Enlivex Therapeutics Ltd.
Form 6-K
March 27, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer

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under the Securities Exchange Act of 1934

For the month of: March 2019

Commission file number: 001-36578

ENLIVEX THERAPEUTICS LTD.

(Translation of registrant's name into English)

14 Einstein Street, Nes Ziona, Israel 7403618

(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 x Form 40-F ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): ¨

This Report on Form 6-K is being furnished in connection with a series of transactions with respect to the business combination between Bioblast Pharma, Ltd. and Enlivex Therapeutics Ltd., which are described herein.

As used in this Report on Form 6-K, (1) the terms "Company," "we," "us," and "our" refer to the combined enterprises of Bioblast Pharma Ltd., a company organized under the laws of the State of Israel ("Bioblast"), and Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel ("Enlivex"), after giving effect to the Merger (as defined below) and the related transactions described herein, (2) the term "Bioblast" refers to the business of Bioblast Pharma Ltd. prior to the Merger, and (3) the term "Enlivex" refers to the business of Enlivex Therapeutics Ltd., prior to the Merger, in each case unless otherwise specifically indicated or as is otherwise contextually required.

Merger

As previously reported in the Report on Form 6-K furnished by Bioblast with the Securities and Exchange Commission ("SEC") on November 19, 2019 (the "Previous 6-K"), Bioblast entered into an Agreement and Plan of Merger (the "Merger Agreement") with Enlivex and Treblast Ltd., a company organized under the laws of the State of Israel and a wholly owned subsidiary of Bioblast ("Merger Sub"), pursuant to which Merger Sub agreed to merge with and into Enlivex (the "Merger"), with Enlivex surviving the Merger as a wholly owned subsidiary of Bioblast. The Merger was structured as a statutory merger pursuant to Sections 314-327 of the Companies Law, 5759-1999 of the State of Israel.

On March 26, 2019 (the "Closing Date"), pursuant to the Merger Agreement, Merger Sub and Enlivex consummated the Merger, and Enlivex became a wholly owned subsidiary of Bioblast. In addition, upon completion of the Merger, the name of the Company changed to Enlivex Therapeutics Ltd., and the Company has been admitted for continued listing on the Nasdaq Capital Market under the new symbol "ENLV".

Pursuant to the Merger Agreement, upon consummation of the Merger (the "Effective Time"), each outstanding ordinary share of Enlivex was converted into approximately 0.04841 ordinary shares of the Company (the "Exchange Ratio").

In addition, all outstanding Enlivex options that were unexercised immediately prior to the Effective Time, whether or not vested, were assumed by the Company, and contain the same terms, conditions, vesting and other provisions, except that each such option is now exercisable for such number of ordinary shares of the Company, as adjusted in accordance with the Exchange Ratio and otherwise in accordance with the Merger Agreement.

Following the Merger, but prior to consummation of the concurrent Private Placement (as defined below), the former equityholders of Enlivex owned approximately 96% of the Company's issued and outstanding equity, and Bioblast shareholders immediately prior to the Merger owned approximately 4% of the Company's issued and outstanding equity, in each case on a fully-diluted basis in accordance with the treasury stock method.

As previously reported in the Previous 6-K, pursuant to a Contingent Value Rights Agreement (the "CVR Agreement"), Bioblast shareholders received one contingent value right ("CVR") for each ordinary share of Bioblast held as of the record date, March 25, 2019, which CVRs entitle the holders to potential payments that the Company receives in connection with a Trehalose transaction, as further described in the Previous 6-K.

The foregoing descriptions of the Merger Agreement and CVR Agreement are only summaries, do not purport to be complete and are qualified in their entirety by reference to the full text of the Merger Agreement and the CVR Agreement, copies of which were filed as Exhibit 99.1 and Exhibit 99.2, respectively, to the Previous 6-K and are incorporated by reference herein.

Private Placement

Additionally, in connection with the Merger Agreement, Bioblast entered into a securities purchase agreement dated March 11, 2019 (the "Purchase Agreement") with certain private investors (the "Investors"), pursuant to which the Investors agreed to purchase an aggregate of 437,733 ordinary shares of Bioblast for a purchase price of $12.25 per share (the "Private Placement"), which closed on the Closing Date upon consummation of the Merger.

None of the ordinary shares of the Company issuable pursuant to the Merger or upon exercise of options assumed in the Merger (collectively, the "Merger Securities") or the ordinary shares issued and sold in the Private Placement have been registered under the Securities Act of 1933, as amended (the "Securities Act"). The Company offered and sold the Merger Securities and the ordinary shares in the Private Placement in reliance upon the exemptions from registration contained in Section 4(a)(2) of the Securities Act and/or Regulation S promulgated under the Securities Act.

The foregoing description of the Purchase Agreement is only a summary and is qualified in its entirety by reference to the complete text of the Purchase Agreement, which is filed as Exhibit 99.1 to this Report on Form 6-K and incorporated by reference herein.

Accounting Treatment

The Merger is being treated as a reverse acquisition of Bioblast for financial accounting and reporting purposes. As such, Enlivex is treated as the acquirer for accounting and financial reporting purposes while Bioblast is treated as the acquired entity for accounting and financial reporting purposes. Further, as a result, the assets and liabilities and the historical operations that will be reflected in the Company's future financial statements filed with the SEC will be those of Enlivex, and the Company's assets, liabilities and results of operations will be consolidated with the assets, liabilities and results of operations of Enlivex.

Amendment of Articles of Association

In connection with the consummation of the Merger, on the Closing Date, the Company amended its Articles of Association (the "Amended and Restated Articles of Association"), in order to change its name from "Bioblast Pharma Ltd." to "Enlivex Therapeutics Ltd." and to change the registered capital of the Company to NIS 18,000,000 divided into 45,000,000 ordinary shares with a nominal value of NIS 0.40 each.

The Amended and Restated Articles of Association are filed as Exhibit 99.2 to this Report on Form 6-K and incorporated by reference herein.

Business Overview

The Company is a clinical stage immunotherapy company, developing an allogeneic drug pipeline for immune system rebalancing. Immune system rebalancing is critical for the treatment of life-threatening immune and inflammatory conditions, which involve the hyper-expression of cytokines (Cytokine Release Syndrome) and for which there are no U.S. Food and Drug Administration ("FDA")-approved treatments, as well as treating solid tumors via modulating immune-checkpoint rebalancing. The Company's innovative immunotherapy candidate, Allocetra™, is a novel immunotherapy candidate based on a unique mechanism of action that targets clinical indications that are defined as "unmet medical needs" such as preventing or treating complications associated with bone marrow transplants ("BMT") and/or hematopoietic stem cell transplants ("HSCT"), sepsis and acute multiple organ failure. The Company also intends to develop its cell-based therapy to be combined with effective treatments of solid tumors via immune checkpoint rebalancing to increase the efficacy of various anti-cancer therapies, including Chimeric Antigen Receptor T-Cell Therapy ("CAR-T") and therapies targeting T-Cell Receptor Therapy ("TCR").

Cytokines are a broad and loose category of small proteins (~5–20 kDa) that are important in immune cell signaling. They are released by cells and affect the behavior of other cells, and include chemokines, interferons, interleukins, lymphokines, tumor necrosis factors and others, but generally not hormones or growth factors.

Cytokines are produced by a broad range of cells, including immune cells, primarily macrophages and dendritic cells, and are especially important in the immune system as they promote, modulate and balance immune responses. Cytokines are important in health and disease, specifically in host responses to infection, immune responses, inflammation, trauma, sepsis, cancer and other conditions. Cytokine Release Syndrome ("CRS") is a systemic inflammatory response in which cytokine release composition and amplitude spirals out of control. It is considered difficult to treat with traditional small molecules or biologics because the condition involves dozens of cytokines that induce multiple biological paths of hyper immune activity. Such hyper immune activity may result in an attack of immune killer cells (e.g., T-Cells, B-Cells and Natural Killer Cells) on healthy organs of the patient, including the heart, brain, lungs, liver, kidney and others, which may lead to organ damage, multiple organ failure and mortality. The Company believes that the only approach to handling such a multi-factorial complex life-threatening situation is via an integrated cell-based immunotherapy that induces the immune system to rebalance itself to normal levels of operation utilizing a mechanism of action used regularly by the immune system and developed through evolution.

There are many clinical conditions in which a patient has the potential to develop Cytokine Release Syndrome. Those clinical conditions include complications associated with HSCT, sepsis, and several autoimmune and inflammatory conditions, such as Crohn's disease, rheumatoid arthritis, gout and multiple sclerosis.

