and non-malignant disorders of the blood and the immune system can often be treated with high doses of chemotherapy and/or radiation therapy. This frequently results in complete depletion of hematopoietic stem cells and hence it is vital to restore them. One of the methods to treat haematological cancer patients is to perform stem cell transplant. This therapy is based on infusing healthy blood-forming stem cells into the body and hence restoring the healthy bone marrow.

As previously mentioned PBSCs in the peripheral blood are present in very low quantities, which are not sufficient to treat patients.

Previously, the only way to collect stem cells for a transplant was through the bone marrow harvest which involved a surgical procedure. Nowadays, the stem cells for transplantation are collected from placental and umbilical cord blood but most often from peripheral blood. There are two types of peripheral blood stem cell transplants, namely autologous (donor is also a recipient) and allogeneic (recipient obtains cells from matched or mismatched donor).

The process in which the cells from the bone marrow are stimulated to migrate into the bloodstream, from where they can be collected, is called stem cell mobilization. In order to achieve that, a donor takes white cell growth factor, such as granulocyte-colony stimulating factor (G-CSF) drug. G-CSF treatment increases MMP-9 which in turns affects the SDF-1/CXCR4 pathway. As a result, the levels of SDF-1 are reduced and the stem cell receptor CXCR4 levels are increased leading to the creation of the chemotactic gradient with the peripheral blood and mobilization of those cells.

Bone marrow-derived stem cell mobilization.[24]



[24] Hoover-Plow J, Gong Y. Challenges for heart disease stem cell therapy. Vascular Health and Risk Management. 2012; 8:99-113. doi:10.2147/VHRM.S25665.

The blood is firstly removed from the donor and the cells collected using a process called apheresis. This process allows the separation of red cells, plasma, white cells and platelets. Stem cells are collected from the white cells and platelets, while the red cells and plasma are transfused back to the donor. Normally it takes one to two cycles of apheresis to collect sufficient number of stem cells from a matched unrelated donor. Those cells are then preserved, frozen, stored and used later for transplantation.[25]

Stem cell transplantation process.[26]

Competitive Landscape

There are only a few agents that can mobilize stem cells. The only one indicated is Mozobil (plerixafor injection), which is always given in combination with granulocyte-colony stimulating factor (G-CSF). Mozobil is injected approximately 11 hours prior to each apheresis session, up to a total of 4 days and is mostly used for autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). It is not intended for patients with leukemia. Filgrastim (Neupogen) is a Granulocyte Colony Stimulating Factor that is used most frequently as mobilization agent.

For allogeneic transplants, only G-CSF agent such as filgrastim sold under the brand name Neupogen amongst others (with or without plerixafor) is used since it is relatively safe and produces positive results in most patients. There is also a PEGylated form of the recombinant human G-CSF analog filgrastim called pegfilgrastim (brand name Neulasta) that was shown to be effective in stem cell mobilization. Other approved agents for hematopoietic progenitor cell mobilization include granulocyte-macrophage-colony-stimulating factor - Sargramostim and a stem cell factor – Ancestim.[27] Most drug candidates are in the early stages of clinical trials. Thus, only Polyphor, Noxxon and Taigen are in direct competition with BL-8040. The Table below summarizes the leading drug candidates in the pipeline.

Leading drug candidates in the stem cell mobilization pipeline.[20]

Specific Agent	Company	Drugs/Pathways	Mode of action	Clinical Trials
POL-6326	Polyphor (SWX:POLN)	CXCL12/CXCR4 modulators	CXCR4 antagonists	Phase 2a
BL-8040	BioLineRx	CXCL12/CXCR4 modulators	CXCR4 antagonists	Phase 3 – see above
TG-0054	Taigen Biotechnology	CXCL12/CXCR4 modulators	CXCR4 antagonists	Phase 2
NOX-A12	NOXXON Pharma	CXCL12/CXCR4	Neutralisation of CXCL12	Phase 2a -

[25] http://www.iwmf.com. Hematopoietic Stem Cell Mobilization and Apheresis. A Practical Guide for Nurses and Other Allied Health Care Professionals Accessed on 25/05/2017
[26] http://www.iwmf.com. Hematopoietic Stem Cell Mobilization and Apheresis. A Practical Guide for Nurses and Other Allied Health Care Professionals Accessed on 25/05/2017
[27] Hopman RK, DiPersio JF. Advances in Stem Cell Mobilization. Blood reviews. 2014; 28(1):31-40. doi:10.1016/j.blre.2014.01.001.

	(EPA:ALNOX)	modulators		complete
SEW-2871	NA	phingosine-1-phosphate Agonists	Alteration of S1P gradient between PB and BM, which may counteract HSC retention in the BM	Animal Studies
BIO-5192	NA	VCAM/VLA-4 (vascular cell adhesion molecule-1/Very Late Antigen 4)Inhibitors	Inhibition of VLA-4 mediated HSC adhesion to VCAM-1 within the bone marrow stroma	Animal Studies
Bortezomib	Celgene (NASDAQ:CELG)	Proteosome Inhibitors	Possible alteration of the VLA-4/VCAM-1 pathway	Phase 3 - complete[28]
SB-251353	NA	Groβ	Release of proteases that alter HSC adhesion to the BM niche	Animal Studies
FG-4497	NA	Stabilisation of hypoxia-inducible factor	Expression of VEGF-A in the BM sinusoids, leading to vasodilatation	Animal Studies

There are also some investigational agents such as parathyroid hormone, antibodies against VLA-4, human growth hormone, TPO-receptor agonists and retinoic acid receptor-α agonists drugs that are being tested in early clinical trials.[29]

The SCM Market

The stem cells mobilization market is based on current marketable agents that are used to mobilize stem cells from a donor's bone marrow into the peripheral blood circulation. Granulocyte-colony stimulating factor (GCSF) analogs such as Neupogen and Neulasta, which generate billions of dollars in sales annually, are the most intensively used for stem cell mobilization for autologous and allogeneic transplantations, but as off-label drugs; they are intended and approved for other indications such as slow white blood cell recovery following chemotherapy. Therefore, they do not entirely reflect the potential BL-8040 market for this indication. Mozobil (plerixafor), on the other hand, is specifically labeled for stem cell mobilization, primarily used for autologous transplantation, and is given to 40-50% of patients in which the use of GCSF alone did not produce sufficient stem cell mobilization to the bloodstream. Thus, we used it as a benchmark to estimate the economic potential for BL-8040. Nevertheless, BL-8040 is investigated as a candidate drug for allogeneic as well as autologous transplantations, in which it will be given solely, or in addition to G-CSF.

