

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the years ended December 31, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-55413

Cell Source, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

32-0379665

(I.R.S. Employer Identification No.)

**57 West 57th Street, Suite 400
New York, NY 10019**

(Address of principal executive offices)

(646) 416-7896

(Issuer's telephone number)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common stock, \$0.001 par value

Indicate by check mark whether the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for completing with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes No

As of June 30, 2018, the aggregate market value of the issued and outstanding common stock held by non-affiliates of the registrant was \$14,303,937 based on the closing sale price as reported on the OTC Markets.

As of March 27, 2019, there were 26,077,611 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE -None.

CELL SOURCE, INC.

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements regarding, among other things, our anticipated financial and operating results. Forward-looking statements reflect our management's current assumptions, beliefs, and expectations. Words such as "anticipate," "believe," "estimate," "seek," "expect," "intend," "could," "plan," and similar expressions are intended to identify forward-looking statements. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there. Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-K is filed with the U.S. Securities and Exchange Commission ("SEC"), and we assume no obligation to update the forward-looking statements after the date hereof whether as a result of new information or events, changed circumstances, or otherwise, except as required by law.

PART I

ITEM 1. BUSINESS.

Overview

Our Business

We are a cell therapy company focused on immunotherapy. Since our inception, we have been involved with the development of proprietary immune system management technology licensed from Yeda Research & Development Company Limited (“Yeda”), the commercial arm of the Weizmann Institute of Technology, Israel.

This technology seeks to address one of the most fundamental challenges within human immunology: *how to tune the immune response such that it tolerates selected desirable foreign cells, but continues to attack all other (undesirable) targets*. In simpler terms, many potentially life-saving treatments have limited effectiveness today because the patient’s immune system rejects them. Today, rejection is partially overcome using aggressive immune suppression treatments that leave the patient exposed to many dangers by compromising their immune system. The ability to overcome rejection without having to compromise the rest of the immune system may open the door to effective treatment of a number of severe medical conditions which are characterized by this need. These include:

- Hematological malignancies (leukemias, lymphomas, etc.). One of the most effective treatments for these conditions is SCT - stem cell transplantation (e.g. bone marrow transplantation). While the challenge finding donors for allogeneic (donor vs. patient derived) SCT can be addressed through haploidentical (partially mismatched donor) transplants, is a risky and difficult procedure primarily because of potential conflicts between host and donor immune systems and also due to viral infections that often follow even successful SCT while the compromised new immune system works to reconstitute itself by using the transplanted stem cells.
- The broader set of cancers, including solid tumors, that can potentially be treated effectively using genetically modified cells such as CAR-T cells, but also face efficacy and economic constraints due to limited persistence based on immune system issues (i.e., the need to be able to safely and efficiently deliver allogeneic CAR-T therapy).
- Organ failure and transplantation. A variety of conditions can be treated by the transplantation of vital organs. However, transplantation is limited both by the insufficient supply of available donor organs and the need for lifelong, daily anti-reject treatments post-transplant.
- Non-malignant hematological conditions (such as sickle cell anemia) which could, in many cases, also be effectively treated by stem cell transplantation if the procedure could be made safer and more accessible by addressing conflicts between host and donor immune systems.

Corporate History

Cell Source, Inc. (the “Company”) is a Nevada corporation formed on June 6, 2012 under the name Ticket to See, Inc. (“TTSI”). Cell Source Ltd. (“Cell Source Israel”) was founded in 2011 in order to commercialize a suite of inventions that were the result of over ten (10) years of research at the Weizmann Institute of Science in Rehovot, Israel (“Weizmann Institute”). Pursuant to a Research and License Agreement by and between Cell Source Israel and Yeda, dated October 3, 2011, as amended in April, 2014 November, 2016, and, most recently, in March, 2018 (the “Yeda License Agreement”), Yeda, the commercial arm of the Weizmann Institute, granted Cell Source Israel an exclusive license to certain patents, discoveries, inventions, and other intellectual property generated (together with others) by Yair Reisner, Ph.D. (“Dr. Reisner”), former head of the Immunology Department at the Weizmann Institute.

Implications of being a Smaller Reporting Company

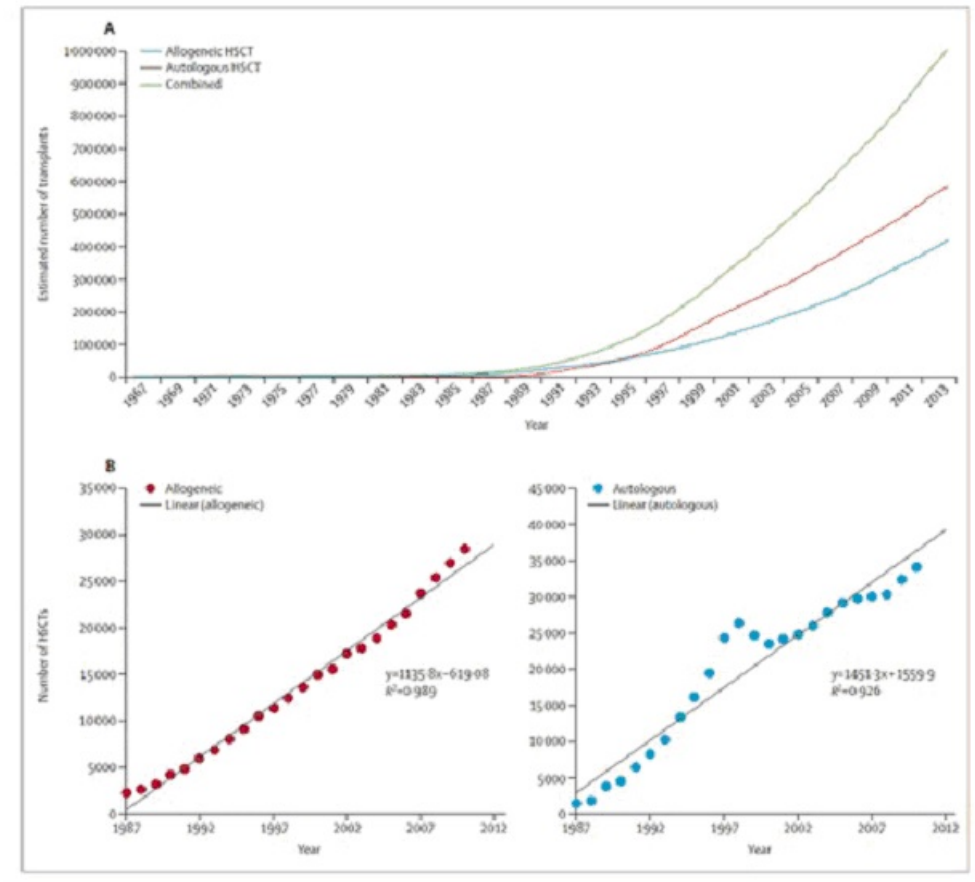
As a company with less than \$100 million in revenue during our last fiscal year and a public float of less than \$250 million, we qualify as a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. A “smaller reporting company” may take advantage of reduced reporting requirements and disclosure obligations that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion & Analysis of Financial Condition and Results of Operations in this report on Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act; and
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements.

We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. Decreased disclosures in our SEC filings due to our status as a “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects.

Hematological Malignancies

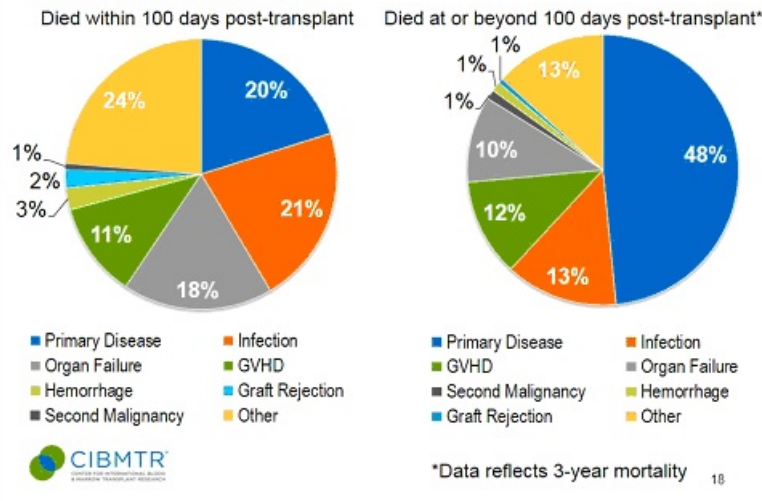
Hematological malignancies (blood cancers) comprise a variety of lymphomas and leukemias. A very important treatment protocol for these malignancies involves the use of hematopoietic stem cell transplantation (“HSCT”). To the best of our knowledge, over 1,000,000 bone marrow transplantations have been performed worldwide with the annual number of procedures exceeding 60,000 (table below). Our technology has immediate relevance for, at a minimum, the roughly 30,000 worldwide bone marrow transplants that are allogeneic (using cells taken from another individual, not the patient). According to the CIMBTR, there were 8,539 allogeneic stem cell transplants in the US in 2016.



Source: Worldwide Network for Blood and Marrow Transplantations

HSCT often has a curative effect when successful. However, it is very risky. HSCT involves destroying the patient’s native immune system with radiation or chemotherapy (myeloablation) before the transplantation, and then suppressing immune response (immunosuppression) with drugs to manage the conflicts between host and donor cells. The majority of patients are unable to find a matched family donor. Approximately 35-40% of all unrelated donor transplant patients die within two years of transplantation. Among these, those who die in the first 100 days post-transplant, 33% die from either infections (associated with a compromised immune system) or GVHD (Graft Versus Host Disease).

Causes of Death after Unrelated Donor HCT done in 2015-2016



Myeloablation and immunosuppression are dangerous and difficult to tolerate, especially in patients over age 50. Therefore, HSCT has been used mainly with younger patients

This means that:

- many blood cancer patients are not candidates for the primary treatment (HSCT) that represents a potential cure;
- there is high mortality among those patients who are candidates for HSCT and do undergo the procedure;

There is widespread awareness of the need for improved immune-system management technologies for HSCT - both to improve outcomes of transplantations for the traditional target set of patients and to expand the use of the procedure by making transplantation safe enough to become appropriate for a broader set of patients.

We aspire to use Veto Cell technology to dramatically improve the outcomes of the allogeneic transplantations already being performed, and thereby to rapidly penetrate the current market. However, our target population greatly exceeds those patients who currently undergo HSCT, as the firm's tolerizing technology could potentially make allogeneic transplantation an option for a much larger proportion of the diseased population. The following table shows the prevalence of the specific hematological malignancies on which we will focus:

Initial Malignancy Indications (note estimates for North America and EU only)	Incidence (Annual New Cases)	Annual Bone Marrow Transplantations
Lymphoma	217,491	20,291
Multiple Myeloma	79,067	20,884
Leukemia	155,080	14,480
Total	451,638	55,655

Source: National Cancer Institute, World Health Organization, Leukemia & Lymphoma Society, Lymphoma Coalition Europe

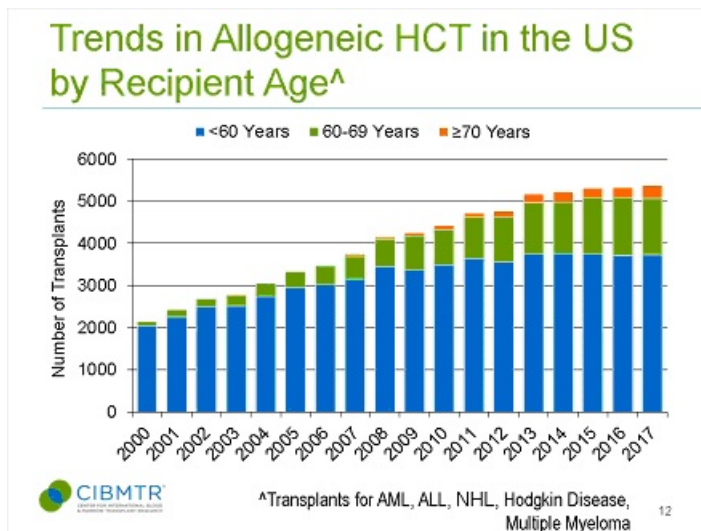
For the purposes of this document, it is assumed that the immediate candidates for Cell Source-enabled HSCT will be the subset of cancer patients that today receive transplantations as part of their cancer treatment (rightmost column in table above). We believe that a portion of these patients will benefit from Veto Cell adjunct therapy, as such therapy aspires to improve the success and reduce the risk and mortality of a procedure that they are having anyway. With time, as Veto Cell treatment becomes more widespread and data is accumulated, we believe that the percentage of patients that will be referred for Veto Cell enabled HSCT will increase significantly.

It is also important to note that incidence of these diseases is increasing. The global market for blood cancer therapeutics was estimated at \$38.5 billion in 2018 and is projected to increase in size to over \$50 billion by 2024 according to "Blood Cancer Therapeutics: Global Markets to 2023." Published by BCC Research. The aging of the US population and the increased incidence of hematologic malignancies are expected to significantly increase the number of older patients who receive allogeneic HSCT.

HSCT Market Trends

There are four important market trends affecting the hematological malignancies market:

- 1) As noted above, increasing incidence of these disorders, largely driven by the aging population.
- 2) Improvement and proliferation of HSCT treatments.
- 3) A "virtuous circle" of lowered death rate due to better transplantations leading to more aggressive focus on HSCT.
- 4) The growing use of milder conditioning regimens, which makes the procedure more survivable for older patients (see table below).



However, despite the above trends, the use of HSCT, especially allogeneic, remains limited because of the risks associated with the myeloablative treatments required to reduce the host immune response and GVHD. This means that the "gold-standard" of treatment is largely unavailable to the age cohort that constitute a significant proportion of sufferers of these diseases.

The Company aspires to address this issue in a distinctive manner by significantly reducing the need for myeloablative treatment and avoiding the risk of GVHD, thereby improving the outlook for allogeneic transplantations and enabling their use in a much larger population set.