Immune System Triggering and Relaxation

The immune system constantly handles multiple challenges of bacterial, viral, fungal and other infections via a sophisticated elevation of immune activity utilizing enhanced cytokine releases from macrophages and dendritic cells, resulting in recruitment of antibodies and immune cells (e.g., T-Cells, B-Cells and Natural Killer Cells). Once the threat has been eliminated, the immune system rebalances itself into a normal state. Such rebalancing occurs naturally through antigen presenting cells, macrophages and dendritic cells that engulf and clear infected cells that have been instigated into apoptosis and cells from the immune system that have gone through programmed cell death, causing a

decrease to normal levels of cytokines and immune activity.

Apoptosis is a natural and critical process in tissue and organ maintenance that occurs when a cell is damaged beyond repair, infected with a virus or undergoing other stressful conditions. Apoptosis involves a series of biochemical events leading to changes in cell morphology and, ultimately, cell death. Immediate removal of the dying cell is performed by antigen presenting cells, macrophages and dendritic cells. The primary function of dendritic cells is phagocytosis, or the capturing and transportation of antigens to draining lymphoid tissues. Immature dendritic cells are capable of large-scale phagocytosis of apoptotic cells.

As many as 3×10^8 cells undergo apoptosis every hour in the human body. One of the primary “eat me” signals expressed by apoptotic cells is phosphatidylserine (PtdSer). Apoptotic cells themselves serve as major contributors to the “non-inflammatory” nature of the engulfment process, some by secreting thrombospondin-1 (TSP-1) or adenosine monophosphate and possibly other immune modulating “calm-down” signals that interact with antigen presenting cells, macrophages and dendritic cells. Apoptotic cells also produce “find me” and “tolerate me” signals to attract and immune-modulate antigen presenting cells, macrophages and dendritic cells that express specific receptors for some of these signals (Trahtemberg and Mevorach; 2017).

Injection of a high volume of densely concentrated early apoptotic cells activates dendritic cells, causing them to migrate to the lymphoid tissues, such as the spleen, where they interact with T-cells and B-cells, which are lymphocytes involved in the regulation of the immune system, remove the apoptotic cells and suppress inflammation. The foregoing process induces immunotolerance, as opposed to general immunosuppression, which would otherwise make the patient more susceptible to infection and other immunological challenges.

The Company’s unique therapeutic approach is based on inducing immunotolerance and the specific normal rebalancing of the immune system by infusing early and stable apoptotic cells (dying cells) into the patient. Once infused, such apoptotic cells interact with macrophages and dendritic cells via well-defined mechanisms causing rebalancing of an over-agitated immune response.

Using this inherent immune pathway, the Company believes that it can use Allocetra™ to shape a patient’s innate immune response to a disease, leading to a decrease in unwanted immune response. During the apoptotic cell removal process, several therapeutic responses are induced, such as inflammation suppression, modulation of macrophage-directed deletion of invading pathogens and regulation of immune responses. These responses are the target of Allocetra™. The Company believes that Allocetra™ can specifically target the immune response without simultaneously diminishing the general immune capabilities of the patient or compromising the patient’s ability to respond to immunological challenges.

The Company’s current clinical development programs focus on preventing or treating complications associated with HSCT, sepsis and solid tumors. The Company’s most advanced product candidate, Allocetra™, has been developed for the prevention of complications post HSCT, treatment of patients who do not respond to steroid treatment upon

occurrence of graft versus host disease ("GvHD") ("steroid refractory patients"), and prevention of organ damage, or multiple organ failure in sepsis patients. Additionally, the Company is currently examining the potential for collaborating with leading CAR-T companies in clinical studies to evaluate the efficacy of immunotherapy treatments in combination with Allocetra™ for treatment of solid tumors.

Complications Associated with Bone Marrow Transplants

Allocetra™ for preventing or treating complications associated with HSCT is an immunomodulation cell-therapy drug in development that involves injection of early-apoptotic cells that have been retrieved from the blood of either (i) a donor matched by his or her human leukocyte antigen (i.e., a protein found on white blood cells that is the standard genetic marker for the regulation of the immune system and is used to match donors and recipients in transplantations), (ii) the patient, or (iii) an allogeneic, unmatched donor and have undergone *ex-vivo* (i.e., prior to infusion) manipulation to stabilize the "early apoptosis" status of the cells for a prolonged period of time. Allocetra's™ specific clinical indications include (i) preventing complications associated with HSCT through an injection *prior to* and two weeks following the bone marrow transplantation procedure, and (ii) treatment of steroid refractory patients upon occurrence of GvHD post HSC transplantation. Systemic corticosteroids are the standard of care for the initial treatment of grade 2–4 GvHD. However, many patients with acute GvHD ("aGvHD") do not experience sustained responses to corticosteroids which may lead to multiple organ failure and potential death, and for which 6-month survival rates among steroid-refractory patients are approximately 49% with long-term survival rates of only 5–30%.

Graft Versus Host Disease (GvHD)

Allogeneic hematopoietic stem-cell transplantation (HSCT) has revolutionized the treatment of hematopoietic malignancies, inherited hematopoietic disorders, aplastic anemia, and other severe diseases (Copelan 2006). The HSCT clinical benefit is in part a result of the graft-versus-leukemia ("GVL") effect, in which a donor immune response is targeted against recipient malignant cells. Although alloreactive donor T-cells play an important role in GVL by targeting tumor cells for elimination, the serious complication of GvHD develops when alloreactive donor cells attack healthy host tissues. Despite promising advances in HSCT methodology, including prophylactic immunosuppressive therapies, approximately 50% of HSCT recipients develop GvHD. GvHD can present as an acute disease, aGvHD, or a chronic ("cGvHD") disease. Both aGvHD and cGvHD are inflammatory disorders initiated by the infiltration of alloreactive T cells into target organs, followed by activation of proinflammatory signaling cascades, tissue damage and organ failure. Previously, the distinction between aGvHD and cGvHD was based solely on the time of onset (i.e., during or after 100 days post-transplant). However, important pathophysiological distinctions have since been identified, requiring evaluation of clinical presentation to make an accurate disease diagnosis. The skin is the organ most typically affected at the onset of aGvHD, followed by the gastrointestinal tract and liver. Several organ systems, including the skin and gastrointestinal tract, are also affected in cGvHD, but clinical distinctions can be made to differentiate cGvHD from aGvHD in these organ systems. Additional diagnostic symptoms of cGvHD manifest in the mouth, genitalia, lungs and muscles. The target organ damage observed in aGvHD is primarily characterized by apoptosis, whereas cGvHD is associated with fibrosis and many autoimmune features, indicative of an expanded role for macrophages and B cells compared with aGvHD (Jagasia et al; 2018). The Allocetra™ clinical development program is aimed to prevent, and in some cases treat, post transplantation complications such as aGvHD.

The standard of care for treatment of complications associated with HSCT, including GvHD, often involves immune-suppressants, such as corticosteroids. Some patients do not respond to corticosteroids, and lack of any other

treatment alternative leave these patients with a bleak survival prognosis. The subset of patients who do respond to corticosteroids faces the risk that the immune system may become so suppressed that the ability of the immune system to fight pathogens severely deteriorates and becomes unable to fight severe infections, which are abundant in a typical hospital setting.

The Company conducted a Phase IIa clinical study, which evaluated the safety, tolerability and preliminary efficacy profile of Allocetra™ for the prevention of complications post HSCT. The study demonstrated that Allocetra™ has the potential to induce immune-tolerance and immune system rebalancing to normal activity levels in a patient post HSCT, thus preventing Cytokine Release Syndrome and complications associated with HSCT, without undermining the ability of the transplanted bone marrow to attack the remainder of the cancer disease in the patient. Specifically, patients who received effective doses of Allocetra™ experienced no Cytokine Release Syndrome and no GvHD grade II-IV and were discharged from the hospital after an average duration of 21 days of hospitalization compared to an historical data expected duration of 41-45 days. In trials to date, Allocetra™ has been well-tolerated, and there has been no observable, significant adverse side effects.

Summary of Allocetra™ Clinical Trials

Phase IIa Trial: Allocetra™ for the prevention of aGvHD

After completing all pre-clinical safety and efficacy testing in animals, the Company began a multi-center Phase IIa clinical trial of Allocetra™ to evaluate the safety, tolerability and preliminary efficacy profile of the drug for the prevention of aGvHD in allogeneic HSCT patients at Hadassah Medical Center, Rambam and Sheba Medical Centers in Israel. The study protocol included 13 patients who were intravenously infused with ranging doses of Allocetra™ 24 hours prior to an allogeneic HSCT procedure and then monitored for 180 days following transplantation. The Company published a summary of the results from such trial in the peer-reviewed journal of the American Society for Blood and Marrow Transplantation, the Biology of Blood and Marrow Transplantation, titled “Single Infusion of Donor Mononuclear Early Apoptotic Cells as Prophylaxis for Graft-versus-Host Disease in Myeloablative HLA-Match Allogeneic Bone Marrow Transplantation: A Phase I/IIa Clinical Trial.”