The following table provides the primary sales of drugs and forecasts, upon which we based our market valuation:

Product	Company	2018	2019	2020	2021	2022	CAGR
Mozobil	Sanofi	178	184	190	195	201	3.0%
Neulasta+Kyowa Hakko Kirin	Amgen	4,390	3,902	3,495	3,117	2,795	-9.0%
Neupogen	Amgen	491	433	392	362	331	-13.0%

Source: EvaluatePharma, WW Sales. All Financial Data in $M

[28] https://seekingalpha.com/news/3361218-celgenes-pomalyst-triplet-therapy-shows-treatment-effect-late-stage-mm-study
[29] Bakanay SM, Demirer T. Novel agents and approaches for stem cell mobilization in normal donors and patients. Bone marrow transplantation. 2012 Sep 9; 47:1154–63.

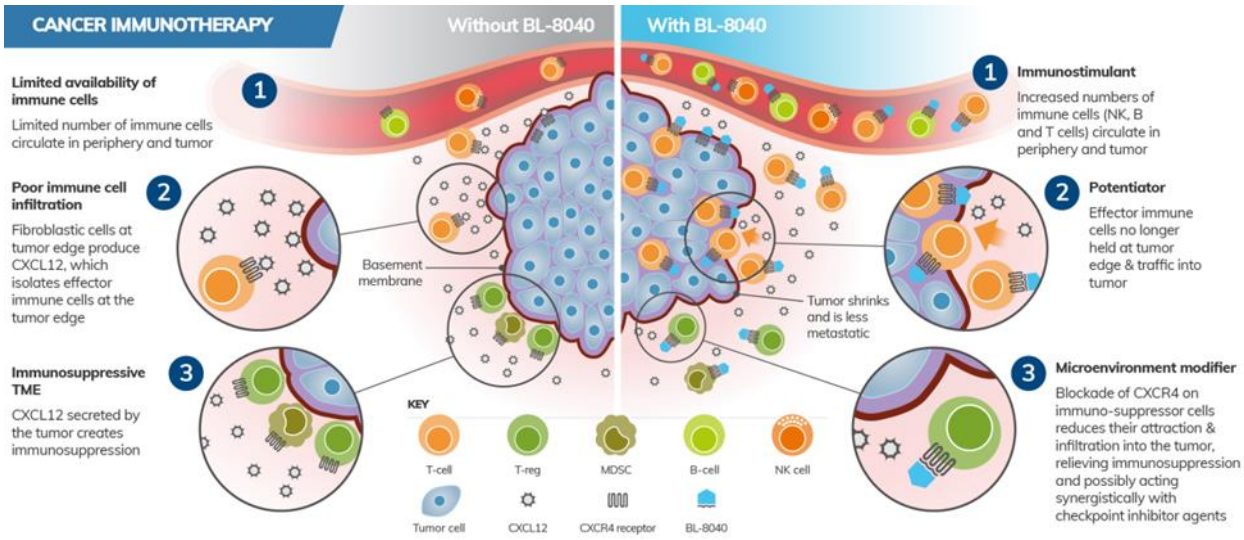
Company's Products

BL-8040 - CXCR4 Antagonist for Multiple Oncology and Hematology Indications

BL-8040 is a 14 amino acid synthetic peptide which is a high-affinity antagonist of CXCR4. Its composition is covered by patents granted in the US, EU and Japan through 2023, not including patent-term extension. CXCR4 antagonist mode of action is relevant to multiple different cancer types and it was shown in a broad range of *in vitro* and *in vivo* studies that BL-8040 can induce apoptosis of cancerous cells, sensitize cancerous cells to chemo- and bio-based anti-cancer therapy, and can facilitate mobilization of stem cells from bone marrow.[30,31,32,33,34]

BL-8040 inhibits the ligand CXCL12 (also called SDF-1) from binding to its CXCR4 receptor expressed in tumor cells and hence impacting a magnitude of tumorigenic processes. This blockage promotes the release of tumor cells from the bone marrow into the bloodstream and hence increases the sensitivity of tumor cells to various chemotherapy treatments. BL-8040 was also found to induce apoptosis of tumor cells and, together with checkpoint inhibitors, significantly impacts tumor microenvironment.

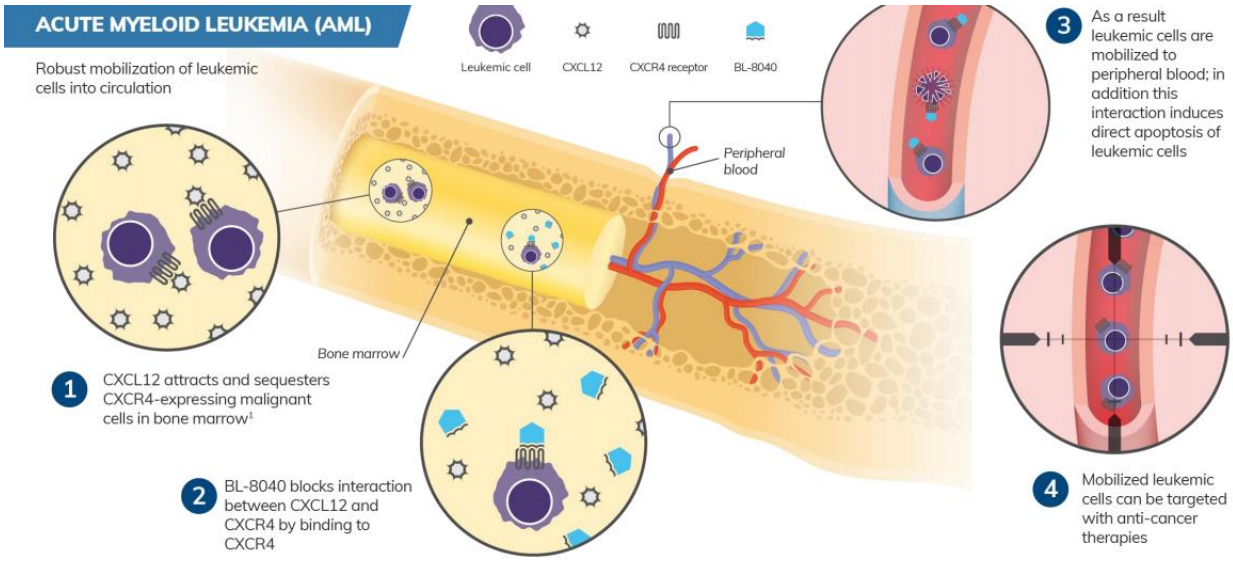
BL-8040 mode of action in cancer immunotherapy.[35]