CAR-T cell therapy

One of the most promising new approaches to treating hematological malignancies is by using genetically modified T cells in treatments such as CAR-T and TCR. CAR-T cell therapy for blood cancers, which has already been approved by the FDA, has shown the ability to attain prolonged remissions in a significant proportion of those patients treated. That said, the number of patients treated has been fairly low, in part due to the significant costs associated with this treatment. Since the approved treatments products rely on autologous (patient derived) production of the CAR-T cells, the costs can run into the hundreds of thousands of dollars for a single treatment, with the cost of the infusion alone ranging between \$373,000 and \$475,000 in the US. The broader hope for CAR-T cell therapy is for an allogeneic or "off the shelf" version that is expected to significantly lower the treatment costs.

Cell Source is currently sponsoring research in collaboration with Professor Zelig Eshhar, the inventor of CAR-T cell technology, to combine CAR-T and Veto Cell technology so as to allow for a successful allogeneic approach to CAR-T, initially for treatment of blood cancers and subsequently to address solid tumor cancers as well.

Relevant Non-Malignant Diseases

While Hematological malignancies represent the Company's initial focus, the Company's selective immune response blocking technology may also be effective in treating certain non-malignant organ diseases as well as blood and immune system disorders. This would represent an additional growth opportunity for the Company.

The target non-malignant diseases are widespread. The Company's first non-malignant disorder target is expected to be support of organ transplantations (kidney, liver, etc.). Approximately 60,000 such procedures are conducted in North America and the EU each year. As with bone marrow transplantations, organ transplantations require substantial immunosuppression to prevent rejection. This ongoing treatment is dangerous, quality-of-life reducing, and costly. The Company's Veto Cell technology can potentially be used to selectively reduce immune response to the transplanted organ, thus reducing the need for aggressive immunosuppression post transplantation.

A second target within non-malignant disorders are blood diseases such as sickle cell disease, aplastic anemia beta thalassemia and scleroderma. Sickle cell anemia, for example, can be effectively treated by HSCT which replaces the defective bone marrow cells. However, because of HSCT's riskiness, the procedure is currently used only in extreme cases. If successful in enabling safer HSCT, the Company will make this treatment available to a broader set of sickle cell anemia sufferers.

Market Access and Channels

The market for transplantation therapies is relatively concentrated. There are approximately 1,600 transplantation centers worldwide, of which some 700 are in North America and Western Europe.

A relatively small subset of these (often termed "Centers of Excellence") tends to set the practice standards for the entire transplantation community. Therefore, as discussed in the "Strategy" section, the Company plans to focus its initial penetration strategy on a relatively small group of influential centers.

Reimbursement issues for our therapies are expected to be relatively straightforward. Once clinical effectiveness and regulatory approval are established, the value-proposition for payors and providers is expected to be clear and compelling. Issues connected with immunosuppression and rejection constitute a major component of bone marrow transplantation costs, and significant improvement in this area is expected to bring substantive cost-savings for payors.

Sector Focus

We are in the overall arena of immunotherapy. The cancer immunotherapy market was estimated at approximately \$60 billion for 2017 and projected to grow to over \$150 billion by 2024, according to Research and Markets.

Within the immunotherapy field, our initial focus is on allogeneic therapies (treatments using donor derived-as opposed to patient derived-cells), with a focus on haploidentical transplantations (transplantations that use cells from partially matched-as opposed to fully matched-donors and recipients). While potentially valuable, allogeneic therapies are relatively complex, risky, and expensive. A key driver of this complexity and associated costs is the conflict between host and donor immune systems, as discussed above.

Our technology, which in preclinical studies, and in the case of the Megadose Drug Combination in a first-in-human proof of concept, has shown the ability to enable tolerance of donor cells without affecting other immune processes, is fundamentally enabling. We expect it to significantly increase the safety, reduce the cost, and therefore broaden the scope of indications for such procedures.

The delivery method for Veto Cell treatments would take the form of a non-invasive cell suspension treatments administered intravenously. For HSCT treatments, Veto Cells are derived from stem cells taken from the same donor who is providing the stem cells for the transplantation itself. In the case of CAR-T Veto Cell therapy, a more generic "off the shelf" modality offering which would be marketed as a pre-packaged suspension of cells and medium, prepared and stored in.

Our Value Drivers

Our current positioning in the cancer immunotherapy value chain is typical of an early clinical stage company: developing, validating and attaining regulatory approvals for the various applications of our technology platforms. Going forward, once the products are commercialized, physician and patient interest in these treatments is expected to drive insurer reimbursement for patients - a key demand lever. The generic value chain for biotechnology development commences with an invention which is formulated, patented and successful in pre-clinical animal trials. We have already passed this stage with our Veto Cell technology platform, for which we have an exclusive license to use from Yeda, the owner of these patents. The next steps in development include human trials (first testing safety and then efficacy). Finally, the offering earns regulatory approval and patient treatment, along with the ensuing revenues, can commence. This can be a particularly lengthy process in the United States and therefore some medical treatments are approved in Europe or Asia and generate revenues there prior to commencing U.S. sales. Recently passed "fast track" regulation in the U.S. is aimed at getting critical treatments for life threatening conditions to patients more quickly.

Our successful preclinical validation of the Veto Cell treatment involved basic laboratory research including both in-vivo (live) animal trials and in-vitro (in a glass dish) human cell trials. This validates the protocol prior to commencing human clinical trials. Human clinical trials fine-tune the treatment protocol and confirm both safety and efficacy in treating patients. In parallel, the patents on the core technology go into the national phase in various countries and are amended with claims associated with exact treatment protocols, bolstering the protection afforded by already issued patents on the base technology.

In some cases, successful biotech companies have been able to capitalize on positive human clinical results (even prior to full approval for patient treatment) by either signing lucrative non-dilutive distribution option deals or by being partially or fully acquired by larger market participants. KITE Pharmaceuticals, a CAR-T cell therapy company, was acquired outright by Gilead Sciences in 2017 for \$11.9 billion in cash, prior to having attained FDA approval and prior to commencing any product sales. In 2018, Juno Therapeutics was acquired by Celgene Corporation for approximately \$9 billion, also without having FDA approval for its CAR-T cell therapy technology. There is no indication or assurance that we are currently under consideration for any option or acquisition deal.

We plan to commence human clinical trials for approval for the Veto Cell based treatments in the United States in mid 2019. We have had positive preclinical results for three of our cell therapy treatments. Yeda, the proprietary owners of the patents underlying our technologies from whom we license our patents, has been granted patents for its original Veto Cell. The revised versions of the Veto Cell are the subject of patent applications which have been granted in some jurisdictions and are pending in others. These newer patent applications leverage the priority of the already granted patents. We plan to conduct human clinical trials. If these trials are successful, they will demonstrate both safety (the patients survived and were not harmed) and initial indications of efficacy (there are signs of successful engraftment, and in the case of cancer patients prolonging the progression free period).

Science and Technology Overview

The patent portfolio that we license from Yeda, includes a variety of cell therapy applications. The portfolio includes both granted and pending patents. The total relevant patent portfolio consists of 12 patent “families” (i.e. grouping of similar patent applications in different territorial jurisdictions) which currently include, 38 granted patents, 2 allowed patents and a further 51 pending patents. The key terms of the agreement pursuant to which we license all of Yeda’s patents related to our technology is set forth in the section entitled “Intellectual Property” herein. The license period (per product, per country) is for the full life of the patents and expires at the later of the patent expiration date in that country or 15 years after the date that the FDA or local equivalent regulatory authority in each country approves that particular product for sale in that country. As long as Cell Source either continues or sponsor research or pays either a nominal license fee of \$50,000 per year (total for use of all the products) or pays royalties on product sales on at least one product as per the license agreement, the license will remain in effect continuously and expire only with the expiration of the patent or 15 years after regulatory approval (later of the two) per product per country as described above. Cell Source voluntarily sponsors research at the Weizmann Institute for the sake of developing its products and treatments from initial invention through to finalization of human treatment protocols. Cell Source extended the initial research period, which originally terminated in October 2014 through June 2019. Furthermore, it plans to sponsor research at the Weizmann Institute through June 2019.

Professor Yair Reisner, the inventor of Veto Cell technology, has recently left the Weizmann Institute of Science in Israel and relocated to the University of Texas M.D. Anderson Cancer Center (“MD Anderson”) in Houston, Texas. He has been awarded a \$6 million grant from the Cancer Research and Prevention Institute of Texas. This coupled with research funding from the University itself, provides him with a total funding commitment of \$10 million for five years. Professor Reisner is now the Head of Stem Cell Research at the Department of Stem Cell Transplantation & Cellular Therapy at MD Anderson.

Cell Source is currently sponsoring ongoing research by Professor Reisner and his team, some of whom have also relocated from the Weizmann Institute to MD Anderson, for developing existing and new applications for Veto Cell technology and plans to license any new intellectual property developed there on an exclusive basis, as it does from Yeda. MD Anderson is the largest HSCT center in the United States, performing over 1,000 transplantations per year. Cell Source plans to conduct human clinical trials for its Anti-Rejection Anti-Viral Veto Cell at MD Anderson commencing in early 2019. Professor Richard Champlin (who Chairs their Department of Stem Cell Transplantation and Cellular Therapy and is a longtime associate and collaborator of Professor Reisner) will serve as Principal Investigator for these trials.

Although Yeda has applied for and been granted various patents related to our technology, a granted patent only provides Yeda, and the Company by virtue of its exclusive license, the right to use the underlying invention. However, in order for our cell-therapy and cancer therapy to be legally sold and administered to patients, the FDA or similar regulatory agencies must approve its use. In other words, having a patent provides legal “freedom to operate” for a certain technology, and may provide the ability to prevent others from using the same technology without the patent holder’s permission. However, in order to legally manufacture and distribute products, a company must go through all of the typical approval steps delineated in the “Overview” section above.

The following sections provide an overview of each platform. Further information on the underlying science is available upon written request and the execution of an appropriate nondisclosure agreement.

Our licensed technology portfolio consists of 12 patent families, 38 granted patents, 2 allowed patents and a further 51 pending patents. The following table lists the patents and patent applications that Yeda holds and which we have a license to use in each of the below-referenced countries:

Name: VETO CELLS EFFECTIVE IN PREVENTING GRAFT REJECTION AND DEVOID OF GRAFT VERSUS HOST POTENTIAL

Country	Patent Number	Filed	Expires	Status	Assignee
USA (Basic)	6,544,506	05-Jan-2000	05-Jan-2020	Granted	Yeda Research and Development Co. Ltd.
USA (National Phase)	7,270,810	28-Dec-2000	5-Dec-2021	Granted	Yeda Research and Development Co. Ltd.
Israel	150440	28-Dec-2000	28-Dec-2020	Granted	Yeda Research and Development Co. Ltd.

Name: ANTI THIRD PARTY CENTRAL MEMORY T CELLS, METHODS OF PRODUCING SAME AND USE OF SAME IN TRANSPLANTATION AND DISEASE TREATMENT

Country	Patent Number	Filed	Expires	Status	Assignee
USA	2011-0212071-A1	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.
Europe	2365823	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.
Israel	212587	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.
India	905/MUMNP/2011	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.
China	ZL200980153053.4	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.
Russian Federation	2506311	29-Oct-2009	29-Oct-2029	Granted	Yeda Research and Development Co. Ltd.

Name: USE OF ANTI THIRD PARTY CENTRAL MEMORY T CELLS FOR ANTI-LEUKEMIA/LYMPHOMA TREATMENT

Country	Patent Number	Filed	Expires	Status	Assignee
USA	9,421,228	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
USA (Continuation)	2016-0354410-A1	08-Sep-2011	08-Sep-2031	Pending	Yeda Research and Development Co. Ltd.
Japan	2013-527738	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.

Canada	2,810,632	08-Sep-2011	08-Sep-2031	Pending	Yeda Research and Development Co. Ltd.
China	CN 103282047 A 9	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
China (Divisional)	CN 105907713 A	08-Sep-2011	08-Sep-2031	Pending	Yeda Research and Development Co. Ltd.
Israel	225102	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Republic of Korea	2013-7008892	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Brazil	BR 11 2013 0057564	08-Sep-2011	08-Sep-2031	Pending	Yeda Research and Development Co. Ltd.
Mexico	357746	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Singapore	188473	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Europe	2613801	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Hong Kong	14100513.2	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.

Name: ANTI THIRD PARTY CENTRAL MEMORY T CELLS, METHODS OF PRODUCING SAME AND USE OF SAME IN TRANSPLANTATION AND DISEASE TREATMENT

Country	Patent Number	Filed	Expires	Status	Assignee
USA	15/825,275	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.
Europe	2753351	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Hong Kong	1200099A	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Japan	2014-529143	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Canada	2,848,121	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.

China	CN 103930130 A	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Australia	2012305931	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Republic of Korea	10-2014-7009267	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.
New Zealand	622749	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
South Africa	2014/01993	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
India	577/MUMNP/2014	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.
Israel	231397	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.
Russian Federation	2014110897	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Brazil	BR 11 2014 005355 3	06-Sep-2012	06-Sep-2032	Pending	Yeda Research and Development Co. Ltd.
Mexico	351226	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Singapore	11201400513P	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.

Name: GENETICALLY MODIFIED ANTI-THIRD PARTY CENTRAL MEMORY T CELLS AND USE OF SAME IN IMMUNOTHERAPY

Country	Patent Number	Filed	Expires	Status	Assignee
USA	2018-0207272-A1	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Europe	3322425	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
China	201680053580.8	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Japan	2018-501339	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Hong Kong	18114191.8	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Israel	256916	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Canada	2,991,690	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Australia	2016291825	14-July-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.

Name: USE OF ANTI THIRD PARTY CENTRAL MEMORY T CELLS

Country	Patent Number	Filed	Expires	Status	Assignee
China	CN 108025026 A	14-Jul-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.
Europe	3322424	14-Jul-2016	16-Jul-2036	Pending	Yeda Research and Development Co. Ltd.

Name: METHODS OF TRANSPLANTATION AND DISEASE TREATMENT

Country	Patent Number	Filed	Expires	Status	Assignee
USA	2018-0207247-A1	14-Jul-2016	14-Jul-2036	Pending	Yeda Research and Development Co. Ltd.