The primary objective of the Phase IIa clinical trial in Israel was to determine the safety profile and tolerability, or dose limiting toxicity, of ascending doses of Allocetra™ within 180 days post-transplantation in subjects undergoing allogeneic HSCT from matched-related donors (i.e., donors’ whose tissues were immunologically compatible with the recipient). The secondary objectives of the trial were to determine (i) the success rate of allogeneic HSCT and the time to successful engraftment, (ii) the rates and severity of aGvHD following Allocetra™ infusion and (iii) the immunological function of the patient following the HSCT procedure and Allocetra™ infusion.

The Company’s clinical data from its Phase IIa trial indicate that Allocetra™ was well-tolerated at all doses administered for up to six months post-transplantation, which was the observed duration of the trial. The Company did not observe

or receive reports of any definite or probable adverse effects related to Allocetra™. Although historical data shows that approximately 50% of patients with aGvHD are expected to advance to the most severe grades of GvHD (i.e., Grades II-IV), none of the six patients treated with the two highest doses of Allocetra™ (defined as the effective doses) in the study advanced to such grades. In fact, the number of overall adverse effects decreased with Allocetra™ dose escalation, Grade I aGvHD was 50% in the same cohorts, and mild chronic GvHD was present in a number of patients. This finding might suggest that Allocetra treatment, as a physiological modality, reduces high grade GvHD rather than abolishing it, supporting a favorable GvL response. In this trial, Allocetra™ injections were not associated with prolongation of time to engraftment, chimerism delay (i.e., an increase in the time it takes for donor immune cells to become immunologically effective in the patient's body), increased mortality rate or serious infections when compared with similar patients described in scientific literature. Patients who received effective doses of Allocetra™ experienced no Cytokine Release Syndrome symptoms and were discharged from the hospital after an average duration of 21 days of hospitalization compared to an expected duration of 41 days as per historical controls, the charts above summarize certain of these findings.

Continuation with Phase II and II/III Clinical Trials

The Company plans, subject to regulatory approvals, to initiate clinical trials with Allocetra™ for the prevention and treatment of complications post-HSCT in early 2020: (i) Phase II/III for prevention of complications post-HSCT from matched unrelated donors (MURs) pursuant to which the Company currently intends to enroll up to 60 patients; and (ii) Phase II for the treatment of steroid-refractory patients with GvHD post-HSCT pursuant to which the Company currently intends to enroll up to 40 patients, both to be conducted in Israel and the European Union (EU).

The FDA granted the Company's orphan drug designation request for the active moiety, or the part of the drug responsible for the physiological or pharmacological action of the drug substance, for the prevention of aGvHD. Orphan designation qualifies the sponsor of the drug or biologic for various development incentives, including tax credits for qualified clinical testing and 7-year marketing exclusivity post commercialization. In addition, Allocetra™ received from the European Medicinal Authority (the "EMA") an (i) Advanced Therapy Medicinal Product ("ATMP") certification for the prevention of aGvHD, and (ii) Orphan medicinal product designation for the indication: Prevention of graft-versus-host disease. This designation may provide Allocetra™ with a 10-year market exclusivity incentive upon commercialization.

Sepsis

The Company is also developing Allocetra™ as an adjunctive immunomodulating cell therapy for avoiding organ failure caused by sepsis. The drug would be administered intravenously to the patient following the diagnosis of sepsis in addition to standard of care treatment.

Sepsis is a highly heterogeneous syndrome that is caused by an unbalanced immune host response to an infection. Sepsis was not clinically defined until the early 1990s when a group of key opinion leaders released the first consensus definition of sepsis. Sepsis has been defined as a systemic inflammatory response syndrome ("SIRS") caused by an infection; and increasing severities have been designated as 'severe sepsis' (referring to sepsis and organ dysfunction) and 'septic shock' (referring to sepsis and refractory hypotension). In the most recent 'Sepsis-3' consensus definition, sepsis is defined as a life-threatening organ dysfunction that is caused by a dysregulated host response to infection, and the term "severe sepsis" has been removed. Of note, although infection is the triggering event in this definition of sepsis, the aberrant immune response often remains after successful treatment of the infection. Sepsis imposes a substantial global burden in terms of morbidity and mortality. Nearly all patients with severe sepsis require treatment in an intensive care unit. Sepsis, which has been identified by the World Health Organization as a global health priority, has no proven pharmacologic treatment other than appropriate antibiotic agents, fluids, and vasopressors. Sepsis affects approximately 1.7 million adults in the United States each year and potentially contributes to more than 250,000 deaths. Various studies estimate that sepsis is present in 30% to 50% of hospitalizations that culminate in death (Rhee et al; 2019) Previous attempts to find a therapy for sepsis failed partially due to the parallel

and complex course of biological activities that occur within a sepsis patient. For many years, a disproportionate inflammatory response to invasive infection was considered to be central to the pathogenesis of sepsis, but it is now clear that the host response is disturbed in a much more complex way, involving both sustained excessive inflammation and immune suppression, and a failure to return to normal homeostasis.

This outcome may lead to organ damage, multiple organ failure and mortality. If the immune system could be rebalanced, we believe that many of the outcomes, specifically organ damage and failure, could be prevented and significantly increase a patient's chance of survival with reduced morbidity.

Preclinical Data, Sepsis

In its preclinical study, the Company utilized a murine cecal ligation puncture ("CLP") sepsis model. The CLP model has been proposed to more closely replicate the nature and course of clinical sepsis, as compared to other models.

We evaluated the effect of Allocetra™ in mice, given 4 hours after the end of a CLP procedure, in combination with Ertapenem© a highly effective antibiotic commonly used for the treatment of severe or high-risk bacterial infections. Mice were monitored for clinical signs and determination of the murine sepsis score. The endpoint was defined as survival (either death or sacrifice when a total clinical score of 15 or maximum score in one of the categories was reached).

As shown in Figure 2A, antibiotic treatment showed a non-significant tendency to ameliorate mortality of the mice (Ertapenem + vehicle, n=15) compared to the control group (CLP only, n=16). Treating CLP mice with the combination of antibiotics and Allocetra™ significantly delayed and prevented mortality in 60% of the animals (Ertapenem + Allocetra™, n=20, $p<0.001$). In comparison to the control group, the Company's study reflected an approximately 10-fold improvement in the survival rate ($p<0.001$ in a log-rank analysis). As shown in Figure 2B, Allocetra™ treated mice had significantly lower murine sepsis clinical scores indicating superior clinical condition. Finally, the Company correlated the clinical score to serum cytokines/chemokines in vivo measurements and as shown in Figure 2C. Allocetra™ downregulated pro-inflammatory cytokines/chemokines. In the preclinical study, Allocetra™ delayed and prevented mortality in animal models with sepsis by rebalancing the immune system.

Figure 2A

Figure 2B

Figure 2C

Initiation of Phase Ib and II clinical studies in Sepsis

The Company has initiated a “Prevention of sepsis related organ dysfunction with Allocetra™ (P-SOFA-1)” p Phase Ib clinical trial in the first quarter of 2019 pursuant to which it plans to enroll 10 patients. Upon the successful completion of this study, the Company is planning to initiate a randomized, multi-center, vehicle-controlled, comparative, open-label, study evaluating safety and efficacy of Allocetra™ for the prevention of cytokine storms and organ dysfunction in patients with sepsis. This study is currently planned to be initiated in late 2019. The study design includes planned enrollment of 40-50 patients. The primary objective will be to evaluate the safety of Allocetra™ and its efficacy in reducing cytokine storms, organ damage and organ failure in patients with sepsis. Secondary objectives will be to assess preliminary clinical efficacy and to support the proposed mechanism of action and biological effect. Each patient will be followed for a period of 28 days.

Solid Tumors, Macrophage Programming and CAR-T Treatments

The Company is also developing Allocetra™ as a next-generation solid cancer immunotherapy. While first-generation immuno-oncology therapies, such as checkpoint inhibitors, are a significant therapeutic advancement, most patients do not achieve durable clinical benefit. Companies such as Novartis, Juno and Kite have made significant advances in treatment of recurring blood cancers via CAR-T therapies, immunological treatments that use the body's own immune system to treat cancerous cells. CAR-T therapies have not proven highly successful against solid tumors.