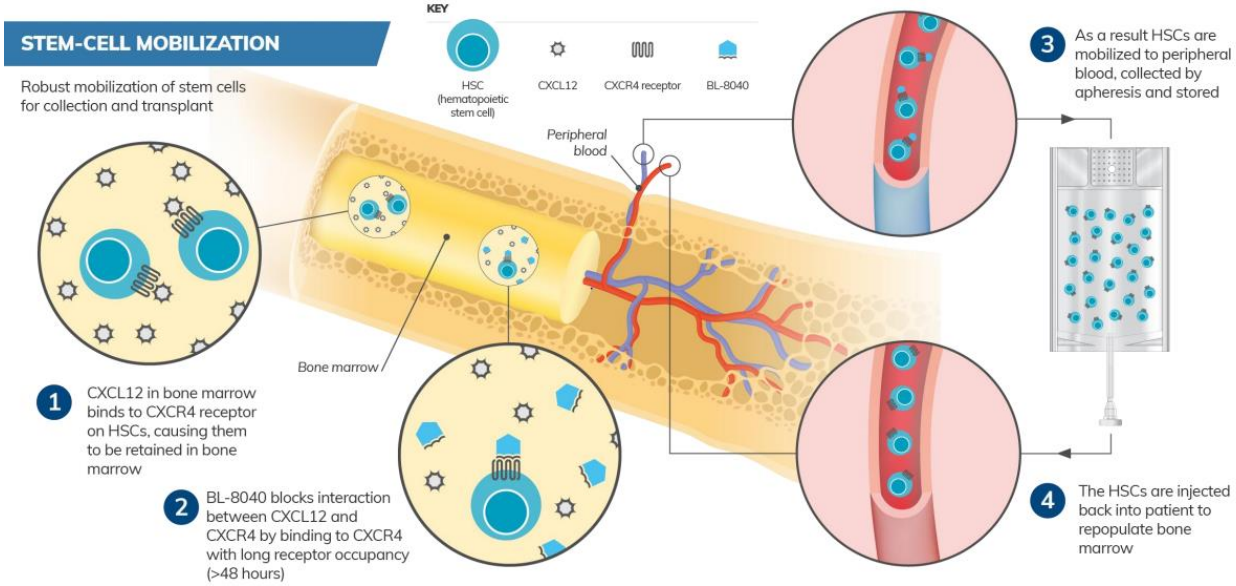
BL-8040 has three key modes of action in immunotherapy. It works as an immunostimulant (mobilizes immune cells from bone marrow and lymph nodes), a potentiator (facilitates immune cells infiltrations into the tumors), and as a microenvironment modifier (decrease CXCR4-mediated migration of immune suppressor cells). In addition, BL-8040 induces apoptosis in AML, and facilitates mobilization of stem cells.

[30] Peled A, Abraham M, Avivi I, Rowe JM, Beider K, Wald H, Tiomkin L, Ribakovsky L, Riback Y, Ramati Y, et al. The high-affinity CXCR4 antagonist BKT140 is safe and induces a robust mobilization of human CD34+ cells in patients with multiple myeloma. Clin Cancer Res. 2014; 20(2):469–79.
[31] Beider, K, Darash-Yahana, M, Blaier, O, Koren-Michowitz, M, Abraham, M, Wald, H, Wald, O, Galun, E, Eizenberg, O, Peled, A & Nagler, A 2014, 'Combination of imatinib with CXCR4 Antagonist BKT140 overcomes the protective effect of stroma and targets CML in vitro and in vivo' Molecular Cancer Therapeutics, vol 13, no. 5, pp. 1155-1169. DOI: 10.1158/1535-7163.MCT-13-0410
[32] Fahham D, Weiss ID, Abraham M, et al. In vitro and in vivo therapeutic efficacy of CXCR4 antagonist BKT140 against human non-small cell lung cancer. J Thorac Cardiovasc Surg. 2012; 144(1167–1175):e1.
[33] Burger JA, Stewart DJ, Wald O, Peled A. Potential of CXCR4 antagonists for the treatment of metastatic lung cancer. Expert Rev Anticancer Ther. 2011; 11:621–630. doi: 10.1586/era.11.11.
[34] Burger J. A., Peled A. (2009). Cxcr4 antagonists: targeting the microenvironment in leukemia and other cancers. Leukemia 23 43–52. 10.1038/leu.2008.299
[35] BioLineRx April 2018 Presentation

Role of BL-8040 in Acute Myeloid Leukemia.[36]



Role of BL-8040 in Stem-Cell Mobilization.[37]