Name: VETO CELLS GENERATED FROM MEMORY CELLS

Country	Patent Number	Filed	Expires	Status	Assignee
USA	16/313,486	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Japan	2018-567129	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Canada	3,029,001	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Australia	2017289879	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
India	201927002672	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Israel	263924	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Russian Federation	2019101826	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Mexico	MX/a/2019/000022	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Republic of Korea	10-2019-7002824	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Singapore	11201811563R	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
Europe	62/354,950	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.
China	62/354,950	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.

Name: METHODS OF TRANSPLANTATION AND DISEASE TREATMENT USING ANTI-THIRD-PARTY CTL VETO CELLS

Country	Patent Number	Filed	Expires	Status	Assignee
USA	2018-0200300-A1	18-Jan-2018	18-Jan-2038	Pending	Yeda Research and Development Co. Ltd.

Name: GENETICALLY MODIFIED VETO CELLS AND USE OF SAME IN IMMUNOTHERAPY

Country	Patent Number	Filed	Expires	Status	Assignee
PCT	WO2018/134824	18-Jan-2018	18-Jan-2038	Pending	Yeda Research and Development Co. Ltd.

Name: A COMBINATION THERAPY FOR A STABLE AND LONG-TERM ENGRAFTMENT

Country	Patent Number	Filed	Expires	Status	Assignee
Singapore	10201801905W	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Mexico	MX/a/2014/007647	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Russian Federation	2014128479	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Israel	233303	20-Dec-2012	20-Dec-2032	Allowed	Yeda Research and Development Co. Ltd.
India	1468/MUMNP/2014	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
South Africa	2014/05071	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
New Zealand	627272	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Republic of Korea	10-2014-7020449	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Australia	2012355990	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Canada	2,859,953	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Europe	2793914	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
USA	2014-0363437-A1	20-Dec-2012	20-Dec-2032	Allowed	Yeda Research and Development Co. Ltd.
Hong Kong	15103467.1	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.

Name: A COMBINATION THERAPY FOR A STABLE AND LONG TERM ENGRAFTMENT USING SPECIFIC PROTOCOLS FOR T/B CELL DEPLETION

Country	Patent Number	Filed	Expires	Status	Assignee
Singapore	11201403456U	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Mexico	MX/a/2014/007648	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Brazil	BR 11 2014 015959 9	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Russian Federation	2014129632	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Israel	233302	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
India	1467/MUMNP/2014	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
South Africa	2014/05298	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
New Zealand	627549	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Australia	2012355989	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Australia (Divisional)	2016259415	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
China	CN 104093314 A 4	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Canada	2,859,952	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Japan	6,313,219	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Europe	EP2797421	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
USA	2014-0369974-A1	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.
Hong Kong	15103468.0	20-Dec-2012	20-Dec-2032	Pending	Yeda Research and Development Co. Ltd.

Background

Our Veto Cell technology is a next generation immunotherapy technology that enables the selective attenuation of the immune system. In other words, pre-clinical studies suggest that the treatment has the ability to reduce the immune response to selective “threats,” with low risk for adverse side effects.

What makes the Veto Cell approach distinctive is the degree to which it leverages the inherent specificity of the human immune system. The immune system defends the body by creating a specific stream of T-cell clones for each of millions of individual threats. A given T-cell will attack only its specific target, ignoring all other threats. Our technology might enable the physician to selectively attenuate immune response, thus effectively “switching-off” an individual stream of T-cell clones without affecting any other such streams of T-cell clones dispatched by the immune system to attack unwanted incursions.

The technology is based on the discovery that certain T-cells can acquire the property of attracting and proactively neutralizing immune attacks on them.

The technology has achieved distinctive results in animal live trial models. *See, e.g., Eran Ophir et al. Murine anti-third party central-memory CD8+ promote hematopoietic chimerism under mild conditioning: lymph-node sequestration and deletion of anti-donor T cells*, BLOOD, Feb. 14, 2013, at 1220; *Towards off-the-shelf genetically modified T cells: prolonging functional engraftment in Mice by CD8 veto T cells*, Leukemia (2017) Dec. 27, 2017 at 1034. If it succeeds in human clinical trials, we believe that it may have meaningful and potentially broad impact on the field of bone marrow transplantation:

- 1) Significantly improve outcomes of transplantations by reducing the host (transplant recipient) rejection rate of T-cell depleted stem cells (e.g. from bone marrow) – thus supporting successful engraftment of the transplanted cells, which is the treatment for the blood cancer itself. In order to improve the safety of this cancer treatment, Veto Cell technology has shown in preclinical studies that it can markedly reduce both the risk of GVHD and the need for using aggressive amounts of immunosuppression medications, as well as preventing viral infections that typically threaten patients post transplantation. This safer means of deliver stem cell transplants would significantly reduce the HSCT mortality rate and therefore lead to broader use of this treatment.
- 2) Substantively increase the number of transplantations by enabling successful engraftment under lower levels of immune suppression and therefore making the therapy accessible to older and sicker patients (who today may not survive ablation).
- 3) Further increase the number of transplantations by making transplantation appropriate for other indications (for which today transplantation would be considered an inappropriately risky treatment).

In addition, our Veto Cell technology may possibly play a role in the treatment of a number of serious and currently poorly treated non-malignant diseases. Furthermore, initial animal trials have shown potential anti-lymphoma activity. Finally, based on preclinical studies using genetically modified cells, we believe that Veto Cells will be able to act as critical enabler for other cell therapies, most notably CAR-T cell therapy, which has recently shown strong initial indications of being effective in cancer treatment.

Yeda, has filed two patent applications that extend the usage of Veto Cell technology as a critical enabler for other cell therapy treatments. These patents have entered the national phase. One patent application highlights, based on preclinical data, the ability of Veto Cells to accompany other cell therapy treatments and help them overcome rejection and avoid Graft vs. Host Disease (GVHD) in an allogeneic (using a third party donor) treatment setting. The other patent application involves a genetically modified Veto Cell that can have sustained survival in the patient’s body while avoiding rejection and GVHD. Both of these applications hold the potential to make CAR-T cells, which to date been effective primarily in an autologous (patient’s own cells) setting, succeed in an allogeneic setting. What follows is a description of the significance of these two new patent applications:

- Gene modified cell therapy is considered to be one of the most promising cancer treatment approaches in decades, with companies like Kite Pharma and JUNO Therapeutics having recently been acquired at multi-billion dollar valuations after having successfully treated relatively small numbers of patients in clinical trials.
- While gene modified treatments such as CAR-T have shown remarkable results in cancer treatment trials, their published successes to date have been mostly limited to “autologous” blood cell cancer treatments using the patient’s own cells. There are concerns that this type of “personalized” treatment may not have favorable economics on a large-scale basis.

- The ideal, more lucrative commercial path for CAR-T and similar genetically engineered cell therapies is to become “allogeneic” or off-the-shelf product with drug-like distribution economics and to treat a broad spectrum of cancers including solid tumors.
- Cell Source licenses Yeda’s patent applications for combining Veto Cells with genetically modified T cells and is currently exploring active collaboration with CAR-T cell providers to move Veto and CAR-T combined cell therapy towards the clinic.

Cell Source has recently begun a collaboration, through its licensing agreement with Yeda, with Professor Zelig Eshhar, the inventor of CAR-T cells. Professor Eshhar, has served as both a scientist at the Weizmann Institute and on the Scientific Advisory Board of KITE Pharma. This collaboration is meant to confirm the strength of combining Veto Cell technology with CAR-T cell therapy. Once the preclinical proof of concept is completed, Cell Source plans to produce its own independent off-the-shelf CAR-T + Veto cell treatment for blood cell cancers and, eventually, solid tumors.

Furthermore, Yeda has filed a patent application, licensed to Cell Source, which is now in the national phase, for an Anti-Viral Veto Cell. Below is an explanation of the potential for this application:

- Other than primary disease (typically blood cell cancer) the leading causes of death in unrelated donor bone marrow transplants are rejection, GVHD (Graft vs. Host Disease), where the donor bone marrow rejects the host or recipient), and infections, which collectively are responsible for 30% of deaths after unrelated donor transplants within the first 100 days post-transplant.
- It is well established that GVHD can be prevented by T cell depletion of the bone marrow transplant. However, this procedure is also associated with an increased rate of graft rejection. Preclinical studies clearly suggest that this problem can be overcome by adding Veto Cells to the bone marrow transplant. However, viruses such as CMV and EBV remain a major threat to patients post-transplant.
- Cell Source has developed a next generation Veto Cell that not only facilitates mismatched transplants but also protects the transplant recipient against these common viruses. During the initial period after a stem cell transplantation the patient’s body undergoes an immune system reconstitution period. While the “new” immune system is building up, the patient is particularly vulnerable to viral infections such as CMV, an infection that is typically development in about half of bone marrow transplant recipients during the first 100 days post transplantation. Veto cells can fend off CMV until such time as the patient’s own immune system reconstitutes to the point that it can fight off the infection on its own.
- Combining GVHD prevention by using T cell depleted transplants with anti-rejection action as well as virus prevention, Veto Cell could potentially significantly increase survival rates post-transplant.
- Based on preclinical data, veto cells can also be used to facilitate organ transplants (e.g. kidney transplant combined with a bone marrow transplant) with partially mismatched donors and either reduce or eliminate the need for lifelong daily anti-rejection treatment currently given to even fully matched donor organ recipients.
- Cell Source is currently in the process of attaining regulatory validation for the production of its Anti-Viral Veto Cells in Europe and plans to commence human clinical trials in the US in 2019.

Mechanism

Our Veto Cell is a CD8 central memory anti-3rd party T-cell that has five critical properties:

- 1) It has an outer surface coating that triggers attack by specific host T-cells (and only those specific T-cells).
- 2) It can annihilate an attacking T-cell without itself being damaged (specifically, it exposes or releases a death-signaling molecule when an attacking T-cell binds to it).
- 3) It has been oriented to attack cells of a simulated third party (i.e., neither host nor donor) and thus exhibits markedly reduced risk of GVHD or graft rejection.
- 4) It is long-lived and endures in the body for extended periods.
- 5) It migrates to the thymus and lymph nodes.

The outcome is that when a large number of these cells are introduced into the body, they effectively eliminate the T-cell clones that the immune system dispatches to attack the desirable, transplanted bone marrow cells.

Thus, for example, if a population of Veto Cells is derived from a donor, they will express the same peptide as do the donor's cells. Therefore, the specific stream of host T-cells that would ordinarily attack the donor stem-cells, are instead directed to "decoy" Veto Cells and disabled before they reach the transplantation.

Described in a Blood editorial as a "substantial advance in Cell Therapy," a notable characteristic of our Veto Cell is that this mechanism is quite specific. Only those specific T-cell clones that were generated to attack cells from this specific donor are disabled. The rest of the immune system essentially remains intact.

This is in marked contrast with conventional immunosuppression which degrades the entire immune system and is therefore associated with severe risk of infection and, in the case of bone marrow transplantations, high mortality.

This effect is long-lived. Firstly, the Veto Cells themselves are long-lived memory cells. Secondly, when infused with stem cells the latter migrate to the thymus where, over time, they create a new "identity" in the host and initiate "chimerism" where the host and donor cells peacefully co-exist. This chimerism has the effect of "educating" new T-cells being generated by the thymus to tolerate donor cells and this tolerance can become permanent. Furthermore, by inducing permanent tolerance to donor cells, Veto Cells may be able to enable both acceptance (i.e. mitigate both host rejection and GvH rejection) and thus persistence (i.e. extended survival resulting in enhanced efficacy) of important cell therapy treatments such as CAR-T cells, TCRs and NK cells in treating both blood cell and solid tumor cancers. Beyond this, Veto Cells can be directed not only to kill host anti-donor rejecting cells, but also common viruses such as EBV and CMV that are a common cause of post-transplantation morbidity and mortality.

Target Indications

Our Veto Cell technology, an intravenously administered cell suspension, if successful, could initially be used in stem cell (e.g. bone marrow) and other transplantations associated with malignant disorders (i.e., cancers). At a later stage, Veto Cell technology may be applied to selected non-malignant conditions. The following sections provide a brief overview of the use of the Veto Cell technology in both of these scenarios.

i. Stem Cell Transplantation

In order to describe the effect of Veto Cells in transplantation, it is helpful to first briefly review the state of the art:

In a conventional stem cell transplant, the recipient first receives myeloablative conditioning - powerful chemotherapy and/or radiation therapy intended to destroy his/her own bone marrow cells. This has a threefold purpose:

- 1) It destroys the host T-cells so they will not attack (reject) the donor bone marrow cells.
- 2) It makes space in the host bone marrow for the new donor cells.
- 3) It destroys diseased host blood cells so that they do not proliferate and cause relapse following the procedure.

In practice however, there are two major problems:

- Host rejection - the myeloablative conditioning does not destroy all of the host T-cells. Those that remain may aggressively attack the donor bone marrow cells before they can engraft.
- "Graft versus Host Disease" (GVHD) - the transplanted cells include donor T-cells which recognize the host's body as foreign and attack it.
- Viral infections are a common complication from HSCT and result in 20% of early patients deaths in unrelated-donor transplants in the US

Rejection, GVHD and viral infections are all potentially life-threatening complications in and of themselves and also lead to the use of dangerous and costly immunosuppression medications.

ii. Veto Cell in Transplantation

The Veto Cell technology addresses not only rejection but also GVHD and infections. In a transplantation scenario, a population of donor Veto Cells is created to “escort” the bone marrow cells when they are transplanted. This population is created by identifying donor cells with Veto Cell properties, exposing them to simulated 3rd party cells (i.e., selecting only those that react to a third person and therefore by definition will not react to either host or donor), and expanding their population in the lab.

The Veto Cells are then introduced into the host along with the transplanted stem cells. The host mounts its normal immune response to the donor cells by generating a population of T-cell clones that will bind to any cells expressing markers from this specific donor. In a conventional transplantation, these T-cells would bind to and destroy donor stem-cells thus causing rejection of the transplant.