Solid tumors are harder to treat primarily due to the complex and interconnected tumor microenvironment. The Company believes that Allocetra™ presents a significant opportunity to engage the body's immune system, enabling anti-cancer therapies such as CAR-T, TCR and others to effectively treat solid tumors thus improving cure rates for patients with a variety of solid cancers.

The data from the Company's preclinical studies show that the Allocetra™ cells, which have demonstrated a strong safety profile in a previous clinical trial, have not only caused a significant increase in duration of survival compared with stand-alone CAR-T treatment, but also have demonstrated an ability for complete remission for some preclinical subjects.

In the Company's preclinical study, SCID-Bg mice were injected intra-peritoneally with 2 consecutive doses of $0.25x10^6$ human HeLa-CD19-luciferase cells (HeLa cancer cells expressing CD19), on days 1 and 2 of the experiment. Mice also received $10x10^6$ Allocetra™ or vehicle, on day 9; and $10x10^6$ CD19-CAR-T (third generation) cells or mock T cells on day 10. Mice were weighed twice a week and monitored daily for clinical signs and peritoneal fluid accumulations. Pre-scheduled sacrifices were performed to characterize the cell and macrophage sub-population profile. The rest of the mice were kept for survival analysis. The survival endpoint was defined by a score based on severe peritoneal fluid accumulation manifested as an enlarged and tense abdomen, and reduced mobility or increased respiratory effort. These preclinical findings correlated to large accumulation of HeLa cells in the peritoneum. Survival analysis was performed according to the Kaplan-Meier Log rank statistical test. The Company is currently examining the potential for collaborating with companies developing leading potential immune therapies to evaluate the efficacy of immune therapy treatments in combination with Allocetra™ for the treatment of solid tumors.

Accelerated Regulatory Approval Processes for Life Saving Therapies

The Company anticipates that its therapeutic drugs and their respective indications could qualify under specific accelerated regulatory paths in both the EU and the United States. Specifically for the EU, an accelerated path allowing conditional marketing approval is available for certain therapeutic drugs following a Phase II study. There is no assurance that the Company will qualify for such accelerated regulatory paths.

If the Company's products continue to indicate that they may increase long-term survival for patients in life-threatening indications, defined as "unmet medical needs," such as sepsis and complications following bone marrow transplantation, the Company could be eligible to initiate marketing of these drugs in the EU if it receives conditional approval, following submission of a marketing application after completion of its Phase II study to the EMA.

In general, therapeutic products are eligible for conditional marketing approval if they meet at least one of the following categories:

a. Aimed at treating, preventing or diagnosing seriously debilitating or life-threatening diseases (complications post HSCT & sepsis fall within this category);
b. Intended for use in emergency situations; or
c. Designated as orphan medicines. (The Company has already obtained an orphan designation for Allocetra™ for prevention of GvHD post HSCT).

For a product to be granted a conditional marketing authorization following submission of a marketing application, it must fulfil all the following criteria:

a. The risk–benefit balance of the medicinal product is positive;
b. It is likely that the applicant will be able to provide the comprehensive clinical data in future studies post initiation of commercialization;
c. Unmet medical needs will be fulfilled; and
d. The benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

Clinical Trial and Commercial Manufacturing of Allocetra™

To prepare for the planned initiation of its clinical trials, the Company has constructed a good manufacturing process ("GMP") manufacturing facility in Israel to support the production of the Allocetra™ drug product for any clinical trial that will be conducted in the EU or Israel.

The Company has filed several patent applications covering products under development. The first patent, titled "Disease Therapy Using Dying Or Dead Cells" was granted by the U.S. patent office (patent number 9,567,568), the EU (patent number 187, 9601), and Israel (patent number 187,122) with a term expiring in 2025-2026 in the United States and Israel, EU (DE, FR, IE, GB), respectively. The second patent, titled "Therapeutic Apoptotic Cell Preparations, Method for Producing Same and Uses Thereof" was granted by the U.S. patent office (patent number 10,077,426 B2) on September 18, 2018 with a term expiring in 2033 and is currently under prosecution in Australia, Canada, China, Europe, Israel and Japan. Various additional patent applications have been filed and are under prosecution.

License Agreements

Tolaren Ltd.

In April 2008, Tolaren Ltd., which we refer to as Tolaren, granted to us an exclusive, irrevocable, worldwide, royalty free and sublicensable license to research, develop, commercialize, manufacture, market, sell, distribute and otherwise use and exploit a certain patent, patent rights and pending patent applications relating to the method for using apoptotic cells as a treatment for various autoimmune and inflammatory disorders and the production processes with respect to the same. The license further stipulates that all intellectual property rights, including, any inventions, developments, discoveries, results, products data, information and know-how developed by the Company based on the licensed intellectual property rights, belong solely and exclusively to the Company and, to the extent such intellectual property rights are registrable, they may be registered in the name of the Company. We have used and continue to use such licensed technology to develop and produce Allocetra™. Pursuant to the license, we have agreed to manage, maintain and defend the licensed patents, including managing the registration of such patents in different countries. The license expires upon the expiration of the licensed patent; however, upon such expiration, we will have a fully paid-up, nonexclusive, unlimited, worldwide, sublicensable license to the technology developed on the basis of the patent and related patent rights and all inventions, know-how and other intellectual property owned or licensed by us and covered by the agreement or related thereto. The license is terminable by the Company upon 30-days prior written notice or by Tolaren if the Company ceases operations for a period of more than 360 days. Otherwise, the license for each of the patents endures until the expiration of such patent, and the license for any other licensed technology survives indefinitely.

Approximately 97% of the issued and outstanding share capital of Toleran is held by Hadasit Bio-Holdings Ltd., which currently holds approximately 18% of our issued and outstanding share capital.

Hadasit Medical Research Services and Development Ltd. and Yissum Research and Development Company Ltd.

In March 2006, the institutes jointly granted us an exclusive, worldwide, royalty free and sublicensable license to research, develop, commercialize, manufacture, market, sell, distribute and otherwise use and exploit a certain patent and patent rights relating to the therapeutic use of dead or dying cells, including apoptotic or necrotic cells, as well as any associated materials, methods or technology, as well as a method of using the heparin-binding domain of TSP thrombospondin-1, or TSP-1, which we may develop in the future as a molecular-based therapy for the treatment of inflammatory bowel disease. The license further stipulates that all intellectual property rights, including, any inventions, developments, discoveries, results, products data, information and know-how developed by the Company based on the licensed intellectual rights, belong solely and exclusively to the Company and, to the extent such intellectual property rights are registrable, they may be registered in the name of the Company. Pursuant to the license, we agreed to manage, maintain and defend the licensed patents, including managing the registration of such patents in

different countries. The license expires upon the expiration of the licensed patent; however, upon such expiration, we will have a fully paid-up, nonexclusive, unlimited, worldwide, sublicensable license to the technology developed on the basis of the patent and related patent rights and all inventions, know-how and other intellectual property owned or licensed by us and covered by the agreement or related thereto. In addition to certain standard termination provisions relating to the financial condition of each party, we may terminate the license upon 30-days' prior written notice, and the Institutes may terminate the license if we cease our operations for more than 120 days or if the Institutes determine, in their reasonable discretion, that we have ceased making reasonable efforts to commercialize the licensed technology.

Hadasit Medical Research Services and Development Ltd. is the technology transfer office of Hadassah Hospital in Jerusalem, where Prof. Dror Mevorach, one of our directors, is currently the Director of the Rheumatology Research Centre.

The Company's Competitive Strengths

The Company believes that its clinical data relating to prevention of complications post HSCT, preclinical data in sepsis and solid tumors strategically position the Company to address the currently unmet medical needs of patients suffering from life-threatening clinical conditions involving an off-balance or uncontrolled immune system.

The Company's competitive strengths include:

- *Systemic immune rebalancing instead of immunosuppression.* Unbalanced immune response, which is associated with HSCT, sepsis, and a variety of autoimmune disorders, involve multiple cytokine expression and immune regulation pathways. Current therapies focus on attempts to resolve certain pathways or block certain cytokines. For clinical conditions in which the immune system is out of control, the Company believes that attempts to solve one pathway may not be effective because multiple clinical trials using this "single drug, single target" approach have failed to produce appropriate results. In contrast, Allocetra™ is designed to provide a comprehensive immunotherapy approach that focuses on rebalancing the mechanism of cytokine expression and regulation and thus may be able to provide more complete therapy than current therapies. The Company believes that the ability to induce immune-tolerance as opposed to general immunosuppression, and the use of a variety of immunological pathways as opposed to a single or few pathways or mechanisms of action, positively position Allocetra™ as a potential leader in the fight against complicated, multi-factorial, immune system imbalances.