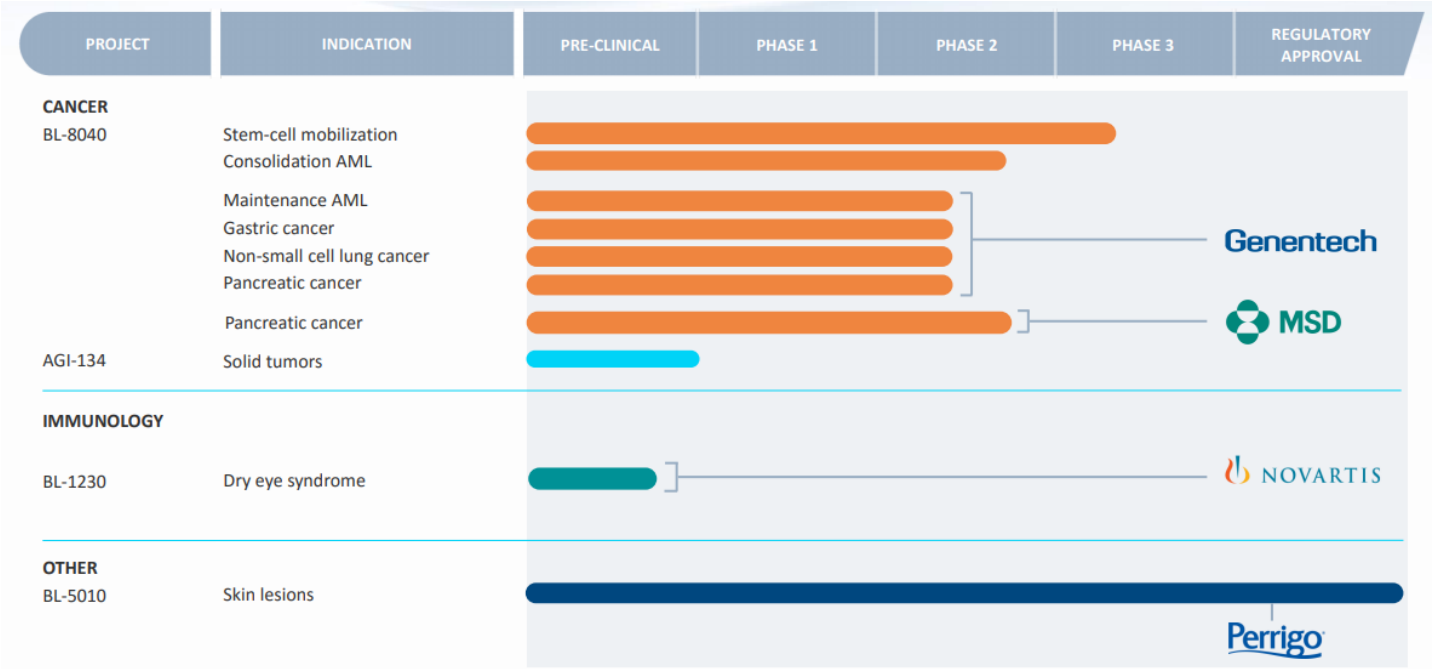
It is worth noting that caution should be taken when inhibition of the SDF-1/CXCR4 signalling pathway is applied in human subjects. Inhibition of CXCR4 signalling attenuates the immune responses; therefore moderate activation of CXCR4 pathway contributes to depression of inflammation and is beneficial for the cancer patients. On the other hand, excessive activation of CXCR4 pathway might dampen the hosts' immune responses and decrease anticancer ability.

BL-8040 has received the Orphan Drug Designation from the FDA for the treatment of AML and SCM. The drug is being investigated as a combination therapy with multiple partners including Merck, MDACC and Genentech (described in the following "Clinical Development" section).

[36] Ibid.
[37] Ibid.

Clinical Development

BL-8040 is in Phase 2 clinical trials for two main indications: AML and pancreatic cancer A Phase 3 study was initiated in combination with G-CSF for the treatment of SCM in Q4 2017 and additional Phase 1b/2 studies for multiple solid tumors (please see details below).



Source: BiolineRx Corporate Presentation, June 2018

Pancreatic Cancer Clinical Trials

The Phase 2a study (known as the COMBAT study) was designed to examine the combination of BL-8040 with Merck's Keytruda (anti-PD1 immune checkpoint inhibitor). The study will recruit approximately 30 patients with metastatic pancreatic adenocarcinoma. This open-label, single-arm trial is being conducted in the US, Israel and South Korea. The primary endpoint of the study is to assess clinical response (objective response rate according to RECIST 1.1 criteria), safety and tolerability of this drug combination, disease control rate, progression-free and overall survival as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. The study commenced at the end of Q3 2016 and partial results announced in H2 2017 showed that BL-8040 increases infiltration of T cells into the tumor in patients with metastatic pancreatic cancer (in 75% of patients), caused a reduction of Tregs in peripheral blood, had long CXCR4 receptor occupancy on lymphocytes, increased absolute number of immune cells in the blood. The top-line results are expected in H2 2018.

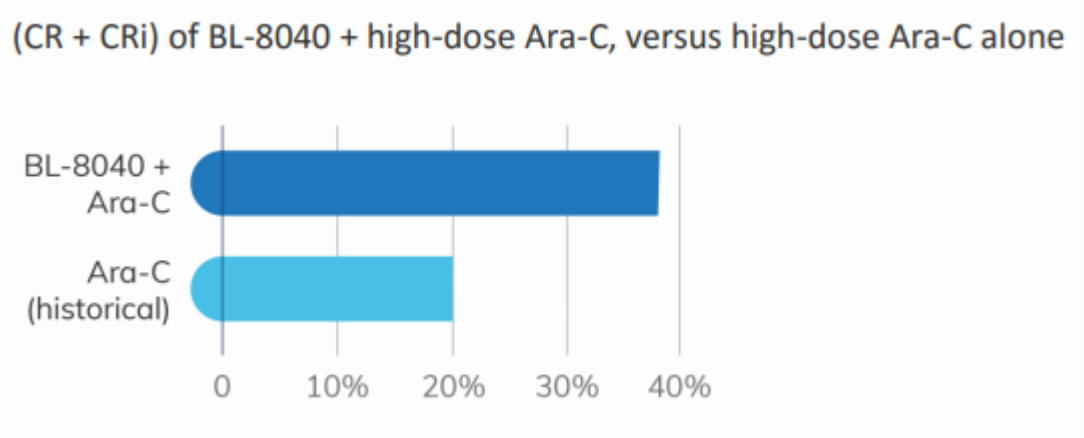
BioLineRx is running an additional study in collaboration with Merck (NYSE:MRK) and MD Anderson Cancer Center. This Phase 2 study was initiated in January 2017 and aims at testing BL-8040 with Keytruda in gastrointestinal cancers. Similarly to the other study, the primary endpoint is to measure efficacy, and also to monitor various biological markers of the anti-tumor response and assess the mechanism-of-action by which both drugs might synergize.

AML Clinical Trials

BioLineRx has also conducted a successful proof-of-concept Phase 2a study in relapsed/refractory AML evaluating safety and efficacy of BL-8040 in combination with cytarabine (Ara-C). The study recruited 42 patients at six world-leading cancer research centers in the U.S. and at five premier sites in Israel and examined both a dose-escalation and a dose-expansion phase. The conducted study examined safety and

tolerability, as well as clinical efficacy. The results indicated robust bone marrow clearance, apoptotic effect and terminal differentiation of AML cells as expected. In May 2018, the Company has announced positive overall survival data from the long-term follow-up part of this study and committed to monitor long-term survival data for patients in the study.

Comparison of the composite response rate.[38]



The final successful results of this study accelerated development in the AML space and highlighted the potential for elimination of the minimal residual disease (MRD).