However, when the transplantation is accompanied by large numbers of Veto Cells, this rejection mechanism is “ambushed.” Since the Veto Cells express the same donor markers as the stem-cells, the host T-cell clones will attempt to bind to the donor-derived Veto Cells as noted above, which act as decoys by attracting and then counterattacking and killing the clones before they ever reach the bone marrow transplantation. These same Veto Cells can potentially be used to concurrently counterattack viruses such as CMV and EBV which are a common source of infections that threaten HSCT patients. Based on additional preclinical data, in June of 2016 Yeda filed a U.S. provisional patent application, which has since entered the national phase, also licensed by Cell Source, which shows the ability of Veto Cells to be directed against these types of viruses typically cause infections in bone marrow transplant patients. This additional functionality, when combined with attacking host anti-donor rejecting cells, may even further enhance survival rates for patients.

iii. Direct Anti-Cancer Effect

HSCT are well known to be an effective treatment for hematological malignancies. Making these treatments safer and more accessible by reducing the need for harmful immune suppression, avoiding GVHD and fending off common post-transplantation viruses are expected to facilitate, through successful Veto Cell treatments, a broader and more successful use of HSCT for not only the most severe cases, but also for older or weaker patients who are not capable of tolerating high intensity conditioning (high levels of radiation and chemotherapy). This is expected to significantly increase the number of patients who can receive successful cancer treatments that require allogeneic HSCT.

A further direct anti-tumor effect of Veto Cells, which complements and bolsters the effect of HSCT as described above, has been noted in mouse and in-vitro studies: donor Veto Cells selectively attack host lymphoma malignant cells. This effect has been robust in animals, in fact completely eradicating lymphoma in mouse models. While the direct anti-cancer effect has been documented for human B cell malignant lines, since Cell Source intends to combine Veto Cell powered HSCT with CAR-T cell therapy for blood cell cancers into a single treatment, this anti-tumor effect will simply serve as a complement to the cancer killing of the CAR-T cell.

iv. Enabling Third Party Cell Therapies

Based on preclinical studies using genetically modified cells, in July of 2015 Yeda filed two U.S. provisional patent applications, both of which have since entered the national phase, which are also licensed exclusively by Cell Source on a worldwide basis. These patent applications show the ability of Veto Cells to enhance the performance of cell therapy treatments involving genetically modified receptors. When combined with CAR-T or TCR cell therapy for example, these would potentially greatly enhance the ability of these treatments to be used in an allogeneic or “off-the-shelf” setting, and also increase their efficacy by avoiding both rejection and GVHD, thus increasing their persistence (survival in the patient’s body).

This combined Veto Cell + CAR-T or similar treatment is expected to result in broadly applicable effective treatments for both blood cell cancers and, eventually, a variety of solid tumor cancers as well.

v. In Non-Malignant Diseases

There are two major categories of non-malignant disorders that the Veto Cell technology aspires to address: organ transplantation and non-malignant hematological disorders.

In the case of organ transplantations and congenital non-malignant hematological disorders, the goal of the Veto Cells is to enable transplantation (bone marrow or organ) by reducing host/donor immune system conflicts. This could potentially allow for mismatched (partial vs. full identity match between donor and host) kidney transplants, for example, and also obviate the need for lifelong daily anti-rejection medication which is the current standard of care. Such an outcome could improve quality of life, reduce cost of care and significantly increase life expectancy for a broader audience of prospective transplant recipients.

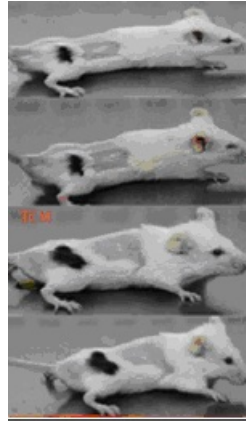
In the case of congenital non-malignant diseases such as sickle cell disease and aplastic anemia, the body's bone marrow produces "flawed" cells. An effective treatment is HSCT which replaces the flawed host bone marrow with healthy donor cells. These cells then produce healthy blood cells, basically curing the anemia. As noted elsewhere however, today HSCT is a risky procedure because of the graft/host immune conflicts. It is therefore used infrequently to treat sickle cell disease. The Veto Cell tolerizing technology would increase the target population for this treatment by significantly reducing these conflicts and by extension the procedure's risk.

Development Status

The Veto Cell platform has been extensively tested by in vitro studies (on both human and mouse disease) and confirmed in animal trials. The results appear to be consistently effective.

1. Inducing chimerism:

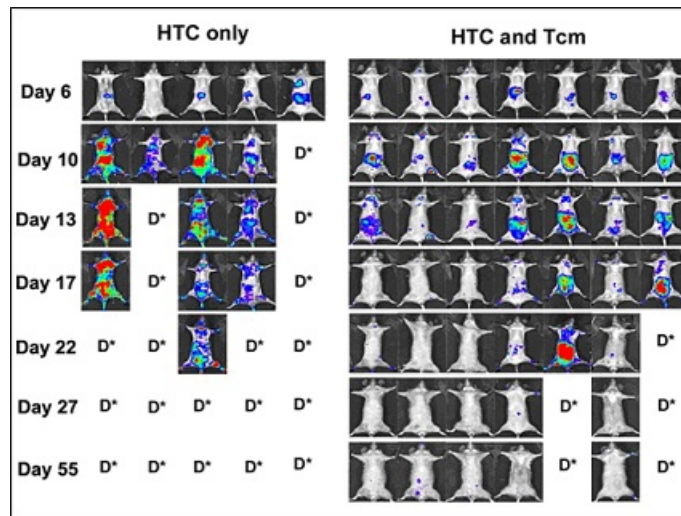
The following images show some example data from the Veto Cell animal studies. Skin of black mice has been grafted onto the backs of white mice. The data show that T-cells from host and donor mice are fully coexisting in the treatment group using the Veto Cells ("chimerism").



2. Successful bone marrow transplantation under reduced levels of immune suppression:

The anti-rejection effect in the data below shows mice with lymphoma treated with Veto Cell therapy.

The control group mice (left side) all die by day 27. By contrast, the Veto Cell treatment group (right side) show far better results.



Administration

We envision that Veto Cell therapy will be administered in an in-patient setting, typically as part of the existing preparation procedures for bone marrow transplantations. Blood will be taken from the donor. The frozen blood will be sent to a regional Company center where the Veto Cells will be developed and expanded - a process that lasts up to two weeks. The Veto Cells will then be sent to the transplantation center where they will be infused to the patient intravenously along with the transplantation.

Patent Status

The earlier versions of the Veto Cell, both the original and the more recent “TcM’ version of the Veto Cell were granted patents in the US, Mexico, Europe, China, Japan, Hong Kong, Korea, Singapore, Israel, India and the Russian Federation as well as Australia, New Zealand and South Africa. The more recent patent applications for the Genetically Modified Veto Cell and the Anti-Viral Veto Cell are both now in the national phase in a broad set of jurisdictions.

Development Roadmap

The Veto Cell platform roadmap comprises two main programs as outlined in the table below. The specific clinical trials planned for each are detailed in the Clinical Trials section of this document.

Offering	Objective	Major Activities	Estimated Start Date
Anti-Rejection, Anti-Viral Veto Cell	Validate and introduce new commercial treatment to increase engraftment of allogeneic bone marrow transplantations	1. Regulatory approval and treatment protocols 2. Conduct human clinical trials 3. Develop plan for commercial exploitation	· Initiate a human clinical trial in the US by 2019 · Commence human trials in Europe in 2020
Veto – CAR-T Cell Therapy	Validate the possibility of combining Veto Cell treatment with CAR-T cell treatment for both blood cell cancer and solid tumor cancer treatment	4. Collaboration with Zelig Eshhar, inventor of Car-T cells 5. Validate combined treatment model in clinical trials	· Proof of concept in completion in 2019 · Commence human trials in 2021 or 2022

Products and Services

Currently, we do not have any products, and there is no assurance that we will be able to develop any products.

The following products are currently planned:

1. *“Anti-rejection, Anti-Viral” Veto Cell tolerance therapy for donor mismatched allogeneic bone marrow transplantations.*

This is our flagship (as an initial platform for increasing transplantation success) and is focused on allogeneic stem cell transplantations. Treatment will comprise infusion of Veto Cells derived from the donor and processed in a Company (or subcontracted) facility that will be accessible to the transplantation center at the time of transplantation.

2. *“Anti-cancer” Veto + CAR-T cell therapy for blood cell and, eventually, solid tumor cancers.*

This therapy is expected to comprise an infusion of donor derived cells that is expected to be combined with CAR-T cell therapy as an “off-the-shelf” treatment.

3. *“Anti-rejection” Veto Cell tolerance therapy for donor mismatched organ transplantation.*

This treatment would be combined with bone marrow transplantation in order to broaden the prospective donor pool and mitigate the need for chronic post-transplant anti-rejection therapy

4. *Veto Cell tolerance therapy for non-malignant disorders.*

This is the application of Veto Cell technology to treatment of non-malignant (i.e., non-cancerous) diseases, as discussed in the Technology section. Target indications for Veto Cell therapy for nonmalignant disorders are likely to be: tolerizing therapy for allogeneic transplantations for sickle cell anemia and aplastic anemia (by using stem cell transplantations as referenced in no. 2 above) and tolerizing therapy for a broader range of congenital immune system related disorders.

Our Overall Development Status and Future Development Program

Prior to commercializing its products, the Company must conduct human clinical trials and obtain FDA approval and/or approvals from comparable foreign regulatory authorities.

Generally speaking, as a preclinical biotechnology firm, Cell Source needs to go through several necessary steps in order to commercialize its products and commence revenue generation. These steps are per product, but can run in parallel for multiple products, which are each in different stages of the development “pipeline”, so that, for example, when a certain product is already in a human clinical trial, another product may still be in preclinical development and a third may be awaiting regulatory approval to commence human trials. These can also take place in parallel, and varied stages, for the same product in different geographic jurisdictions. The typical steps per product (and range of time frame for each) are:

- 1) Complete development of human treatment protocol (2-5 years)
- 2) Apply for and receive approval to commence human trials (9-18 months)
- 3) Recruit patients (1-6 months)
- 4) Conduct Phase I trials showing safety of product (1-2 years)
- 5) Apply for and receive approval to conduct trials showing product efficacy (6-12 months)
- 6) Data collecting and analysis (6-12 months)
- 7) Conduct Phase II efficacy trials (2-3 years)
- 8) Data collecting and analysis (6-12 months)
- 9) Apply for and receive approval to conduct trials showing efficacy in larger numbers of patients (6-12 months)
- 10) Conduct Phase III efficacy trials with larger numbers of patients (2-4 years)
- 11) Data collecting and analysis (6-12 months)
- 12) Apply for and receive approval for production scale manufacturing facilities (6-12 months)
- 13) Contract third party or establish own production facilities (6-30 months)
- 14) Contract third party or establish own distribution platform (6-18 months)
- 15) Commence manufacturing and distribution (6-12 months)

Notably, steps 12-15 can be conducted in parallel with some of the steps above. In the case of Cell Source and other firms that treat terminal patients with either rare diseases or those for which there is currently no effective treatment, or where preclinical studies indicate a reasonable expectation to increase life expectancy and survival rates by a substantive margin, several of these steps can be combined and or shortened, subject to regulatory discretion. For example, Phase I and II (safety and efficacy) can be combined in a single concurrent step; approvals for subsequent steps can be accelerated; in some countries patients can already be treated commercially after the end of Phase II, foregoing the requirement for Phase III data.

The specific detailed next steps the company must take to get the treatments or products to market include the following:

In the case of the Megadose Drug Combination, the Hematology and Bone Marrow Transplantation Unit of the University of Parma in Italy on May 14, 2014 requested and on October 23, 2014 obtained approval from the Italian Medicine Association (the Italian equivalent of the U.S. FDA) to conduct human clinical trials using the “Megadose + Drug Combination.” While we are not mentioned in the application nor in the approval, we may indirectly benefit from the outcome of the trial, if successful, although we are not the sponsor of this trial. There are no written or verbal agreements between the hospital and Cell Source regarding the use of the technology. That said, Cell Source is aware and in favor of the hospital plans to use the technology and would of course find a positive initial outcome encouraging. Since the treatment is being done on compassionate grounds as a non-commercial clinical trial, there is no legal requirement for the hospital to obtain approval to use the treatment protocol. The hospital has successfully treated the first cancer patient using the Megadose Drug Combination technology that Cell Source exclusively licenses from Yeda. The patient who was suffering from late stage multiple myeloma, was released from hospital within a month of being treated and has since been cancer free for over four years, with no GVHD, as initially reported in *Blood Advances*, vol. 1 no. 24 2166-2175 which was published online October 27, 2017.

While Cell Source is not a sponsor of the trial, the results provide a positive initial indication with respect to the technology. The patient received a bone marrow transplantation from a haploidentical or “mismatched” donor under a reduced intensity conditioning regimen (i.e., a relatively low level of immune suppression treatment). There was successful initial engraftment of the transplantation in the absence of GVHD.

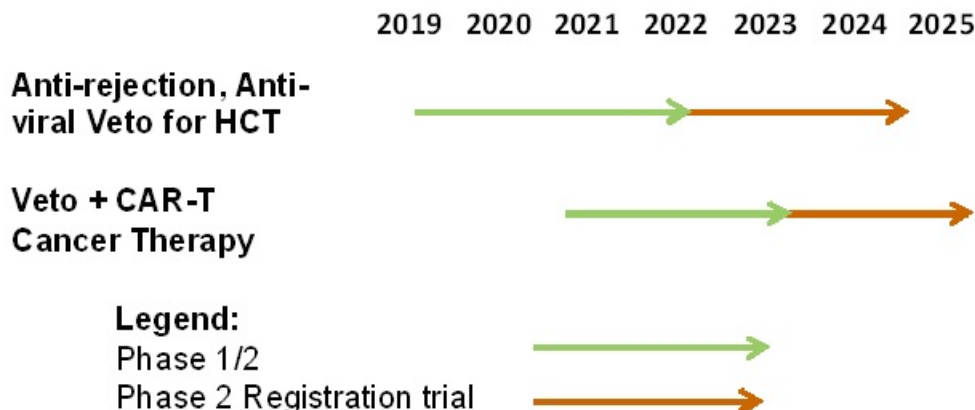
In November of 2018, we executed a sponsored research agreement with MD Anderson Cancer Center in Texas. In February of 2019, we executed a second agreement with MD Anderson for the production of Veto Cells and the conducting of a Phase I/II FDA trial for the Anti-Rejection, Anti-Viral Veto Cell. The treatment protocol was submitted to the FDA by MD Anderson in February of 2019. Cell Source has conducted Veto Cell production development in cooperation with the Medical Center at the Julius Maximilian University of Würzburg in Germany. The final version of the cell production protocol that was submitted to the FDA is currently being in the process of being prepared for submission for regulatory approval in Germany.