- *Extensive knowledge and expertise in diseases associated with an unbalanced immune system combined with research and development involving clearance of apoptotic cells.* The Company's management team, scientific advisors, personnel and affiliates have extensive knowledge and experience in the treatment of immune and inflammatory disorders and the research and development of therapies based on the clearance of apoptotic cells. The Company's founder and Chief Scientific & Medical Officer, Professor Dror Mevorach, is a leading physician and scientist who has been investigating over expression and hyper expression of cytokines for the past 18 years, as well as the biological cascade involved with the removal of apoptotic cells. The Company believes that his knowledge and experience will strongly support the clinical development of its product candidates.

- *Broad and comprehensive intellectual property position.* The Company believes that its licensed and owned patents, and patents that may be issued pursuant to its licensed and owned pending patent applications, provide broad and comprehensive coverage for the production processes and use of Allocetra™ for its products under clinical development. Its policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from

third parties, and to protect the technology, inventions and improvements that are commercially important to the development of its business. The Company also relies on trade secrets, know-how and continuing technological innovation to develop and maintain its proprietary position. In addition, the FDA orphan drug designation granted to the active moiety of Allocetra™ for the prevention of aGvHD may result in additional marketing exclusivity for such indication for up to seven years following FDA regulatory approval, and the EMA orphan medicinal product designation granted to Allocetra™ for the prevention of GvHD may provide similar exclusivity in Europe for up to 12 years.

Strategy

The Company's strategy is to build a specialized cell immunotherapy company that discovers, develops and commercializes novel autologous and allogeneic drugs for the treatment of immune, autoimmune and inflammatory conditions. Key elements of the Company's strategy include:

- *Utilizing available accelerated regulatory programs for life-saving advanced therapies*. The Company anticipates that it may be able to initiate commercialization of its products for bone marrow transplantation and sepsis in the EU following its planned Phase II clinical trials, subject to conditional marketing approval from the EMA.

- *Coordinating the European clinical and regulatory development with accelerated regulatory pathways available under FDA guidelines to seek FDA approval of the Company's life-saving therapies,* potentially a regenerative medicine advanced therapy designation, or RMAT, and other potential breakthrough designations.

- *Initiating two clinical trials in 2019*. The Company initiated a Phase Ib in the first quarter of 2019 and plans to initiate a Phase II clinical trial for sepsis in the fourth quarter of 2019, a Phase II/III clinical trial for the prevention of complications post bone marrow transplantation in the first quarter of 2020 and a Phase II clinical study for steroid refractory GvHD patients during 2020.

- *Seeking strategic partnerships during 2019 to explore the increased clinical benefit of the Company's product candidate for treatment of solid tumors in combination with CAR-T and other anti-cancer therapies*.

Description of Property and Facilities

The Company's corporate headquarters are located at 14 Einstein Street, Nes Ziona, Israel 7403618, where it leases and occupies approximately 420 square meters of space. The facility includes office space and current good manufacturing practice ("cGMP") clean rooms, which are designed to enable the manufacturing of clinical batches to support the planned clinical trials in Israel and EU and commercial products for these regions. The lease for this space expires on August 31, 2023 at which time the Company may extend the lease for an additional 60 months' period. In addition, the Company leases and occupies approximately 283 square meters of office and research labs space at the BioPark Building, Hadassah Ein-Kerem Campus, Jerusalem, Israel. The lease for BioPark space expires on December 31, 2019 at which time the Company may extend the lease for an additional 48 months. The Company also leases 12 square meters of laboratory space from Hadassah Medical Center in Jerusalem, Israel to conduct its research and development activities. The Company also has access to and utilizes, on an as-needed basis, additional research and development facilities and services located at the Hadassah Medical Center, including, without limitation, testing equipment, cell collection equipment and services and blood bank services. The Company believes that its facilities are suitable and adequate for its current needs.

Employees

As of March 1, 2019, the Company had 31 full time employees. The Company's Chief Scientific & Medical Officer provides services on a part-time basis pursuant to a consulting agreement. Twenty-five of such employees are involved in product development and six provide general and administrative services. All of these employees are located in Israel. Given its limited number of employees, in order to continue the development and planned commercialization of its product candidates and future products, if any, the Company will need to substantially increase its operations, including expanding its employee base of managerial, operational and financial personnel.

None of the Company's employees are party to any collective bargaining agreements or represented by any labor unions. However, in Israel, the Company is subject to certain Israeli labor laws, regulations, rulings of Israeli labor courts and certain provisions of collective bargaining agreements that apply to its employees by virtue of extension orders issued by the Israel Ministry of Economy and which apply such agreement provisions to the Company's employees even though they are not part of a union that has signed a collective bargaining agreement. These labor laws and regulations primarily govern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. The Company generally provides its employees with benefits and working conditions above the required minimums. The Company has never experienced any employment-related work stoppages and believes its relationship with its employees is good.

All of the Company's employment agreements include employees' undertakings with respect to non-competition, confidentiality and the assignment to the Company of intellectual property rights developed in the course of employment. However, under current applicable Israeli labor laws, the Company may not be able to enforce (either in whole or in part) covenants not to compete and therefore may be unable to prevent its competitors from benefiting from the expertise of some of the Company's former employees.

Liquidity and Capital Resources

As of the date hereof and after giving effect to the Private Placement, we expect that our cash balance will suffice to fund operations and multiple potential clinical milestones during the next 24 months. The Company's cash equivalents are short-term, highly liquid investments that are readily convertible into cash with maturities of three months or less. The Company's cash equivalents are deposited in a major bank in Israel.

The Company's capital resources are intended to be used primarily to fund the research and development of the product candidates in the Company's pipeline and for working capital and general corporate purposes. The Company's

capital resources are expected to be sufficient to fund its business through multiple value creation milestones and into early clinical development during the two years following the date hereof, specifically, a Phase II trial in sepsis, estimated to enroll 40-50 patients with an expected total study cost of $2.5 million and interim results expected in 2020, the Phase II part of an intended Phase II/III trial in prevention of complications post bone-marrow transplantations, estimated to enroll up to 60 patients with a total anticipated study cost of $6.0 million and interim results expected in 2020, and a Phase II trial in steroid-refractory GvHD patients, estimated to enroll up to 40 patients with a total expected study cost of $3.5 million, pursuant to which interim results are expected in 2021.

Legal Proceedings

The Company currently is not a party to any legal, arbitration or governmental proceedings that have had or, in the opinion of the Company's management, may have, material adverse effects on the Company.

Management Following the Merger

Executive Officers and Directors

Resignation of Former Executive Officers and Directors of Bioblast

The directors and executive officers of Bioblast immediately prior to the completion of the Merger have resigned.

Executive Officers and Directors of the Combined Company Following the Merger

Unless otherwise noted herein, and except for the composition of the Board of the Company and its committees, the policies and procedures of the Board and its committees will remain unchanged from the policies and procedures of Bioblast's Board and its committees immediately preceding the closing of the Merger. Please refer to "Board practices" in Part I, Item 6.C of the Company's Annual Report on Form 20-F for the year ended December 31, 2017 for a more detailed description of such practices.

The following table lists the names and positions of the current executive officers and directors of the Company:

Name	Age	Position
Shai Novik, MBA	53	Chairman of the Board
Shmuel Hess, Ph.D.	46	Chief Executive Officer
Prof. Dror Mevorach, M.D.	63	Chief Scientific & Medical Officer
Shachar Shlosberger, CPA	42	Chief Financial Officer
Abraham Havron, Ph.D.	71	Director
Gili Hart, Ph.D.	44	Director
Baruch Halpert	52	Director
Michel Habib	52	Director
Sangwoo Lee	47	Director
Hyun Gyu Lee, M.D, Ph.D	42	Director
Bernhard Kirschbaum, Ph.D	60	Director

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Shai Novik is the Company's Executive Chairman of the Board and has been such since 2014. Mr. Novik founded PROLOR Biotech, Inc. in 2005, and served as its President until 2014. PROLOR Biotech was listed on the NYSE MKT (N/K/A NYSE American) in 2010 and was sold in 2013, the second largest biotech exit ($560 million) in the history of Israeli biotech. Mr. Novik has also served as the Chairman of Innovsion Labs Inc., a neuroscience technology company, since 2007, and as Vice Chairman of CRYPTALGO Holdings AG, a global cryptocurrency and security tokens secondary trading and liquidity platform. Mr. Novik previously served as Chief Operating Officer and Head of Strategic Planning of THCG, Inc., a technology and life sciences investment company. THCG was a portfolio company of Greenwich Street Partners, one of the largest U.S. private equity funds. THCG's portfolio included several life sciences and medical devices companies. Mr. Novik received his M.B.A., with distinction, from Cornell University.