Additionally, a consolidation AML Phase 2b study (known as BLAST study) commenced in September 2015 that aims to evaluate the addition of BL-8040 to the standard consolidation therapy with cytarabine in AML patients who have responded to standard induction treatment and are in complete first remission. Half of the participants will receive BL-8040 and cytarabine in combination, while the other half will receive placebo and cytarabine. The study is a double-blind, placebo-controlled, randomized, multi-center study and will recruit a total of 194 patients at 25 different sites in Germany. It will be conducted in collaboration with the German Study Alliance Leukemia Group and the primary endpoints are to assess relapse-free survival [Time Frame: 18 months], while the secondary endpoints are to evaluate overall survival, time to relapse, relapse-free survival [Time Frame: 6, 9, 12 and 18 months], minimal residual disease and toxicity. The study's partial results are expected in H2 2018 while top-line results are expected in 2020.

BioLineRx has also initiated in September 2017 a Phase 1b/2 study in maintenance AML for intermediate- and high-risk AML patients with complete response following induction and consolidation therapy (n=60). This single arm, open-label study will assess the safety and efficacy of BL-8040 in combination with atezolizumab for maintenance treatment in AML patients 60 years or older. It will be conducted at approximately 22 sites in the U.S., Europe and Israel.

Stem Cell Mobilization Clinical Trials

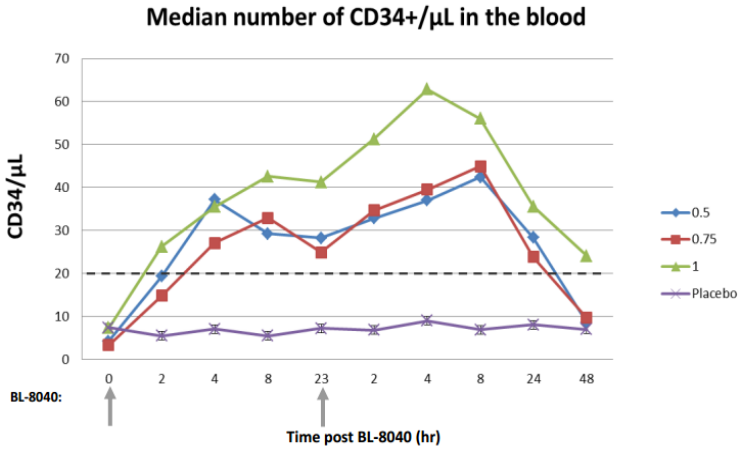
SCM for Allogeneic BMT

BioLineRx has completed a successful proof-of-concept Phase I study in 2015 for allogeneic bone marrow transplantation at Hadassah Medical Center in Jerusalem. The aim of the study was to determine whether BL-8040 is safe, tolerable and effective in the mobilization of Hematopoietic Stem Cells (HSC) in healthy volunteers.

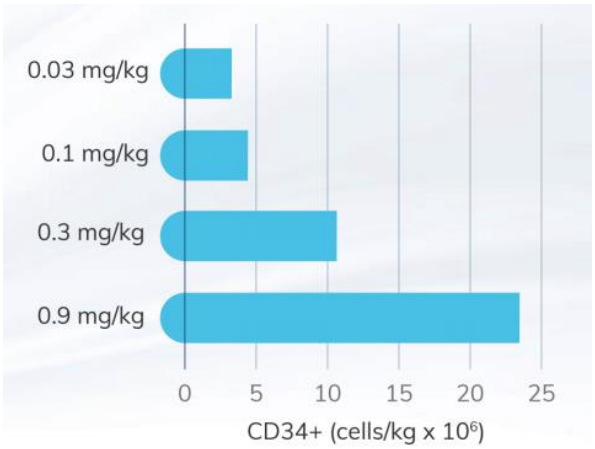
This study showed substantial HSC mobilization (CD34+ cells) from bone marrow to peripheral blood, compared to the placebo treated group after a single administration of BL-8040. Single apheresis resulted in the robust collection of stem cells; the yield exceeded the required amounts to support a transplant.

[38] BioLineRx April 2018 Presentation

HSC mobilization (CD34+ cells) from bone marrow to peripheral blood.[39]



BL-8040 increases HSC mobilization in a dose dependent manner.[40]



In addition, the study indicated that BL-8040 was safe and well tolerated by healthy volunteers; as a result of those positive findings, the Phase 2a study was launched in collaboration with the Washington University School of Medicine and aimed at evaluating the number of donors who were able to mobilize more than 2 x 10^6 CD34+ cells per kg (weight of patient) after a single administration of BL-8040. Successful partial results were announced in March 2017 stating that a single injection of BL-8040 mobilized sufficient amounts of cells without the need for G-CSF. In addition, all transplant recipients experienced successful neutrophil engraftment. The secondary endpoints that were also being investigated included safety and tolerability, but also the incidence of any acute and chronic graft versus host disease (GVHD) events. The positive top line results were announced in May 2018.

The randomized, controlled Phase 3 trial of BL-8040 for the mobilization of HSCs for autologous transplantation in patients with multiple myeloma was commenced in December 2017. The study comprises of a lead-in period for dose confirmation (n=30 patients), and progress to the randomized placebo-controlled study in combination with G-CSF in 177 multiple myeloma patients in approximately 15 centers. The primary endpoint includes the assessment of proportion of subjects mobilizing ≥6.0 x 106 CD34+ cells/kg with up to 2 apheresis sessions in preparation for auto-HCT after a single administration of BL-8040 or placebo + G-CSF. The results from the lead-in period of the study are expected in mid-2018, and top-line results of placebo-controlled part of the study are expected in 2020.

[39] BioLineRx Corporate Presentations April 2018
[40] BioLineRx Corporate presentations, April and May 2018 (respectively).

Future Developments

BioLineRx is also conducting Phase 1b/2 studies in collaboration with Genentech (VOX:ROG). They were initiated in H2 2017, and aim at investigating the combination of BL-8040 with Genentech (VOX:ROG)'s Tecentriq (Atezolizumab - anti-PDL1 immune checkpoint inhibitor) for multiple indications including pancreatic cancer, gastric cancer and non-small cell lung cancer (NSCLC).

The agreement with Genentech (VOX:ROG) mandates they will sponsor and conduct three Phase 1b studies in multiple solid tumors while BioLineRx will be responsible for sponsoring and conducting a single Phase 1b study in (maintenance) AML. All of them will be open-label, repeated administration studies conducted on a group of up to 60 patients. The primary endpoint for those studies is to assess clinical response, safety and tolerability as well as to investigate multiple pharmacodynamic parameters. The studies' partial results are expected in H2 2018.