For the Anti-Rejection, Anti-Viral Veto Cell product candidate, Cell Source expects to commence Phase I/II human clinical trials in the US starting sometime in 2019 and in Europe starting in 2020. Cell Source anticipates that the US Phase I/II trial will last until 2021 or 2022. This would be followed by completion of a Phase II trial and Phase III trial, which would last another 2-3 years each, so that full approval, if successful, would be expected sometime in 2026. In both the US and Europe there is a possibility of approval for commercial use on a “conditional” basis at the end of Phase II, which could take place by 2024. In 2018, Cell Source entered into a collaboration with Professor Zelig Eshhar, the inventor of CAR-T cell therapy, with respect to combining CAR-T cell therapy with Veto Cell therapy and commenced a pre-clinical proof of concept trial. If successful, this could lead to a commencement of a CAR-T Veto Cell FDA trial in 2021 or 2022, which may last until 2027 or 2028.

It is possible that Cell Source treatments could qualify for any or all of Fast Track, Breakthrough Therapy, Accelerated Approval, RMAT or Priority Review designation under the FDA, which would hasten their approval if successful. The estimated costs for each step of development, in terms of clinical trials, are delineated below:

Cell Source estimates the cost of clinical trials alone to be up to \$5 million over the coming two years and another \$25-50 million in order to reach commercialization for the Veto Cell products. This would mean that Cell Source will need to secure one or more significant capital infusions in order to reach the point that meaningful revenues could be generated.

The following table summarizes the development plan through 2024:



Competition

The development and commercialization of new cell therapies is highly competitive. Our products are focused on treatment of blood cancers, non-malignant blood disorders and organ transplantations. Various products are currently marketed for the treatment of blood cancers. A number of companies are also developing new treatments. In addition to competition from a variety of other nascent unconventional medical treatments, we also face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions worldwide. For instance, our competitors include the technology developed by Kiadis Pharma, MolMed and Bellicum Pharmaceuticals for facilitating haploidentical HSCT with reduced incidence of GVHD. All three of these are using high intensity conditioning and are therefore less safe than the reduced intensity conditioning Cell Source plans to provide, and also all are still showing, while reduced, marked incidence of both acute and chronic GVHD, whereas Cell Source plans to virtually eliminate GVHD for HSCT patients. A number of companies are developing alternative approaches for addressing allogeneic BMT including umbilical cord blood solutions (e.g. Gamida Cell), treatment of post-transplant GVHD (e.g. Mesoblast). Cell Source believes that its all-in-one solution for addressing engraftment, GVHD and viruses as well as inbuilt additional anti-tumor effect will provide, once successful in trials, an attractive alternative for physicians as the safety associated with a reduced intensity conditioning regimen combined with the compound benefits addressing major HSCT patient issues can provide a compelling treatment approach for a broad set of patients who require allogeneic HSCT.

In the area of Chimeric Antigen Receptor (CAR) technology, both Novartis and Kite Pharma (now part of Gilead Sciences), have received FDA approval for their lead treatment candidates. JUNO Therapeutics (now part of Celgene) Inc. and Bluebird Bio (in collaboration with Celgene) are currently in human trials for Car-T cell therapy. The success of their patient treatments to date has chiefly been confined to treatment hematological malignancies using the patient’s own cells. This autologous treatment approach brings with it both high costs (Novartis’ Kymriah at \$475,000 per treatment; Gilead (KITE) Yescarta at \$373,000 per treatment) as well as quality and safety issues. While some companies (e.g. Cellectis – in partnership with Servier and Pfizer, more recently under license to Allogene) have presented allogeneic CAR-T data, there has been very limited success in this area thus far. A number of companies, including Celyad and Ziopharm, are actively in development of potential off-the-shelf CAR-T cancer therapy solutions. Others are working on TCR, NK and other genetically modified cell structures for allogeneic cancer treatment.

Cell Source plans to offer allogenic CAR-T with lower costs and better safety outcomes than the currently approved products and aspires to compete with products that are currently under development but combining increased persistence with enhanced efficacy using Veto Cell technology to overcome rejection of CAR-T cells and, in the case of treating blood cell cancers, avoid GVHD.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. While our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than our own products, we believe that if our human trials show efficacy at the same levels of our animal trials, we would have the potential to develop at least a niche market share. Also, a number of large US cancer centers such as Johns Hopkins in Baltimore, Fred Hutchinson in Seattle, City of Hope in Duarte, CA and Dana Farber in Boston are conducting clinical trials and providing treatments on a compassionate care basis that can be funded on a not for profit basis and provide competition to Cell Source.

We expect that our ability to compete effectively will depend upon our capacity to:

- successfully complete adequate and well-controlled clinical trials that demonstrate statistically significant safety and efficacy and to obtain all requisite regulatory approvals in a timely and cost-effective manner;
- effectively use patents and possibly exclusive partnership agreements with important third-party treatment providers and collaboration partners to maintain a stable competitive stance for our Technology;
- attract and retain appropriate clinical and commercial personnel and service providers; and
- establish adequate distribution relationships for our products.

Failure in efficiently developing and executing these capabilities may have an adverse effect on our business, financial condition or results of operations.

Strategy Overview

Our strategy is based on two underlying drivers: (a) that animal studies show Veto Cell technology to be consistently effective and have advantages over competitors; and (b) that the lead indications (the most common blood cancers) are relatively common, have high mortality and have limited treatment options today.

Based on the foregoing drivers, we have developed a business plan with the objective of obtaining regulatory approvals and subsequently launching product sales with a focus on the United States, Europe and Asia.

Key Strategy Elements

We are pursuing a staged entry strategy. The first several years will be narrowly focused, both in terms of market segments (blood cancers) and products (Anti-Rejection, Anti-Viral Veto Cell for mismatched HSCT and CAR-T + Veto for direct cancer treatment).

Subsequently, we plan to broaden the segmentation strategy to include additional bone marrow transplantation indications, major organ transplants combined with HSCT, selected genetic non-malignant diseases and, by combining Veto Cells with CAR-T cell therapy, eventually solid tumor cancers.

Our strategy can be summarized as follows:

Strategy Element	Introductory period (years 1 -3 post FDA approval)	Years 4+
Market Segments	<ul style="list-style-type: none"> · Lymphoma and Leukemia · Multiple Myeloma 	<ul style="list-style-type: none"> · Same as before plus broader set of solid tumor cancer targets, kidney and liver failure, sickle cell anemia beta thalassemia and other non-malignant hematological disorders;
Product Rollout	<ul style="list-style-type: none"> · Veto Cell therapy for B-cell malignancies · Veto+CAR-T Veto Cell therapy for both blood cell cancers cancers 	<ul style="list-style-type: none"> · Veto Cell tolerizing treatment for HSCT and organ transplantation · Veto Cell therapy for both liquid and solid tumor cancers as well as non-malignant disorders;
Customer/ Geographic Focus	<ul style="list-style-type: none"> · North America · Western Europe · China 	<ul style="list-style-type: none"> · North America, Western & Eastern Europe, Australia/New Zealand, Russia, Brazil, selected Asian markets
Channels/Go to Market	<ul style="list-style-type: none"> · Direct relationships with leading transplantation centers · International production and distribution through partners 	<ul style="list-style-type: none"> · Partnership with global market leaders
Pricing	<ul style="list-style-type: none"> · Consistent with other cell therapy offerings currently associated with transplantations and immuno-oncology 	<ul style="list-style-type: none"> · Potentially higher volume, lower cost for “off the shelf” offerings
Operations	<ul style="list-style-type: none"> · Three production centers: <ul style="list-style-type: none"> - US - Western Europe - Far East · Initial capacity leased from or situated adjacent to major transplantation center. 	<ul style="list-style-type: none"> · Regional production centers owned or JV with partners

Segment Selection

Within the general market for immune therapies, we have selected target market segments (i.e., medical conditions) for initial focus based on two (2) key criteria:

- 1) Severity of unmet medical need: degree of severity of the indication and the effectiveness of existing treatments. These criteria help determine the proper regulatory pathway.
- 2) Technology relevance: relative value of the ability to manage immune response to the treatment of a given indication.

We will initially focus on indications that score highly with respect to both criteria (e.g., Multiple Myeloma, AML). These conditions may qualify for Fast Track status with the FDA, and, due to the cost and relative efficacy of current treatment alternatives, could potentially support profitable price points for effective new treatments.

Product Rollout

Cell Source plans to seek approval initially in the US and Europe and, in parallel but with a delayed start, in China and possibly Japan. A successful parallel Phase I/II trial in the US and Europe, which could be concluded by 2021 or 2022, would serve as a strong foundation for trials in other countries. Limited sales on a “compassionate grounds” basis may, depending on qualification for Breakthrough Therapy or other Accelerated Approval designation, commence as early as 2024 or 2025. Full approval by the FDA in the U.S. can take as long as 8 years, or 2027.

Future products may include Veto Cell tolerance induction therapy for allogeneic stem cell and organ transplantations as well as Veto + CAR-T cell therapy for blood cancers and, eventually, solid tumor cancers. Following the initial market penetration and establishment of solid market positioning, we plan to broaden the product offering to address a wider variety of indications which may include custom Veto Cell developments for specific collaborations with other cell therapy treatments. For example, we believe that one area in which we could broaden our product offerings is to utilize our Veto Cell technology, if successful in humans, to address the rejection problems being faced by companies developing NK, TCR and similar cell therapy products, as an enabler for these treatments to help them overcome some of the rejection and persistence related performance issues their technology currently seems to be facing. If our Veto Cell technology proves to be successful in humans, we plan to continue to explore such potential applications in the future.

Customer/Geographic Focus

Assuming positive clinical trials, we will initially focus our sales efforts of Veto Cell anti-rejection therapy on centers dealing with late stage B-cell malignancies. High profile, high volume HSCT facilities can be targeted to market this treatment.

Current plans are to introduce the products first in North America and Western Europe, and, perhaps concurrently, in China. Focusing on key transplantation facilities in target geographic markets will allow us to both refine the administration of our products and bolster our reputation in both these and a broader set of geographic markets.

After the introductory period, we plan to expand its activities in its initial markets while simultaneously broadening geographic coverage. In Stage 2, we plan to initiate active marketing efforts in the remaining Western European countries, Japan, Australia, Eastern Europe, and possibly Russia and India.

Marketing Strategy

The initial target market is concentrated and networked. It comprises the approximately 40 leading transplantation centers in the target geographies. As discussed in the “Market Access” and “Channels” section, these centers are well connected to each other and tend to quickly share innovations and best practices.

The planned penetration strategy is to introduce Veto Cell into the best-known and most influential centers in North America and Western Europe, and benefit from the exposure and industry leadership provided by these centers.

This initial penetration strategy includes incorporating some of these centers into clinical trials so as to expose and involve their medical leadership.

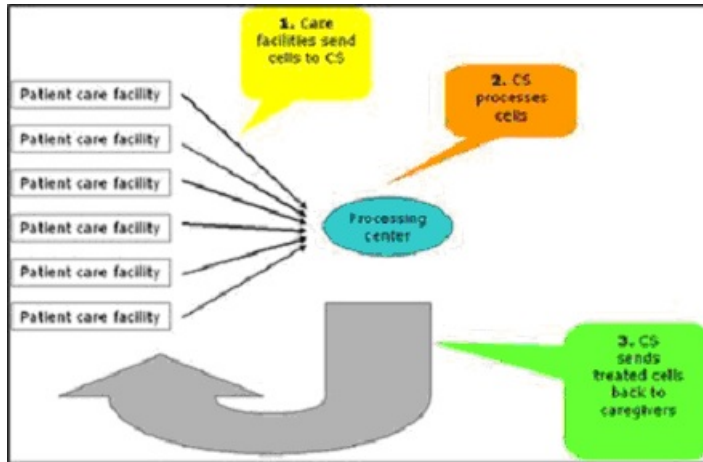
In the longer term, we plan to drive use and awareness within and across the broader oncology community in order to encourage oncologists to refer their patients to centers that already use our products and therapies and to encourage pull-influence on additional centers to adopt our products and therapies.

The broader provider community will be addressed both through a presence in leading peer-reviewed publications and by attending conventions where research and best clinical practices are shared, seminars are conducted, and networking opportunities are provided for the physicians.

Operating Strategy

Veto Cell doses are to be prepared by Cell Source facilities or qualified production partners. This is to both protect trade-secrets and directly control quality during the initial stages.

The graphic below outlines the general operating model in each geographic market.



Patient care facilities send frozen cells to a Cell Source processing center. Most likely, the first processing center will consist of lab space leased from or adjacent to a large transplantation center. Such a transplantation center has appropriate equipment and infrastructure, along with available production capacity, and will also represent an immediate market for our offerings for use in their own procedures. The Cell Source processing center processes the cells and sends the treated cells and appropriate protocols back to the caregiver for infusion at time of transplantation.

In the introductory period, we plan on establishing one center in the U.S., one in Western Europe (most likely Germany), and one in the Far East. Specific locations and timing are to be determined. Initially, we plan to outsource production capacity from existing facilities operated by Contract Manufacturing Organizations (CMO) adjacent to large hospitals, or, where capacity is available, contract directly with major cancer treatment centers who have accredited GMP facilities and experienced cell production staff for Veto Cell production. Subsequently, sales from these centers can justify and fund stand-alone facilities.