Shmulik Hess, Ph.D., has been the Company's Chief Executive Officer since November 1, 2018. Dr. Hess received his Ph.D. in Pharmaceutical Science from the Hebrew University, Israel and was a research fellow at Harvard-MIT Health Sciences and Technology (HST). Prior to joining the Company, Dr. Hess served as the Chief Executive Officer of Valin Technologies Ltd. from its inception in 2009 until October 2018 and oversaw the execution of Valin's activities and its achievements, including the development, technology transfer, and establishment of cGMP manufacturing facilities for several biosimilars, the first of which has received marketing approval in China; and the in-licensing and acquisition of three early stage innovative drugs. Formerly, Dr. Hess served in global operations at SciGen Ltd. Dr. Hess is the inventor of multiple patents and author of numerous publications in peer reviewed scientific journals.

Prof. Dror Mevorach, M.D., the Company's founder, has been the Company's Chief Scientific & Medical Officer since 2009. Prof. Mevorach is a leading scientist on the removal of apoptotic cells and the Co-Chair of the 2015 Apoptotic Cell Recognition and Clearance Gordon Research Conference at the University of New England in Maine. Prof. Mevorach is currently the Director of the Rheumatology Research Centre of Hadassah Hospital and a Senior Lecturer

in Medicine at the Hebrew University of Jerusalem, Hadassah School of Medicine. Since 2009, Prof. Mevorach has managed the internal medicine department at Hadassah Hospital in Jerusalem. Prof. Mevorach published more than 112 scientific papers, and lectures frequently at international conferences. Prof. Mevorach earned his M.D. from The Technion – Israel Institute of Technology in Haifa, Israel.

Shachar Shlosberger, CPA., has served as the Chief Financial Officer of the Company since 2016, bringing with her more than 11 years of financial experience in the Hi-Tech and Biotechnology Industries. Prior to her position at the Company, Mrs. Shlosberger worked for 4 years at PROLOR Biotech Ltd (NYSE-American: PBTH) as Finance Director where she was responsible for the overall financial operations in Israel and the US. Mrs. Shlosberger is a Certified Public Accountant and holds a M.B.A. in Accounting and Business Administration from the College of Management in Israel.

Bernhard Kirschbaum, Ph.D., has been a Director of the Company since 2018. Dr. Kirschbaum served as Executive Vice President and a member of the Board at Merck Serono, and Head of Global Research & Early Development reporting to the Chief Executive Officer of Merck Serono from 2011 to 2013. He led a global team of more than 1,200 employees, with a 400 million Euro annual budget. Since then, he has served as a member of the board of directors of several biotechnology companies, including Redx Pharma Plc, Protagen Diagnostics, Omeicos Therapeutics GmbH, BioMedx, KAHR Medical, Ltd. and FutuRx. Dr. Kirschbaum has significant expertise in a broad range of disease areas, including rheumatology/immunology, thrombosis, cardiometabolic diseases, oncology and neurology. He has successfully participated in the profiling of several drugs in their course to the market or during market expansion, including Arava, Velcade, Lovenox, Erbitux and Avelumab. Dr. Kirschbaum led drug portfolio re-allocation with focus on the therapeutic areas: oncology, neurodegenerative diseases (MS, Alzheimers, Parkinsons), autoimmune and inflammatory diseases. Dr. Kirschbaum has also been involved in research activities with respect to fertility, mainly focusing on embryo technologies. He implemented the new Merck Serono research organization, including an exploratory medicine department and all non-clinical development functions (toxicology, general & safety pharmacology, Chemistry, Manufacturing and Control (CMC) development and Drug Metabolism and Pharmacokinetics (DMPK)). Previously, Dr. Kirschbaum was Vice President Discovery Research, Global Head of Thrombosis and Angiogenesis at Sanofi-Aventis; and Vice President, Drug Innovation and Approval at Sanofi-Aventis. Dr. Kirschbaum earned his Ph.D. in biochemistry, summa cum laude, from the University of Konstanz, Germany, was a postdoctoral fellow with Dr. R.G. Roeder, at the Rockefeller University in New York, and a Research Associate with Dr. M. Buckingham at Institut Pasteur in Paris.

Abraham (Avri) Havron, Ph.D., has been a Director of the Company since 2014. Dr. Havron served as the Chief Executive Officer of PROLOR Biotech, Inc. from 2005 through 2013. Dr. Havron is a 35-year veteran of the biotechnology industry and was a member of the founding team and Director of Research and Development of Interpharm Laboratories (then, a subsidiary of Serono, later acquired by Merck) from 1980 to 1987, and headed the development of the multiple sclerosis drug REBIF, with current sales of more than $1.5 billion annually. Dr. Havron served as Vice-President Manufacturing and Process-Development of BioTechnology General Ltd., from 1987 to 1999; and Vice President and Chief Technology Officer of Clal Biotechnology Industries Ltd. from 1999 to 2003. Dr. Havron's managerial responsibilities included the co-development of several therapeutic proteins and other bio-pharmaceuticals currently in the market, including recombinant human growth hormone (BioTropin), recombinant Hepatitis B Vaccine (Bio-Hep-B), recombinant Beta Interferon (REBIF), recombinant human insulin and hyaluronic acid for ophthalmic and orthopedic applications. Dr. Havron earned his Ph.D. in Bio-Organic Chemistry from the Weizmann Institute of Science, and served as a Research Fellow in the Harvard Medical School, Department of Radiology. Dr. Havron served as a director of Kamada Ltd. (KMDA) from 2010 to 2018. Dr. Havron also currently serves on the board of directors of Collplant Holdings Ltd. (CLGN), which position he has held since 2016, and PamBio, a private biotech company.

Gili Hart, Ph.D., has been a Director of the Company since 2014. Dr. Hart previously held various positions at OPKO Biologics (f.k.a. PROLOR Biotech) and led the pre-clinical, clinical and pharmacological activities there from 2008 until her move in 2018 to Mitoconix Bio Ltd., a biopharmaceutical company developing disease modifying therapies addressing unmet medical needs by improving mitochondrial health, where she currently serves as Chief Executive Officer. Dr. Hart was a research fellow in the Immunology Department of Yale University from 2005 to 2007 and a research fellow at the Immunology Department of the Weizmann Institute of Science in Israel. Dr. Hart currently serves as a member of the board of directors of Collplant Holdings Ltd. (CLGN), which position she has held since 2017. Dr. Hart received her Ph.D. with distinction from the Immunology Department of the Weizmann Institute of Science in Immunology, and a M.S. degree in Biotechnology Engineering, summa cum laude, from the Technion Institute in Israel. Dr. Hart has published numerous papers and patents, in each case focusing on autoimmunity disease and immune system activation.

Sangwoo Lee has been a Director of the Company since 2017. Mr. Lee has served as an Executive Director of the Investment Department at Korea Investment Partners Co. Ltd., the largest capital venture fund in Korea, since 2014 and head of its U.S. branch since 2017. Korea Investment Partners Co. Ltd. is an affiliate of KIP Global Pharma Private Equity Fund, one of the Company's major shareholders. He is responsible for sourcing and evaluation of start-up companies, investment and participation in business development and growth expansion of the fund's investments in the United States and Europe. Previously, from 2013 to 2014, Mr. Lee was General Manager of the MSC Department at Samsung Electronics, responsible for strategic and business planning; and from 2004 to 2013, Vice President, CTO & Foreign Marketing Group Leader at Polidigm Co. Ltd. Mr. Lee received his B.Sc. and M.Sc. from Seoul National University, Department of Control and Instrumentation.

Hyun Gyu Lee M.D, Ph.D has been a Director of the Company since 2017. Mr. Lee has served as an Executive Director, Investment Division, of Korea Investment Partners Co. Ltd., the largest venture capital fund in Korea, since 2016. Korea Investment Partners Co. Ltd. is an affiliate of KIP Global Pharma Private Equity Fund, one of the

Company's major shareholders. He was from 2011 to 2016 Research Assistant Professor with the Department of Microbiology and Immunology, Institute for Immunology and Immunological Diseases, Yonsei University, College of Medicine in Seoul, Korea. He received his Ph.D. in Immuno-Pathology from the Seoul National University, College of Medicine in Seoul, Korea, and his M.D. from Seoul National University, College of Medicine in Seoul, Korea.