Pipeline Competition

Since CXCR4 signalling was shown to be involved in a range of pathological processes, small-molecule antagonists directed against CXCR4 are of great interest as potential therapeutic use. A large number of drug candidates targeting CXCR4 have been discovered, however so far only one, plerixafor, has been approved by the FDA for the mobilization of HSPCs for autologous transplantation in patients with non-Hodgkin's lymphoma. A few therapeutic drugs that are in the clinical pipeline and directly competing with BL-8040's mechanism of action are presented in the table below.

CXCR4 competitive landscape

Drug	Company	Development stage (Indication)	Remarks
X4P-001	X4 Pharmaceuticals	Phase 2/3 (WHIM) Phase 1/2(refractory clear cell renal cell carcinoma (ccRCC), melanoma, and other solid tumors)	Low-dose formulation of X4P-001, an oral, small molecule inhibitor of CXCR4, or C-X-C receptor type 4
Mozobil	Genzyme/Sanofi (EPA:SAN)	Launched for SCM, being tested in multiple clinical trials for various indications	Mozobil (plerixafor injection) is approved by FDA to be used with another agent, granulocyte-colony stimulating factor (G-CSF)
POL-6326	Polyphor (SWX:POLN)	Phase 1 (mobilizes and collects hematopoietic stem cells) Phase 2 (tissue repair in acute myocardial infarction-Terminated)	Orally bioavailable inhibitor of CXC chemokine receptor 4 (CXCR4) with receptor binding and hematopoietic stem cell mobilization activities
PF-06747143	Pfizer (NYSE:PFE)	Phase 1 (Acute Myeloid Leukemia (Biologic))	Novel-humanized IgG1 CXCR4 antagonist antibody
USL-311	Proximagen	Phase 1/2 - discontinued	USL-311 is a CXCR4 inhibitor, under development by Proximagen for the treatment of glioblastoma and solid tumors
GMI-1359	GlycoMimetics (NASDAQ:GLYC)	Phase1 (hematologic malignancies)	GMI-1359 is a lead compound targeting both E-Selectin and CXCR4

Summary of competitive analysis

The BL-8040 is a platform that can be used in multiple indications as shown above. It has a very distinct mechanism of action combining the ability to impact tumor microenvironment, induce apoptosis and facilitate mobilization of stem cells, immune cells and malignant cells from bone marrow.

It is believed to have the greatest potential when used in combination with checkpoint inhibitors and therefore collaboration with Genentech (**VOX:ROG**) and Merck (**NYSE:MRK**) are crucial for the success of this platform in the oncology field.

BL-8040 has also been shown as a potent therapeutic candidate for the treatment of AML. The competition in the AML field is fierce and there are hundreds of drugs under development. The direct competitor would be an Ulocuplumab-a fully human IgG4 anti-CXCR4 antibody that induces cell death in chronic lymphocytic leukaemia. Unlike BL-8040, Ulocuplumab has significantly lower mobilization properties, milder apoptotic effect, and there are no published data on T-cell infiltration into tumors.

In the stem cell mobilization field, there is a scarcity of approved therapies that offer sufficient standard of care. BL-8040 does not have much competition and offers an advantage over current standard of care. Mozobil injections are administered approximately 11 hours prior to each apheresis session, up to a total of 4 days and on average one to four apheresis are required to collect a sufficient number of cells for transplant. In addition, Mozobil was shown to have a lower affinity for CXCR4, lower mobilization properties, and has no effect on cancer cell apoptosis and hence it is inferior in comparison to BL-8040. There are a couple of drugs in the pipeline positioned at a similar developmental stage that aim at modulating CXCL12/CXCR4 pathway. Hence, should BL-8040 reach the market, its sales could be hampered by those investigational agents.

Near Clinical Therapeutic Candidate

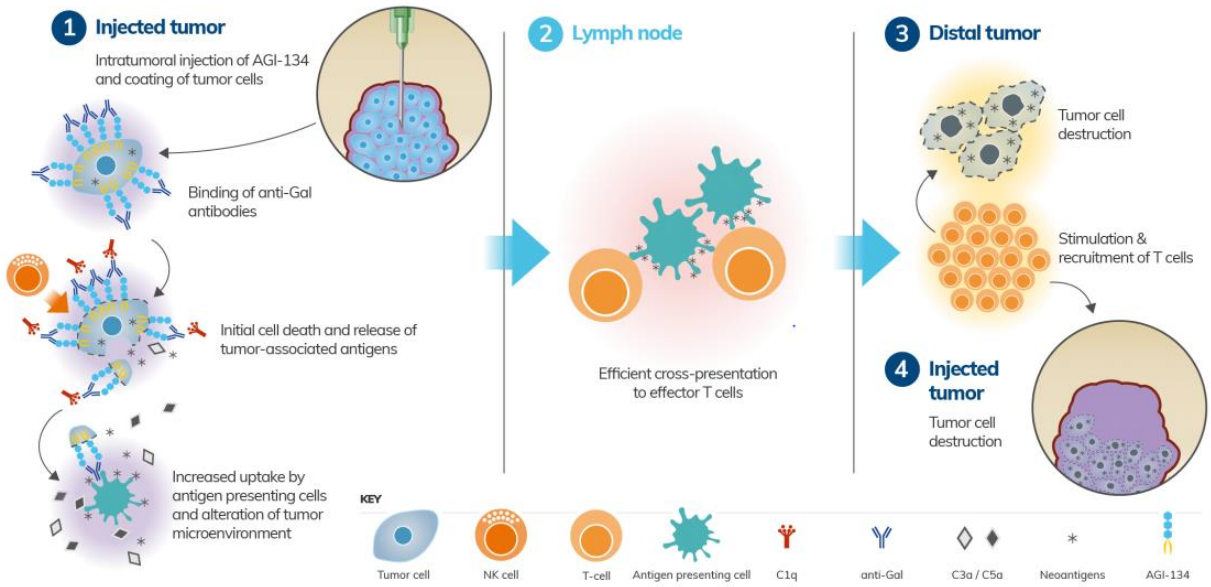
AGI-134: alpha-Gal immunotherapy for multiple solid tumor indications

BioLineRx acquired Agalimmune, a UK-based oncology company, for $6 million in cash and stock in H1 2017. Agalimmune has a key flagship immunotherapy product for the treatment of various solid tumors. This AGI-134 product is a fully synthetic αGal glycoprotein for intratumoral injection into solid tumors.