The general goal of the initial centers is to support the FDA process, provide full coverage for the North American and European markets, and provide access to the Chinese market. Following the introductory period in each respective market, we may elect to migrate the production facilities from leased space in transplantation center laboratories or contract services with specialized CMOs to company-owned stand-alone facilities.

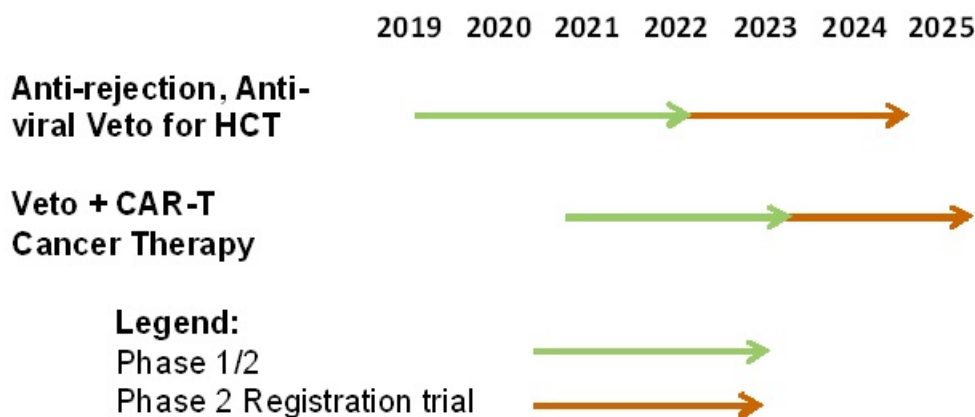
In general, we assume a capital cost per stand-alone production facility of \$8 million. This estimate is based, in part, on the projected high costs of GMP “clean rooms,” each of which can cost \$1 million to set up. We will need to obtain financing in order to fund the setup of such facilities. There can be no assurance that financing will be available in amounts or on terms acceptable to us, if at all.

Clinical Trials Overview

We will initially focus our clinical trials on stem cell transplantation for patients suffering from blood cancers (lymphoma, leukemia, myeloma), for which our Veto Cell technology constitutes a potential breakthrough. These indications have unmet needs as evidenced by the valuations of leading CAR-T players who thus far have chiefly presented data treating these diseases.

We expect to initiate a company-sponsored Phase 1/2 clinical trial in early 2019. These trials combine traditional Phase 1 safety trials with Phase 2 efficacy trials inasmuch as they are safety trials conducted on sick patients, so they are able to both establish safety and show initial indications of efficacy concurrently. The goal is to demonstrate safety and initial efficacy in several indications. Management has structured the trials such that an additional goal of showing initial markers pointing to successful engraftment, in the absence of GvHD, while preventing viral infections, already within Phase 1/2.

The chart below provides an overview of the current trials plan, which can of course vary based on both finalization of human protocols and timing or regulatory approvals:



Trial Plans

Trials are planned for the US and Europe. The US trial plans to treat 24 patients. We plan to focus on haploidentical (donor mismatched) stem cell bone transplantation under reduced intensity conditioning (reduced levels of immune suppression treatment) for B-cell malignancies. We are currently conducting preclinical trials for Veto + CAR-T cell therapy, working with Zelig Eshhar, the inventor of CAR-T technology. Once we complete a proof of concept, we plan to develop our own independent CAR-T cells and launch a clinical trial for blood cell cancer. In the future, we plan to conduct clinical trials for solid tumor patients as well. Also, once we have shown safety and efficacy for Veto Cell based stem cell transplants, we plan to combine these with haploidentical kidney transplants in patient trials.

Regulatory Issues Overview

We are seeking regulatory approval from the U.S. FDA, the European Medicines Agency (“EMA”) in Europe and plan to approach similar agencies elsewhere for approvals to both produce and sell our products.

We are targeting approval for the production of Anti-Rejection, Anti-Viral Veto Cells in both the United States and Germany by the end of 2019. We plan to commence human clinical trials for this, our lead product candidate, in the US in 2019 and in Germany in 2020.

Regulatory Process and Expectations

We have developed and will continue to develop our clinical trial protocols with the support of highly experienced medical practitioners who have vast experience in working with their local regulators. MD Anderson, for example, as the largest stem cell transplantation center and leading cancer treatment facility in the US, has a thoroughgoing internal protocol approval process which serves to refine every aspect of each patient protocol, in great detail, in anticipation of any potential issues that the FDA would typically wish to see addressed.

The clinical trials outlined in the previous section are designed to lead to regulatory approval for Veto Cell-based therapy in treating blood cancers and stem cell transplantation applications and, thereafter, solid organ transplantations and, eventually, solid tumor cancers.

Interim Revenue Opportunities

While our focus is to conclude Phase 3 approval for cancer treatments, the Company is also exploring complementary shorter-term opportunities for generating revenue before additional FDA approvals are received, namely:

- 1) Treating patients after the end of Phase 2 (based on US Fast Track approvals and/or European Marketing Authorization Approvals) with either partial or full insurance reimbursement available); and
- 2) Potential upfront and milestone driven licensing revenues from collaborations with third parties.

Intellectual Property

Pursuant to the Yeda License Agreement, Yeda granted the Company an exclusive worldwide license to certain patents, discoveries, inventions and other intellectual property generated (together with others) by Professor Yair Reisner at the Immunology Department at the Weizmann Institute. Under the Yeda License Agreement, The Company grants Yeda a 4% royalty on sales of patented products. Currently, the Company voluntarily funds research (on its own behalf) at the Weizmann Institute for the preclinical development of its products and plans to do so through June 2019. Should the Company elect to curtail such funding, it would have to pay a \$50,000 annual license fee until such times as payment of royalties commences. The Yeda License Agreement also requires the Company to proceed with the development of the technologies on a timely basis.

The license period (per product, per country) is for the full life of the patents and expires at the later of the patent expiration date in that country or 15 years after the date that the FDA or local equivalent regulatory authority in each country approves that particular product for sale in that country. As long as Cell Source sponsors research or pays either a nominal license fee of \$50,000 per year (total for use of all the products) or pays royalties on product sales on at least one product as per the license agreement, the license will remain in effect continuously and expire only with the expiration of the patent or 15 years after regulatory approval (later of the two) per product per country as described above. Cell Source voluntarily sponsors Research at the Weizmann Institute for the sake of developing its products and treatments from initial invention through to finalization of human treatment protocols. In 2018, Cell Source extended the research period, which was scheduled to have been terminated in October of 2018, through June of 2019.

Also, under the Yeda License Agreement, the Company agreed to fund Yeda's research until October 3, 2018, with an aggregate annual payment of \$800,000 paid in quarterly \$200,000 installments. As of the date of filing, under the current amendments to that agreement, the Company's commitment to research funding in the period ending June 30, 2019 is \$25,000. If the Company fails to achieve any one of the milestones set forth in the Yeda License Agreement (as per the current amended version) which are listed below, then Yeda will be entitled to (i) modify the related license such that it will become non-exclusive or (ii) terminate the Yeda License Agreement upon thirty (30) days written notice:

- a. by January 1, 2022, to have commenced Phase II clinical trials in a respect of a Product;
- b. by January 1, 2025, to have either commenced Phase III clinical trials or to have received FDA or EMA marketing approval in a respect of a Product ("Marketing Approval");
- c. within 12 (twelve) months from the date of Marketing Approval, to have made a First Commercial Sale of a Product; or
- d. in case commercial sale of any Product having commenced, there shall be a period of 12 (twelve) months or more during which no sales of any Product shall take place by the Company or its Sublicensees (except as a result of force majeure or other factors beyond the control of the Company)."

Additionally, the Yeda License Agreement also provides that:

- **Title.** All right, title and interest in and to the Licensed Information and the Patents (as those terms are defined in the Yeda License Agreement) and all right, title and interest in and to any drawings, plans, diagrams, specifications, other documents, models, or any other physical matter in any way containing, representing or embodying any of the foregoing, vest and shall vest in Yeda and subject to the license granted in the Yeda License Agreement.
- **Patents.** Both Yeda and the Company shall consult with one another on the filing of patent applications for any portion of Licensed Information and/or corresponding to patent application existing at the time the Yeda License Agreement was executed. Yeda shall retain outside patent counsel that will be approved by Cell Source, to prepare, file and prosecute patent applications. All applications will be filed in Yeda's name.
- **Patents; Patent Infringements.** Where the Company determines that a third party is infringing one or more of the Patents or is sued, in prosecuting or defending such litigation, the Company must pay any expenses or costs or other liabilities incurred in connection with such litigation (including attorney's fees, costs and other sums awarded to the counterparty in such action). The Company agreed to indemnify Yeda against any such expenses or costs or other liabilities.
- **License.** With regard to the expiration of Patents, a Product is deemed to be covered by a Patent so long as such Product is protected by "Orphan Drug" status (or the like). The Company has an exclusive worldwide license under the Licensed Information and the Patents for the development, manufacture and sales of the Products. License remains in force in each country with respect to each Product until the later of (i) the expiration of the last Patent in such country covering such Product or (ii) the expiration of a 15-year period commencing the day FDA New Drug Approval is received for a Product in such country.

The Company may grant a Sublicense only with the prior written consent, which shall not be withheld unreasonably provided that:

- i. the proposed Sublicense is for monetary consideration only;
- ii. the proposed Sublicense is to be granted in a bona fide arm's length commercial transaction;
- iii. a copy of the agreement granting the Sublicense and all amendments thereof shall be made available to Yeda, 14 days before their execution and Cell Source shall submit to Yeda copies of all such Sublicenses and all amendments thereof promptly upon execution thereof; and
- iv. the proposed Sublicense is made by written agreement, the provisions of which are consistent with the terms of the License and contain, inter alia, the following terms and conditions, including: the Sublicense shall expire automatically on the termination of the License for any reason.

However, Yeda's prior written consent is not needed if the sublicense is limited to China, and the Company grants it to a Chinese affiliated entity of the Company.

- **Termination.** The Yeda License Agreement terminates on the later of: (i) the expiration of the last of the Patents or (ii) the expiry of a continuous period of 20 years during which there shall not have been a First commercial sale of any product in any country. Yeda may terminate by written notice, effective immediately, if the Company challenges the validity of any of the Patents. If a challenge is unsuccessful, then in addition to Yeda's right to termination, the Company shall pay to Yeda liquidated damages in the amount of \$8,000,000. Either the Company or Yeda may terminate the Yeda License Agreement and the License by serving a written notice upon (i) occurrence of a material breach or (ii) the granting of a winding-up order. Additionally, Yeda may terminate for failure to reimburse Yeda for patent application and/or prosecution expenses.

Our technology portfolio includes a patented platform termed "Veto Cell" (more formally described as "Anti 3rd party central memory T cell"), which is an immune tolerance biotechnology that enables the selective blocking of immune responses.

For a list of all the patents and pending patents that Yeda holds and which we have a license to use, please refer to the table in the section entitled "*Science and Technology Overview*" above.

Patents & Proprietary Rights

Our success will depend in part on our ability to protect our existing product candidates and the products we acquire or license by obtaining and maintaining a strong proprietary position. To develop and maintain our position, we intend to continue relying upon patent protection, orphan drug status, Hatch-Waxman exclusivity, trade secrets, know-how, continuing technological innovations and licensing opportunities. We intend to seek patent protection whenever available for any products or product candidates and related technology we acquire in the future.

We may also seek orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and Canada, and 10 years in the EU. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for a different clinical indication.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information made known to the individual during the course of the individual's relationship with us is to be kept confidential and may not be disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property.

Government Regulation and Product Approval

We have only recently submitted our first IND application to the FDA, which was done on our behalf by MD Anderson in February 2019. Cell Source itself has not had any contact with any regulator anywhere regarding treatment approvals or clinical trials associated with regulatory approvals. We are aware that a hospital in Italy has independently requested and received approval to conduct a trial with a treatment protocol the patents for which we license from Yeda, which today forms part of the broader protocol that we plan to use in the US and European clinical trials, but we are not mentioned in the application nor in the approval. However, we may indirectly benefit from the outcome of the trial, if successful, although we are not the sponsor of this trial. There are no written or verbal agreements between the hospital and Cell Source regarding the use of the technology. That said, Cell Source is aware and in favor of the hospital's plans to use the technology and would find a positive initial outcome encouraging. Since the treatment is being done on compassionate grounds as a non-commercial clinical trial, there is no legal requirement for the hospital to obtain approval to use the treatment protocol.

Cell Source plans to conduct human clinical trials in 2019 to show initial safety, and possibly efficacy, results in the US, and later in Europe. As of the date of this filing, the Company has had no direct contact with any regulator regarding such approvals.

Regulation by governmental authorities in the U.S. and other countries is a significant factor, affecting the cost and time of our research and product development activities, and will be a significant factor in the manufacture and marketing of any approved products. All of our products require regulatory approval by governmental agencies prior to commercialization. In particular, our products are subject to rigorous pre-clinical and clinical testing and other approval requirements by the FDA and similar regulatory authorities in other countries. Various statutes and regulations also govern or influence the manufacturing, safety, reporting, labeling, transport and storage, record keeping and marketing of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, the necessary regulatory approvals could harm our business.

The regulatory requirements relating to the testing, manufacturing and marketing of our products may change from time to time and this may impact our ability to conduct clinical trials and the ability of independent investigators to conduct their own research with support from us.

The clinical development, manufacturing and marketing of our products are subject to regulation by various authorities in the U.S., the EU and other countries, including, in the U.S., the FDA, in Canada, Health Canada, and, in the EU, the EMA. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act in the U.S. and numerous directives, regulations, local laws and guidelines in Canada and the EU and elsewhere govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Product development and approval within these regulatory frameworks takes a number of years and involves the expenditure of substantial resources.

Regulatory approval will be required in all the major markets in which we seek to develop our products. At a minimum, approval requires the generation and evaluation of data relating to the quality, safety, and efficacy of an investigational product for its proposed use. The specific types of data required and the regulations relating to this data will differ depending on the territory, the treatment candidate involved, the proposed indication and the stage of development.