Baruch Halpert has been a Director of the Company since 2017. With more than 20 years of experience in venture capital and private equity as an entrepreneur, corporate finance advisor, senior executive and an investor, Mr. Halpert has developed a large network of contacts across the globe. Since 2010, Mr. Halpert has been involved in turn-arounds through active management and private equity investments of high yield opportunities. In this capacity, Mr. Halpert is active in investing in companies with annual revenues of at least $100 million in special situations and took part in the successful turnarounds of, among others, Hemaclear (www.hemaclear.com), Apnano (www.nisusacorp.com) and HBL (www.hbl.co.il). Mr. Halpert currently serves as Executive Chairman of Terragenic International Limited, which position he has held since 2018. Early in his career, Mr. Halpert was active in oil and gas exploration in Israel. In that capacity he obtained, developed and sold the rights to an Israeli oil and gas exploration license, the Megiddo Prospect, to Ultra Petroleum Corp. (Nasdaq: UPL). In 1997, Mr. Halpert founded E*TRADE Israel (www.etrade.com). After obtaining a license from E*TRADE, Mr. Halpert put together a core management team and headed several successful rounds of financing. Following E*TRADE, Mr. Halpert was Head of Corporate Finance at Fantine Capital. Mr. Halpert holds an LLB Degree (Hons.) from Reading University, United Kingdom.

Michel Habib has been a Director of the Company since 2017. Mr. Habib is the Chief Executive Officer of Hadasit Bio-Holdings Ltd., which position he has held since 2018. Hadasit Bio-Holdings currently beneficially owns 18.23% of the outstanding shares of the Company. Mr. Habib was the co-founder and managed Agate Medical Investments and Agate MaC VC funds from 2007-2016 with over $100 million under management. His portfolio companies have attracted investments from leading global and Chinese companies, including Boston Scientific, Johnson & Johnson, Medtronic, Haisco, Longtech, and Xio. Currently, Mr. Habib serves on the board of several investment companies and startups, including Xenia Ventures, Kahr Medical (Chairman), Cellcure, Bioprotect and Ornim Medical. Prior to that he managed Matar Capital Advisors, a venture boutique. Mr. Habib served for nearly four years as Business Development Director of Elron (TASE: ELRN), focusing on the medical devices sector. Prior to Elron, he established and managed the investment banking activity of ING Barings in Israel. Formerly, he served as Vice President Investment Banking at Cukierman & Co. where he led private placements and IPOs in Europe. During the 1990s, Mr. Habib served as a diplomat in Israel's foreign service, where he served as Economic Consul in Boston, and earlier as the first Commercial Attaché to Seoul, South Korea. As Navy Officer (Captain Res.) in the Israel Defense Forces, he was involved in the development of advanced Naval warfare systems for the Navy's elite unit. Mr. Habib holds an Aeronautical Engineering degree from the Technion-Israel Institute of Technology, and is a graduate from Harvard Law School Executive Program On Negotiation. He is a graduate from the foreign service cadet school, and member of the Technion Alumni "100 Club." Mr. Habib was born in Paris, France, and immigrated to Israel in 1973.

Board of Directors

Under the Articles, the Board must consist of at least five and not more than eleven directors. The Board of the Company is currently composed of eight members, and includes Mr. Shai Novik, Dr. Bernhard Kirschbaum, Dr. Abraham (Avri) Havron, Dr. Gili Hart, Mr. Sangwoo Lee, Mr. Hyun Gyu Lee, Mr. Baruch Halpert and Mr. Michel Habib. These directors were nominated immediately after the closing of the Merger and will serve until the next annual general meeting of shareholders of the Company or until their respective successors are duly elected and qualified.

Under the Israeli Companies Law 5759-1999 (the "Companies Law"), the Board must determine the minimum number of directors who are required to have accounting and financial expertise. Under applicable regulations, a director with accounting and financial expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements, sufficient to be able to thoroughly comprehend the financial statements of the combined company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the Board must consider, among other things, the type and size of the combined company and the scope and complexity of its operations. The existing Board of the Company has determined that the Company requires one director with such expertise, and that Mr. Shai Novik has such accounting and financial expertise.

External Directors

Under the Companies Law, except as provided below, companies incorporated under the laws of the State of Israel that are publicly traded, including Israeli companies with shares listed on the Nasdaq such as the Company, are required to appoint at least two external directors, who meet the qualifications requirements set forth in the Companies Law.

Pursuant to regulations under the Companies Law, the board of directors of a company, such as the Company, is not required to have external directors if: (i) the company does not have a controlling shareholder (as such term is defined in the Companies Law); (ii) a majority of the directors serving on the board of directors are “independent,” as defined under Nasdaq Listing Rule 5605(a)(2); and (iii) the company complies with the Nasdaq Listing Rules as to the required composition of the audit and compensation committees of the Board (which require that such committees consist solely of independent directors (at least three and two members, respectively)), as described under the Nasdaq Listing Rules. The Company meets all of these requirements and does not have external directors.

Leadership Structure of the Board

In accordance with the Companies Law and the Articles, the Board is required to appoint one of its members to serve as Chairman of the Board. The Board has appointed Mr. Shai Novik to serve as Chairman of the Board.

Audit Committee

Under the Nasdaq Listing Rules, the Company is required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

The audit committee of the Company (the "Audit Committee") consists of three members, all of whom are independent under the listing standards of the Nasdaq Listing Rules. The members of the Audit Committee are Mr. Shai Novik, Dr. Avri Havron, and Dr. Gili Hart. The Board of the Company has determined that Mr. Novik is an audit committee financial expert as defined by the SEC rules and has the requisite financial sophistication as defined by the Nasdaq Listing Rules. All of the members of the Audit Committee meet the requirements for financial literacy under the applicable Nasdaq Listing Rules.

Each member of the Audit Committee is required to be "independent" as such term is defined in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Compensation Committee

Under the Nasdaq Listing Rules, the Company is required to maintain a compensation committee consisting entirely of independent directors (or the determination of such compensation solely by the independent members of the Board of the combined company).

The compensation committee of the Company (the "Compensation Committee") consists of three members, Mr. Shai Novik, Dr. Avri Havron, and Dr. Gili Hart, all of whom are independent under the listing standards of the Nasdaq Listing Rules.

Employment Agreements and Arrangements with Directors and Related Parties

Agreement with A.S. Novik and Shai Novik

On September 7, 2018, we entered into an agreement with A.S. Novik Ltd., a company organized under the laws of Israel and family-owned entity of Shai Novik ("A.S. Novik"), pursuant to which we retained Shai Novik as our Executive Chairman of the Board for an initial term of two years, to be automatically extended for additional one-year periods, unless either party provides at least 180 days written notice prior to the expiration of the term. A.S. Novik is entitled to a base retainer of $150,000, payable in equal monthly installments, subject to review and adjustment upon certain specified events. Upon the closing of the Merger, A.S. Novik's base retainer was increased to $250,000, which will increase to $350,000 upon the Company having a cash and cash equivalents balance of $20 million. A.S. Novik is eligible to receive an annual cash bonus up to 100% of the base retainer, as determined by the Board, which will be based upon performance criteria established by the Board. If we terminate Mr. Novik's Board service other than for cause, A.S. Novik is entitled to the base retainer for the twelve-month period following the effective date of termination. We have also agreed to reimburse A.S. Novik for up to $3,000 of monthly expenses in connection with Mr. Novik's Board service as our Executive Chairman. Mr. Novik is also entitled to certain other stock option payments upon termination.

Employment Agreement with Shmuel Hess

On November 1, 2018, we entered into an employment agreement (the "Hess Employment Agreement") with Shmuel Hess, Ph.D., to serve as our Chief Executive Officer, for an undefined term, unless and until terminated by either party. Dr. Hess is entitled to a monthly salary of NIS 63,000. The Hess Employment Agreement provides for certain other benefits, including pension, expense reimbursement and use of a company car. The Hess Employment Agreement may be terminated by either party, at any time and for any reason, pursuant to 90-days prior written notice by the terminating party.

Employment Agreement with Shachar Shlosberger

On May 3, 2016, we entered into an employment agreement (the "Shlosberger Employment Agreement") with Shachar Shlosberger, to serve as our Chief Financial Officer, for an undefined term, unless and until terminated by either party. The Shlosberger Employment Agreement may be terminated by either party, at any time and for any reason, pursuant to 30-days prior written notice by the terminating party. Ms. Shlosberger is entitled to a monthly salary of NIS 23,040 and an annual bonus of up to 15% of her annual salary, at the Company's discretion. The Shlosberger Employment Agreement provides for certain other benefits, including pension benefits and use of a cellphone.