Abundantly and naturally present, anti-αGal (anti-Gal) antibodies can be recruited to the sites on tumors so that the body's natural immune response is stimulated to attack cancerous cells. AGI-134 is injected into the tumor, where it coats the tumor cell membrane and hence presents αGal antigen on the surface. Anti-Gal antibodies bind to the αGal part of AGI-134 to induce an initial immune response that activates certain pathways of cellular cytotoxicity, or cell death. This cytotoxicity generates immune-tagged tumor cells and cellular debris that generate a follow-on systemic immune response by activation and expansion of T-cells to the patient's own neo-antigens.

This approach not only targets the primary injectable tumor, but has also demonstrated efficacy against existing distant secondary tumors and metastases. The mechanism of action also suggests the potential of long-term protection against future metastases (figure below).

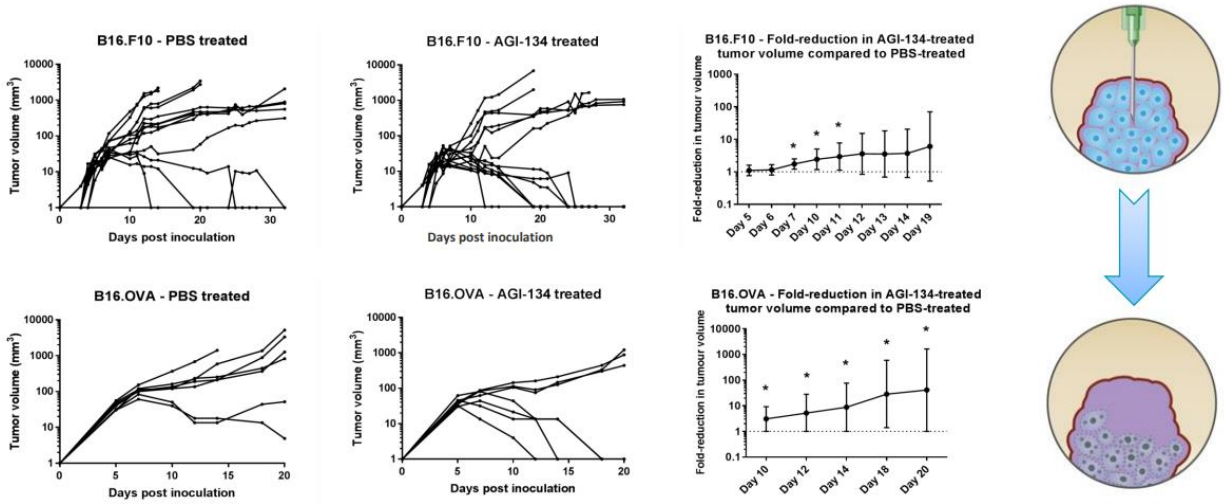
AGI-134 Mode of Action.[41]



AGI-134 has completed multiple pre-clinical studies. Upon single injection tested on a model of melanoma, robust protection against secondary cancer was demonstrated for over 90 days.

[41] BioLineRx April 2018 Presentation

Results from pre-clinical studies showed regression of established melanoma primary tumors in GT KO mice upon AGI-134 intratumoral administration.[42]



In addition, AGI-134 was also tested in combination with PD-1 immune checkpoint inhibitor and showed positive results (increased efficacy over monotherapy effect of either agent). With regards to the latter, it was found that checkpoint drugs work best in highly mutated tumors that are highly infiltrated with immune cells, known as “hot tumors”. Unfortunately, the overwhelming majority of human tumors are “cold” tumors, without immune cells. Therefore, transforming a cold tumor into a hot tumor is a major objective in a cancer treatment.

With AGI-134, which harnesses naturally occurring, pre-existing antibodies to elicit a tumor-specific immune response, the resulting activation and clonal expansion of T-cells to the patient’s own neo-antigens has the potential to transform cold tumors to hot tumors, thereby significantly expanding treatment potential

A 28-day, repeated-administration GLP toxicology study in monkey with AGI-134 was also completed.
“In March 2018, the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent application claiming the use of AGI-134 for the treatment of solid cancer tumors. This patent, when issued, will be valid until May 2035 with a possibility of up to five years patent term extension. Additional corresponding patent applications for AGI-134 are pending in Europe, Japan, China, Canada, Australia and Israel.

AGI-134 is likely to commence a first-in-man study in patients with solid tumors in mid-2018.

[42] BioLineRx April 2018 Presentation

Pre-Clinical Programs

BL-1230 under the Collaboration with Novartis (**VTX:NOVN**)

BioLineRx has a collaboration with Novartis for joint development of innovative drug candidate.

BL-1230, developed by Professor Raphael Mechoulam (Medicine of the Hebrew University) for the treatment of dry eye syndrome (DES), is an additional drug candidate. The BL-1230 is a selective cannabinoid receptor type 2 (CB2R) agonist. CB2R has been shown to be involved in the immune modulation tempering inflammation associated with DES but also may induce analgesic effects. The eye drops with BL-1230 have been shown to have significant anti-inflammatory effects in three ocular inflammatory models.

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Philip Serlin, CPA, MBA
Chief Executive Officer
Mr. Serlin has served as CEO since October 2016. From May 2009 to October 2016, Mr. Serlin served as Chief Financial and Operating Officer. From January 2008 to August 2008, Mr. Serlin served as the Chief Financial Officer and Chief Operating Officer of Kayote Networks Inc. From January 2006 to December 2007, he served as the Chief Financial Officer of Tescom Software Systems Testing Ltd., an IT services company publicly traded in both Tel Aviv and London. Mr. Serlin currently serves as an external director at Vascular Biogenics Ltd. (**Nasdaq:VBLT**). Mr. Serlin is a CPA and holds a B.Sc. in accounting from Yeshiva University and a Master's degree in economics and public policy from The George Washington University.

Mali Zeevi, CPA
Chief Financial Officer
Ms. Zeevi has served as our Chief Financial Officer since October 2016. Prior to becoming Chief Financial Officer, Ms. Zeevi served as our Senior Director of Finance and Reporting beginning in 2011 and as our Director of Finance and Reporting beginning in 2009. Before joining BioLineRx, Ms. Zeevi was employed by Tescom Software Systems Testing Ltd., her last position there being Vice President Finance. She holds a B.A. in business and accountancy from the College of Management Academic Studies in Israel.