In general, new cell compositions are tested in animals until adequate evidence of safety is established to support the proposed clinical study protocol designs. Clinical trials for new products are typically conducted in three sequential phases that may overlap. In Phase I, the initial introduction of the pharmaceutical into either healthy human volunteers or patients with the disease (typically 20 to 50 subjects), the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase II involves studies in a limited patient population (typically 50 to 200 patients) to determine the initial efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks. Once a treatment protocol shows preliminary evidence of some efficacy and is found to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to more fully evaluate clinical outcomes in a larger patient population in adequate and well-controlled studies designed to yield statistically sufficient clinical data to demonstrate efficacy and safety.

In the U.S., specific pre-clinical data, manufacturing and chemical data, as described above, need to be submitted to the FDA as part of an IND application, which, unless the FDA objects, will become effective thirty (30) days following receipt by the FDA. Phase I studies in human volunteers may commence only after the application becomes effective. Prior regulatory approval for human healthy volunteer studies is also required in member states of the EU. Currently, in each member state of the EU, following successful completion of Phase I studies, data are submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase II studies. In many places in Europe, a two-tiered approval system mandates approval at the regional level prior to applying for national approval. Regional approval cycle times, including multiple iterations where questions are answered and the specific details of the protocol may be fine-tuned, can last several months prior to applying to the national (federal government level) regulator. The national regulatory authorities in the EU typically have between one and three months in which to raise any objections to the proposed study, and they often have the right to extend this review period at their discretion. In the U.S., following completion of Phase I studies, further submissions to regulatory authorities are necessary in relation to Phase II and III studies to update the existing IND. Authorities may require additional data before allowing the studies to commence and could demand that the studies be discontinued at any time if there are significant safety issues. In addition to the regulatory review, a study involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body will differ from country to country. In the U.S., for example, each study will be conducted under the auspices of an independent institutional review board at each institution at which the study is conducted. This board considers among other things, the design of the study, ethical factors, the privacy of protected health information as defined under the Health Insurance Portability and Accountability Act, the safety of the human subjects and the possible liability risk for the institution. Equivalent rules to protect subjects' rights and welfare apply in each member state of the EU, where one or more independent ethics committees, which typically operate similarly to an institutional review board, will review the ethics of conducting the proposed research. These ethical review committees typically exist at the regional level, where approval is required prior to applying for national approval. Other regulatory authorities around the rest of the world have slightly differing requirements involving both the execution of clinical trials and the import/export of pharmaceutical products. It is our responsibility to ensure we conduct our business in accordance with the regulations of each relevant territory.

By leveraging existing pre-clinical and clinical data, we are seeking build upon an existing pre-clinical safety and efficacy database to accelerate our research. In addition, our focus on an end-stage population which has limited current treatment options, commercialization, may result in relatively shorter approval cycle times. Approval by the FDA in this category generally has been based on objective response rates and duration of responses rather than demonstration of survival benefit. As a result, trials of drugs to treat end-stage refractory cancer indications have historically involved fewer patients and generally have been faster to complete than trials of drugs for other indications. We are aware that the FDA and other similar agencies are regularly reviewing the use of objective endpoints for commercial approval and that policy changes may impact the size of trials required for approval, timelines and expenditures significantly. The trend over the past few years has been to shorten approval cycles for terminal patients in the U.S. by employing a "fast track" approach.

In order to gain marketing approval, we must submit a dossier to the relevant authority for review, which is known in the U.S. as an NDA and in the EU as a marketing authorization application, or MAA. The format is usually specific and laid out by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as the non-clinical and clinical data. Once the submitted NDA is accepted for filing by the FDA, it undertakes the review process that takes ten (10) months, unless an expedited priority review is granted which takes six (6) months to complete. Approval can take several months to several years, if multiple ten (10) month review cycles are needed before final approval is obtained, if at all.

The approval process can be affected by a number of factors. The NDA may be approvable requiring additional pre-clinical, manufacturing data or clinical trials which may be requested at the end of the ten (10) month NDA review cycle, thereby delaying marketing approval until the additional data are submitted and may involve substantial unbudgeted costs. The regulatory authorities usually will conduct an inspection of relevant manufacturing facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor for adverse effects or other additional studies as deemed appropriate. After approval for the initial indication, further clinical studies are usually necessary to gain approval for any additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

The FDA offers a number of regulatory mechanisms that provide expedited or accelerated approval procedures for selected drugs in the indications on which we are focusing our efforts. These include accelerated approval under Subpart H of the agency's NDA approval regulations, fast track drug development procedures and priority review. At this time, we have not determined whether any of these approval procedures will apply to any of our current treatment candidates.

The US, EU and other jurisdictions may grant orphan drug designation to drugs intended to treat a “rare disease or condition,” which, in the US, is generally a disease or condition that affects no more than 200,000 individuals. In the EU, orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than fifty (50) in 100,000 persons in the EU; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and ten (10) years in the EU. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. Orphan drug designation must be requested before submitting an NDA or MAA. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process; however, this designation provides an exemption from marketing authorization (NDA) fees.

We are also subject to numerous environmental and safety laws and regulations, including those governing the use and disposal of hazardous materials. The cost of compliance with and any violation of these regulations could have a material adverse effect on our business and results of operations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury from these materials may occur. Compliance with laws and regulations relating to the protection of the environment has not had a material effect on our capital expenditures or our competitive position. However, we are not able to predict the extent of government regulation, and the cost and effect thereof on our competitive position, which might result from any legislative or administrative action pertaining to environmental or safety matters.

In various countries, animal rights activism has led to either formal or informal boycotting of certain types of animal trials. As we rely on animal experiments as precursors to human trials.

Employees

Other than our Chief Executive Officer, we currently do not have any full-time employees, but retain the services of independent contractors/consultants on a contract-employment basis. Our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit and train new employees. Although we have done so in the past and expect to do so in the future, there can be no assurance that we will be able to successfully attract and retain skilled and experienced personnel. We anticipate that in the near future, other key personnel will enter into employment agreements with the Company on customary terms.

ITEM 1A. RISK FACTORS.

An investment in the Company’s Common Stock involves a high degree of risk. You should carefully consider the risks described below as well as other information provided to you in this Annual Report on Form 10-K, including information in the section of this document entitled “Information Regarding Forward Looking Statements.” The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our Common Stock could decline, and you may lose all or part of your investment.

Risks related to our Business and our Industry

We have a limited operating history and a history of operating losses and expect to incur significant additional operating losses.

Our planned principal operations are the development and commercialization of new cell therapy products focused on treatment of blood cancers, certain non-malignant disorders and organ transplantations and regeneration. We are currently conducting research and development activities in order to facilitate the transition of the patent technology we license from the laboratory to clinical trials. We have a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated net losses since we began operations, including \$2,117,446 for the year ended December 31, 2018. We expect to incur substantial additional net expenses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the preclinical and clinical development of our product candidates; obtaining necessary regulatory approvals from the U.S. Food and Drug Administration (the “FDA”) and international regulatory agencies; successful manufacturing, sales, and marketing arrangements; and raising sufficient funds to finance our activities. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We may need to secure additional financing.

We anticipate that we will incur operating losses for the foreseeable future. Our historical cash burn rate was approximately \$200,000 per month. As of December 31, 2018, we had cash in the amount of \$18,934. Based on our current resources, we will not be able to continue to operate without additional immediate funding. If we are not successful in securing additional financing, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products.

Our auditors have issued a “going concern” audit opinion.

Our independent auditors have indicated, in their report on our December 31, 2018 consolidated financial statements, that there is substantial doubt about our ability to continue as a going concern. A “going concern” opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

We are an early-stage company with an unproven business strategy and may never achieve commercialization of our candidate products or profitability.

We are at an early stage of development and commercialization of our technologies and product candidates. We have not yet begun to market any products and, accordingly, have not begun to generate revenues from the commercialization of our products. Our products will require significant additional clinical testing and investment prior to commercialization. A commitment of substantial resources by ourselves and, potentially, our partners to conduct time-consuming research and clinical trials will be required if we are to complete the development of our product candidates. There can be no assurance that any of our product candidates will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed. Most of our product candidates are not expected to be commercially available for several years, if at all.

We are dependent on our collaborative partners and service providers the loss of which would hurt our business.

Our strategy is to enter into various arrangements with corporate and academic collaborators, licensors, licensees, service providers and others for the research, development, clinical testing and commercialization of our products. We intend to or have entered into agreements with academic, medical and commercial organizations to research, develop and test our products. In addition, we intend to enter into corporate partnerships to commercialize the Company’s core products. There can be no assurance that such collaborations can be established on favorable terms, if at all.

Should any collaborative partner or service provider fail to appropriately research, develop, test or successfully commercialize any product to which the Company has rights, our business may be adversely affected. Failure of a collaborative partner or service provider to successfully conduct or complete their activities or to remain a viable collaborative partner or commercialize enterprise for any particular program could delay or halt the development or commercialization of any products arising out of such program. While management believes that collaborative partners and service providers will have sufficient economic motivation to continue their activities, there can be no assurance that any of these collaborations or provisions of required services will be continued or result in successfully commercialized products.

Notably, we maintain an exclusive worldwide license to certain intellectual property owned by Yeda pursuant to the Yeda License Agreement, as further discussed in the “Intellectual Property” section hereinafter. If we should default under the License Agreement, then our rights to Yeda’s intellectual property would extinguish, and we would lose all rights to operate the licenses. In such an event, we would effectively cease to operate unless we re-obtained licensing with Yeda.

In addition, there can be no assurance that the collaborative research or commercialization partners will not pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our programs.

Our ability and our collaborators' ability to sell therapeutic products will depend to a large extent upon reimbursement from health care insurance companies.

Our success may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us or our collaborative partners to establish and maintain price levels that are sufficient for realization of an appropriate return on investment in product development.

We do not own any patents and rely on the patents we license from Yeda Research and Development Limited.

We do not currently own any patents and only have an exclusive worldwide license to certain intellectual property owned by Yeda pursuant to a license agreement between us and Yeda. Under the license agreement with Yeda, Yeda retains ownership of the licensed patents. If we were to default under the license agreement, then our rights to Yeda's intellectual property would be extinguished and we would lose all rights to operate the license. In such an event, we would effectively cease to operate unless we re-obtained licensing with Yeda.

We are dependent on protecting our proprietary rights.

Our success and competitive position and future overall revenues will depend in part on our ability to obtain and maintain patent protection over the patents that we have an exclusive license to use for our product candidates, methods, process and other technologies to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. Although our patents and related technologies are owned by Yeda, under our exclusive license agreement, we are required to pay all patent related expenses for applications, renewals, etc., as well as any and all legal or other costs associated with the defending and protecting such proprietary rights. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent the patents that we license;
- whether or not others will obtain patents claiming aspects similar to those covered by the patents that we license; or
- whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

For a complete list of the patents that we license from Yeda, please see the section entitled "Science and Technology Overview" of this Annual Report on Form 10-K.

We may be required to obtain licenses from third parties to avoid infringing patents or other proprietary rights. No assurance can be given that any licenses required under any such patents or proprietary rights would be made available, if at all, on terms we find acceptable. If we do not obtain such licenses, we could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited.

A number of pharmaceutical, biopharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain. Such conflict may also result in the denial of our patent applications. In addition, if patents that cover our activities are issued to other companies, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology. If we do not obtain such licenses, we could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited. In addition, we could incur substantial costs in defending ourselves in suits brought against us on patents that our products might infringe or in filing suits against others to have such patents declared invalid.

Patent applications in the U.S. are maintained in secrecy and not published if either: i) the application is a provisional application or, ii) the application is filed and we request no publication and certify that the invention disclosed "has not and will not" be the subject of a published foreign application. Otherwise, U.S. applications or foreign counterparts, if any, publish 18 months after the priority application has been filed. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we or any licensor were the first creator of inventions covered by pending patent applications or that we or such licensor was the first to file patent applications for such inventions. Moreover, we might have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, even if the eventual outcome were favorable to us. There can be no assurance that our patents, if issued, would be held valid or enforceable by a court or that a competitor's technology or product would be found to infringe such patents

Much of our know-how and technology may not be patentable. To protect our rights, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, our business may be adversely affected by competitors who independently develop competing technologies, especially if we obtain no, or only narrow, patent protection.

We are subject to various government regulations.

The manufacture and sale of human therapeutic and diagnostic products in the U.S., Canada and foreign jurisdictions are governed by a variety of statutes and regulations. These laws require approval of manufacturing facilities, controlled research and testing of products and government review and approval of a submission containing manufacturing, preclinical and clinical data in order to obtain marketing approval based on establishing the safety and efficacy of the product for each use sought, including adherence to current Good Manufacturing Practice (or cGMP) during production and storage, and control of marketing activities, including advertising and labeling.

The products we are currently developing will require significant development, preclinical and clinical testing and investment of substantial funds prior to their commercialization. The process of obtaining required approvals can be costly and time-consuming, and there can be no assurance that future products will be successfully developed and will prove to be safe and effective in clinical trials or receive applicable regulatory approvals. Markets other than the U.S. and Canada have similar restrictions. Potential investors and shareholders should be aware of the risks, problems, delays, expenses and difficulties which we may encounter in view of the extensive regulatory environment which controls our business.

We may become subject to increased government regulation.

Increased government regulation could: (i) reduce our revenues; (ii) increase our operating expenses; and (iii) expose us to significant liabilities. We cannot be sure what effect any future material noncompliance by us with any future laws and regulations or any material changes in current laws and regulations could have on our business, operating results and financial condition.

If we are unable to keep up with rapid technological changes in our field or compete effectively, we will be unable to operate profitably.