Consulting Agreement with Prof. Dror Mevorach and Hadasit Medical Research Services

Prof. Dror Mevorach, M.D., our founder, has also served as our Chief Scientific Officer and as a member of our Board since 2005. On January 1, 2017, we entered into a consulting agreement (the "Consulting Agreement") with Hadasit Medical Research Services and Development ("Hadasit") and Prof. Mevorach for the provision by Prof. Mevorach of services as our Chief Scientific Officer for an initial period of 12 months, which is automatically extended for additional twelve-month periods thereafter, unless earlier terminated by either party. The Consulting Agreement, which may be terminated upon certain breaches or actions, is also terminable by either party upon 30 days prior written notice. Prof. Mevorach is entitled to an annual fee of $180,000 to be paid in monthly installments. We paid Hadasit $63,333.33 pursuant to the Agreement. We also granted options to purchase pre-merger Enlivex ordinary shares to Prof. Mevorach and Hadasit pursuant to the Consulting Agreement, which include an aggregate of 419,281 ordinary shares of the Company granted to Prof. Mevorach and 110,304 ordinary shares of the Company granted to Hadasit which are exercisable at a price of $2.68 per share and additional grants of 145,237 and 29,047 ordinary shares of the Company to Prof. Mevorach and Hadasit, respectively, which are exercisable at a price of $6.22 per share.

Indemnification Agreements

Our Articles permit us to exculpate, indemnify and insure each of our directors and officers to the fullest extent permitted by the Companies Law. We have entered into agreements with each of our directors and Professor Mevorach, exculpating them, to the fullest extent permitted by the Companies Law, from liability for monetary or other damages due to, or arising or resulting from, a breach of the duty of care to the Company and undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from certain acts performed by such office holders in their capacity as an office holder of the Company, our subsidiaries or affiliates. The indemnification is limited both in terms of amount and coverage.

Share Ownership of Major Shareholders and Directors and Officers

The following table and the related notes present information on the beneficial ownership of ordinary shares of the Company by:

- each shareholder known by us to beneficially own more than 5% of the Company's outstanding ordinary shares immediately following the closing of the Merger and the Private Placement;
- each director of the Company;
- each executive officer of the Company; and
- all of the Company's directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. The number of ordinary shares beneficially owned and the percentage of ordinary shares beneficially owned represents amounts after the consummation of the Merger and the closing of the Private Placement, for a total of 9,868,809 ordinary shares issued and outstanding.

Ordinary shares of the Company that may be acquired by an individual or group within 60 days of the date hereof, pursuant to the exercise of options or warrants or the conversion of a security, are deemed outstanding for the purposes of computing the percentage of ordinary shares beneficially owned by such individual or group, but are not deemed outstanding for purposes of computing the percentage of ordinary shares beneficially owned by any other individual or group shown in the table.

Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percentage of Ordinary Shares Beneficially Owned	
The Company's 5% or Greater Shareholders (other than Directors and Executive Officers)			
HBL-Hadasit Bio-Holdings Ltd	1,798,727	18.2	%
Michael Hobi	1,522,283	15.4	%
KIP Global Pharma-Ecosystem Private Equity Fund	1,417,950	14.4	%

Directors and Executive Officers

Shai Novik, Executive Chairman (1)	882,515	8.8	%
Avri Havron, Director (2)	488,356	4.9	%
Dror Mevorach (3)	455,591	4.4	%
Gili Hart, Director (4)	95,192		*
Sangwoo Lee (5)	13,298		*
Hyun-Gyu Lee (5)	13,298		*
Michel Habib (5)	13,298		*
Baruch Halpert (6)	24,412		*
Dr. Shmulik Hess	-		*
Shachar Shlosberger (7)	2,058		*
All directors and executive officers as a group	1,988,018	18.7	%

*Less than 1%.
(1) Includes 169,289 shares underlying options exercisable within 60 days from the date hereof.
(2) Includes 53,192 shares underlying options exercisable within 60 days from the date hereof.
(3) Includes 455,591 shares underlying options exercisable within 60 days from the date hereof.
(4) Includes 66,490 shares underlying options exercisable within 60 days from the date hereof.
(5) Includes 13,298 shares underlying options exercisable within 60 days from the date hereof.
(6) Includes 24,412 shares underlying options exercisable within 60 days from the date hereof.
(7) Includes 2,058 shares underlying options exercisable within 60 days from the date hereof.

Financial Statements

The unaudited financial statements for Enlivex as of and for the three and nine months ended September 30, 2018 and September 30, 2017 and the audited financial statements for Enlivex as of and for the years ended December 31, 2017 and 2016 are filed as Exhibit 99.3 and Exhibit 99.4, respectively, to this Report on Form 6-K and incorporated by reference herein. The audited financial statements for Enlivex as of and for the year ended December 31, 2018 will be filed with the Company's annual report on Form 20-F for the year ended December 31, 2018 to be filed with the SEC within the period required pursuant to applicable SEC rules.

Press Release

On March 26, 2019, the Company issued a press release announcing the closing of the Merger. A copy of the press release is attached as Exhibit 99.5 to this Report on Form 6-K and incorporated by reference herein.

Cautionary Note Regarding Forward-Looking Statements

This Report on Form 6-K includes statements relating to current expectations, estimates, forecasts and projections about future events that are "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include but are not limited to statements about:

- our ability to continue as a going concern and to meet our financial needs, as well as potential raising of funds and their effect on our shareholders;
- our expectations regarding the timing of clinical trials with respect to Allocetra™, if at all;
- the continued listing of our ordinary shares on Nasdaq;
- our expectations regarding the progress of our clinical trials, including the duration, cost and whether such trials will be conducted at all;

- our intention to successfully complete clinical trials in order to be in a position to submit applications for accelerated regulatory paths in the EU and the United States;

- the possibility that we will apply in the future for regulatory approval for our current and any future product candidates we may develop, and the costs and timing of such regulatory approvals;

- the likelihood of regulatory approvals for any product candidate we may develop;

- the timing, cost or other aspects of the commercial launch of any product candidate we may develop, including the possibility that we will build a commercial infrastructure to support commercialization of our current and any future product candidates we may develop;

- future sales of our product candidates or any other future products or product candidates;

- our ability to achieve favorable pricing for our product candidates;

- the potential for our product candidates to receive designation as an orphan drug and implications if they do not receive such designation;

- that any product candidate we develop potentially offers effective solutions for various diseases;

- whether we will develop any future product candidates internally or through strategic partnerships;

- our expectations regarding the manufacturing and supply of any product candidate for use in our clinical trials, and the commercial supply of those product candidates;
- third-party payer reimbursement for our current or any future product candidates;
- our estimates regarding anticipated expenses, capital requirements and our needs for substantial additional financing;
- patient market sizes and market adoption of our current or any future product candidates by physicians and patients;
- completion and receiving favorable results of clinical trials for our product candidates;
- protection of our intellectual property, including issuance of patents to us by the United States Patent and Trademark Office, or USPTO, and other governmental patent agencies;
- our intention to pursue marketing and orphan drug exclusivity periods that are available to us under regulatory provisions in certain countries;
- the development and approval of the use of our current or any future product candidates for additional indications other than complications associated with bone marrow transplants and GvHD;
- our expectations regarding commercial and pre-commercial activities;
- our expectations regarding licensing, acquisitions, and strategic operations; and
- our liquidity.

Forward-looking statements may be identified by the use of forward-looking terminology, such as “may,” “will,” “expect,” “anticipate,” “estimate,” “continue,” “believe,” “should,” “intend,” “plan,” “project,” “hope,” “goal,” “target,” “suggest,” “likel words and phrases of similar meanings, the negative of these terms, and similar references to anticipated or expected events, activities, trends, future periods or results. These forward-looking statements are based upon the Company’s current estimates and projections of future results or trends and are subject to a number of risks, uncertainties and assumptions, including those described above. Actual results may differ materially from those projected as a result of those and other risks and uncertainties. These forward-looking statements are made only as of the date hereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Report on Form 6-K as well as Exhibits 99.1, 99.2, 99.3 and 99.4 are incorporated by reference into the registration statements on Form S-8 (File No. 333-203114 and File No. 333-210459) of the Company, filed with the SEC, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.

99.1	Securities Purchase Agreement, dated March 11, 2019
99.2	Amended and Restated Articles of Association
99.3	Unaudited financial statements for Enlivex as of and for the three and nine months ended September 30, 2018 and September 30, 2017
99.4	Audited financial statements for Enlivex as of and for the years ended December 31, 2017 and 2016
99.5	Consent of Yarel + Partners
99.6	Press Release issued by Bioblast Pharma Ltd. on March 26, 2019

SIGNATURES

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.

Enlivex Therapeutics Ltd.
(Registrant)

By: /s/ Shai Novik
Name: Shai Novik
Title: Executive Chairman

Date: March 27, 2019