Hillit Mannor Shachar, MD, MBA, MSFS
Vice President Business Development
Hillit Mannor Shachar, MD, MBA, MSFS, became our Vice President Business Development in April 2018 and is responsible for our business development, commercialization of assets and pipeline strategy. Dr. Shachar joins the Company with over 15 years of experience in senior business development, corporate development and venture capital positions in the life sciences field. Her recent experience has included service as Vice President Business Development of Pluristem Therapeutics (**NASDAQ:PSTI**). Dr. Shachar received her B.A. and M.D. from Northwestern University, her M.S.F.S. from Georgetown University School of Foreign Service and her MBA from the Kellogg Recanati School of Management at Tel Aviv University.

Ella Sorani, PhD
Vice President Research and Development
Ella Sorani, Ph.D., has served as our Vice President Development since February 2017. Before joining BioLineRx, from 2000 through 2016, Dr. Sorani served in a number of management positions in the global R&D division at Teva Pharmaceutical Industries Ltd. (**NYSE:TEVA**; **TLV:TEVA**) In her most recent position as Senior Director and Global Project Leader, Dr. Sorani led the development of one of Teva's leading innovative late stage compounds. Dr. Sorani holds a B.Sc. in chemistry and a M.Sc. and Ph.D. in pharmacology, all from Tel Aviv University

Abi Vainstein-Haras, MD
Vice President Clinical and Medical Affairs
Abi Vainstein-Haras, M.D., has served as our Vice President Clinical and Medical Affairs since January 2017. From June 2014 to January 2017, Dr. Vainstein-Haras served as our Senior Medical Director responsible for the clinical development of all our clinical phase projects. Prior to joining the Company, from 2012 to 2014, she served as the Director and Clinical Program Leader for COPAXONE® at Teva (**NYSE:TEVA**; **TLV:TEVA**), and from 2007 to 2012; she served in several medical positions in Innovative R&D at Teva. Dr. Vainstein-Haras holds an M.D. from University of Buenos Aires and is licensed to practice medicine in Israel.

Appendix

Appendix I - Financial Reports

Balance Sheet (USD 000s)	31.12.2015	31.12.2016	31.12.2017	31.3.2018
Current Assets				
Cash and cash equivalents	5,544	2,469	5,110	7,810
Short-term bank deposits	42,119	33,154	44,373	36,388
Prepaid expenses	229	255	307	564
Other receivables	291	223	586	782
Total current assets	**48,183**	**36,101**	**50,376**	**45,544**
Non-current Assets				
Restricted deposits	0	0	61	60
Long-term prepaid expenses	58	52	1,000	1,000
Net PPE	2,909	2,605	2,505	2,432
Intangible assets, net	152	181	7,023	7,039
Total non-current assets	3,119	2,838	10,589	10,531
Total assets	**51,302**	**38,939**	**60,965**	**56,075**
Current Liabilities				
Current maturities of long-term bank loan	93	93	93	93
Accounts payable and accruals: Trade	1,910	2,590	5,516	4,941
Other Accounts payable and accruals	1,137	978	1,113	1,146
Total current liabilities	**3,140**	**3,661**	**6,722**	**6,180**
Non-current Liabilities				
Long-term bank loan, net of current maturities	344	250	157	133
Warrants 5,240 1,500 208	208	1	1,205	740
Total non-current liabilities	552	251	1,362	873
Total Liabilities	**3,692**	**3,912**	**8,084**	**7,053**
Total equity	**47,610**	**35,027**	**52,881**	**49,022**
Total liabilities and equity	**51,302**	**38,939**	**60,965**	**56,075**

Statement of Comprehensive Loss				USD 000s
Reporting Year	**2016**	**2017**	**31.3.2017**	**31.3.2018**
Research and Development Expenses, Net	(11,177)	(19,510)	(3,590)	(5,070)
Sales and Marketing Expenses	(1,352)	(1,693)	(681)	(484)
General and Administrative Expenses	(3,984)	(4,037)	(1,030)	(1,075)
Operating Loss	**(16,513)**	**(25,240)**	**(5,301)**	**(6,629)**
Non-Operating income, net	**214**	**(260)**	**(5)**	**462**
Financial Income	480	1,169	457	175
Financial Expenses	(22)	(21)	(6)	(206)
Net Loss	**(15,841)**	**(24,352)**	**(4,855)**	**(6,198)**
Currency translation differences	0		0	0
Comprehensive Loss	**(15,841)**	**(24,352)**	**(4,855)**	**(6,198)**
Loss per ordinary share – basic and diluted	(0.28)	(0.27)	(0.08)	(0.06)

Appendix II – Team Bios

Kobi Hazan is the Lead Analyst for Frost & Sullivan's Independent Equity Research practice. He has over 14 years of experience in capital markets, including research, analysis, investment advisory, and management. Mr. Hazan served as a Fund Manager for provident and mutual funds at Analyst Ltd. and, since 2012, he runs the Amida Israel Fund, a hedge fund specializing in Israeli equities. Kobi holds a BA (Economics and Management) from The College of Management Academic Studies. He is licensed as an Investment Advisor in Israel.

Dr. Tiran Rothman is Director of Operations at Frost & Sullivan, Israel and also oversees the Firm's Independent Equity Research practice. He has over a decade's experience in financial research and analysis, obtained through positions at a boutique office for economic valuations, as chief economist at the AMPAL group, and as co-founder and analyst at Bioassociate Biotech Consulting. Dr. Rothman also serves as Head of the Economics & Management School at Wizo Academic College, Haifa. Tiran holds a PhD (Economics), MBA (Finance), and was a visiting scholar at Stern Business School, NYU.

Dr. Anna Cirmirakis has been a Senior Consultant for Frost & Sullivan Transformational Healthcare team since February 2015, after spending four years at pharmaceutical giant, GlaxoSmithKline (**LON:GSK**). She works primarily with biotech, pharma and diagnostics companies on a wide range of strategic projects including product evaluation, market analysis as well as competitive intelligence. Dr Cirmirakis holds BSc (Hons) and PHD degrees in Human Genetics and Biotechnology respectively, from University College London. She is a specialist in the field of monoclonal antibody production with keen interest in regenerative medicine, immunotherapies and biologics.

Daniel Grunstein is a Consulting Analyst at Frost & Sullivan in Israel and has been working on the TASE since joining the company in February 2017. Daniel has five years of work experience in research and international business development in Australia and Israel. Daniel holds a BA (Economics) from the University of Sydney, and an MBA (Innovation & Strategy) from Tel Aviv University.

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For further inquiries, please contact our lead analyst.

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