We are engaged in a rapidly changing field. Other products and therapies that will compete directly with the products that we are seeking to develop and market currently exist or are being developed. Competition from fully integrated pharmaceutical companies and more established biotechnology companies is intense and is expected to increase. Most of these companies have significantly greater financial resources and expertise in discovery and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than us. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biopharmaceutical or biotechnology companies. Many of these competitors have significant products that have been approved or are in development and operate large, well-funded discovery and development programs. Academic institutions, governmental agencies and other public and private research organizations also conduct research, seek patent protection and establish collaborative arrangements for therapeutic products and clinical development and marketing. These companies and institutions compete with us in recruiting and retaining highly qualified scientific and management personnel. In addition to the above factors, we will face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, price and patent position. There is no assurance that our competitors will not develop more effective or more affordable products, or achieve earlier patent protection or product commercialization, than our own.

Other companies may succeed in developing products earlier than ourselves, obtaining Health Canada, European Medicines Agency (the “EMA”) and FDA approvals for such products more rapidly than we will, or in developing products that are more effective than products we propose to develop. While we will seek to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop, or that any therapy we develop will be preferred to any existing or newly developed technologies.

Clinical trials for our product candidates are expensive and time consuming, and their outcome is uncertain

The process of obtaining and maintaining regulatory approvals for new therapeutic products is expensive, lengthy and uncertain. Costs and timing of clinical trials may vary significantly over the life of a project owing to any or all of the following non-exclusive reasons:

- the duration of the clinical trial;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required and ability to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- per patient trial costs;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- our final product candidates having different properties in humans than in laboratory testing;
- the need to suspend or terminate our clinical trials;
- insufficient or inadequate supply of quality of necessary materials to conduct our trials;
- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;
- problems engaging institutional review boards (“IRB”) to oversee trials or in obtaining and maintaining IRB approval of studies;
- the duration of patient follow-up;
- the efficacy and safety profile of a product candidate;
- the costs and timing of obtaining regulatory approvals; and
- the costs involved in enforcing or defending patent claims or other intellectual property rights.

Late stage clinical trials are especially expensive, typically requiring tens of millions of dollars, and take years to reach their outcomes. Such outcomes often fail to reproduce the results of earlier trials. It is often necessary to conduct multiple late stage trials, including multiple Phase III trials, in order to obtain sufficient results to support product approval, which further increases the expense. Sometimes trials are further complicated by changes in requirements while the trials are under way (for example, when the standard of care changes for the disease that is being studied in the trial). Accordingly, any of our current or future product candidates could take a significantly longer time to gain regulatory approval than we expect, or may never gain approval, either of which could delay or stop the commercialization of our product candidates.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

We may not receive regulatory approvals for our product candidates or there may be a delay in obtaining such approvals.

Our products and our ongoing development activities are subject to regulation by regulatory authorities in the countries in which we or our collaborators and distributors wish to test, manufacture or market our products. For instance, the FDA will regulate the product in the U.S. and equivalent authorities, such as the EMA, will regulate in Europe. Regulatory approval by these authorities will be subject to the evaluation of data relating to the quality, efficacy and safety of the product for its proposed use, and there can be no assurance that the regulatory authorities will find our data sufficient to support product approval.

The time required to obtain regulatory approval varies between countries. In the U.S., for products without “Fast Track” status, it can take up to eighteen (18) months after submission of an application for product approval to receive the FDA’s decision. Even with Fast Track status, FDA review and decision can take up to twelve (12) months.

Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements as well as case load at the regulatory agency at the time.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will be commenced or completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- delays in the commencement of clinical trials as a result of clinical trial holds or the need to obtain additional information to complete an Investigational New Drug Application (IND);
- delays in obtaining regulatory approval to commence new trials;
- adverse safety events experienced during our clinical trials;
- insufficient efficacy during trials leading to withdrawal of product candidate;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials; and
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval.

If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of subsequent human clinical trials.

Preclinical studies, including studies of our product candidates in animal models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of our products may not predict the ability of these products to treat humans. Our technology may be found not to be efficacious when studied in human clinical trials.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from Phase 1/2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the investigational drug under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients by clinical trial programs for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

We may in the future conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan.

We may fail to comply with regulatory requirements.

Our success will be dependent upon our ability, and our collaborative partners' abilities, to maintain compliance with regulatory requirements, including cGMP, and safety reporting obligations. The failure to comply with applicable regulatory requirements can result in, among other things, fines, injunctions, civil penalties, total or partial suspension of regulatory approvals, refusal to approve pending applications, recalls or seizures of products, operating and production restrictions and criminal prosecutions.

Regulatory approval of our product candidates may be withdrawn at any time.

After regulatory approval has been obtained for medicinal products, the product and the manufacturer are subject to continual review, including the review of adverse experiences and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturer and manufacturing facilities we use to make any of our products will also be subject to periodic review and inspection by the FDA or EMA, as applicable. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. We will continue to be subject to the FDA or EMA requirements, as applicable, governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA or EMA, as applicable, had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

There may not be a viable market for our products.

We believe that there will be many different applications for our products. We also believe that the anticipated market for our products will continue to expand. These assumptions may prove to be incorrect for a variety of reasons, including competition from other products and the degree of our products' commercial viability.

We rely on key personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to grow effectively.

We are dependent on our Chief Executive Officer, Itamar Shimrat, our Executive Chairman, Dennis Brown, and on scientific and drug development consultants, the loss of services of one or more of whom could materially adversely affect us.

Other than our Chief Executive Officer, we currently do not have full-time employees, but we retain the services of independent contractors/consultants on a contract-employment basis. Our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit and train new employees. Although we have done so in the past and expect to do so in the future, there can be no assurance that we will be able to successfully attract and retain skilled and experienced personnel.

We may be subject to foreign exchange fluctuation.

We maintain our accounts in both U.S. dollars and Israeli shekels. A portion of our expenditures are in foreign currencies, most notably in U.S. dollars, and therefore we are subject to foreign currency fluctuations, which may, from time to time, impact our financial position and results. We may enter into hedging arrangements under specific circumstances, typically through the use of forward or futures currency contracts, to minimize the impact of increases in the value of the U.S. dollar. In order to minimize our exposure to foreign exchange fluctuations we may hold sufficient U.S. dollars to cover our expected U.S. dollar expenditures.

We may be exposed to potential product and clinical trials liability.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of therapeutic products. Human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. While we will continue to take precautions we deem appropriate, there can be no assurance that we will be able to avoid significant product liability exposure. We do not currently maintain liability insurance coverage as such insurance is expensive and difficult to obtain. In the event clinical trials are commenced, we plan to obtain liability insurance coverage in the jurisdictions applicable to such clinical trials. However, when we seek such insurance, it may not be available on acceptable terms, if at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit our ability to conduct clinical trials in certain jurisdiction or the commercialization of our current or potential products. A product liability claim brought against us in a clinical trial or a product withdrawal could have a material adverse effect upon us and our financial condition. Should the insurance coverage be insufficient in amount or scope to address multiple and diverse claims, liabilities not covered by insurance could represent a significant financial liability for Cell Source. Since Yeda does not conduct human trials, there is no need for Cell Source to have insurance for trials there. When Cell Source begins to contract facilities at hospitals to conduct human trials on its behalf, it will ensure that full and proper insurance coverage will be in place with respect to such clinical facilities. Cell Source plans to insure its participation in any and all clinical trials, above and beyond whatever insurance coverage is already held by the institutions and facilities providing services with respect to such clinical trials.

We may become subject to liabilities related to risks inherent in working with hazardous materials.

Our discovery and development processes involve the controlled use of hazardous and radioactive materials. We are subject to federal, state, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. We are not specifically insured with respect to this liability. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations and currently do not expect to make material capital expenditures for environmental control facilities in the near-term, there can be no assurance that we will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

Some of our research and development activities are located in Israel and, therefore, our business, financial condition and results of operation may be adversely affected by political, economic and military instability in Israel.

Our Chief Executive Officer resides in Israel, and substantially all of our assets and most of the assets of this person are located in Israel. Therefore, a judgment obtained against any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult to effect service of process on this person in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

The Company functions using an outsourcing driven model, where research is performed by employees of the Weizmann Institute of Science, and commencing in 2019, will be conducted by employees of MD Anderson, on their premises as funded by Cell Source and planned development such as production of Veto Cells and human clinical trials expected to take place at third party facilities, including hospitals and laboratories, mainly outside of Israel. For this reason, the Company has not acquired or leased office space in Israel but rather uses services provided by its general counsel for office services in Israel and third party contracted office services in the United States.

Risks Related to Our Common Stock

There may be additional issuances of shares of preferred stock in the future.

Our Articles of Incorporation permit us to issue up to 10,000,000 shares of preferred stock and our board of directors has authorized 1,000,000 shares of Series A Convertible Preferred, for issuance. Our board of directors could authorize the issuance of additional series of preferred stock in the future and such preferred stock could grant holders preferred rights on parity with the Series A Preferred as to dividend payments and liquidation preference. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series A Preferred in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series A Preferred if we do not have sufficient funds to pay dividends on all Series A Preferred outstanding and outstanding parity preferred stock.

The liquidation preference of the Series A Preferred may be lower than the net tangible value of our Common Stock.

The Series A Convertible Preferred has a liquidation preference of \$7.50 per share which may be lower than the net tangible book value of our common stock upon conversion.

There is not an active liquid trading market for the Company's Common Stock.

The Company is required to report under the Exchange Act and its Common Stock is eligible for quotation on the OTC Markets. However, there is no regular active trading market in the Company's Common Stock, and we cannot give an assurance that an active trading market will develop. If an active market for the Company's Common Stock develops, there is a significant risk that the Company's stock price may fluctuate dramatically in the future in response to any of the following factors, some of which are beyond our control:

- variations in our quarterly operating results;
- announcements that our revenue or income are below analysts' expectations;
- general economic slowdowns;
- sales of large blocks of the Company's Common Stock; and
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments.

Our Common Stock is subject to the "penny stock" rules of the Securities and Exchange Commission, which may make it more difficult for stockholders to sell our Common Stock.

The SEC has adopted Rule 15c-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks, and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person, and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination, and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of the Company's Common Stock if and when such shares are eligible for sale and may cause a decline in the market value of its stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock.

We may not be able to attract the attention of brokerage firms because we became a public company by means of a reverse acquisition.

Because we became public through a "reverse acquisition," securities analysts of brokerage firms may not provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our Common Stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of the Company in the future.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for the Company to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of its Common Stock.

The Company may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. The Company may have difficulty attracting and retaining directors with the requisite qualifications. If the Company is unable to attract and retain qualified officers and directors, the management of its business and its ability to obtain or retain listing of our shares of Common Stock on any stock exchange (assuming the Company elects to seek and are successful in obtaining such listing) could be adversely affected.

If the Company fails to maintain an effective system of internal controls, it may not be able to accurately report its financial results or detect fraud. Consequently, investors could lose confidence in the Company's financial reporting and this may decrease the trading price of its stock.

The Company must maintain effective internal controls to provide reliable financial reports and detect fraud. As a result of the Company's inability to file periodic reports with the Securities and Exchange Commission on a timely basis with respect to the years ended December 31, 2016 and December 31, 2017 and the quarters ended March 31, 2017, June 30, 2017, September 30, 2017, March 31, 2018 and June 30, 2018 due to a lack of financial resources, management previously concluded that the Company's internal controls over financial reporting were not effective as of the end of each of such periods. Although management believes that the Company's internal controls were effective as of December 31, 2018, failure to maintain an effective system of internal controls could harm its operating results and cause investors to lose confidence in the Company's reported financial information. Any such loss of confidence would have a negative effect on the trading price of the Company's stock.

Voting power of our shareholders is highly concentrated by insiders.

Our officers, directors and affiliates currently own approximately 34.7% of our outstanding common stock. Such concentrated control of the Company may adversely affect the value of our ordinary shares. If you acquire our ordinary shares, you may have no effective voice in our management. Sales by our insiders or affiliates, along with any other market transactions, could affect the value of our ordinary shares.

We do not intend to pay dividends to holders of Common Stock for the foreseeable future.

We have paid no dividends on our Common Stock to date and it is not anticipated that any dividends will be paid to holders of our Common Stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment in our Company.

Our articles of incorporation allow for our board to create a new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our Common Stock.

Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors have the authority to issue up to 10,000,000 shares of our preferred stock terms of which may be determined by the Board without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of Common Stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our Common Stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than our Common Stock or that is convertible into our Common Stock, which could decrease the relative voting power of our Common Stock or result in dilution to our existing stockholders. Although we have no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

You may experience dilution of your ownership interests because of the future issuance of additional shares of common stock.

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our shareholders. We may also issue additional shares of our securities that are convertible into or exercisable for Common Stock, as the case may be, in connection with hiring or retaining employees, future acquisitions, future sales of its securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of Common Stock may create downward pressure on the value of our securities. There can be no assurance that we will not be required to issue additional shares of Common Stock, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which our shares may be valued or are trading in a public market.

The Company does not currently have revenues and as such, our ability to continue our operations is dependent on the execution of management's plans, which include the raising of capital through the debt and/or equity markets, until such time that funds provided by operations are sufficient to fund working capital requirements. We may need to incur additional liabilities with certain related parties to sustain our existence. There can be no assurances that we will be successful in generating additional cash from equity or debt financings or other sources to be used for operations. In the event that further equity capital is raised, there is a risk that investors will incur dilution of their holdings.

The Company has used a combination of equity and debt capital to fund its operations. Some of the debt capital is in the form of convertible notes. Some of these notes may be convertible to equity at a 70% discount to the price of the current offering. The note holders may also receive warrants on conversion. In the event that these notes are converted to equity, investors in the current offering with incur dilution. Otherwise, some of the proceeds of the offering may be used to repay debt, which limits the use of proceeds to fund expenditures for the Company's ongoing operations. The investors in the private placement that the company conducted in 2014 prior to its share exchange with TTSI, have been allotted price protection features which were not offered to investors in Cell Source as a public company. In the event that these features are triggered, this could result in further dilution of investors in the future.

Below is a summary of the notes issued by the Company:

- Eleven notes payable with principal amounts totaling \$1,613,000; and
- Seventeen convertible notes payable with principal amounts totaling \$1,060,000.

As further described in the financial statement footnotes contained elsewhere in this report, these notes are convertible into shares of common stock under various circumstances at the lower of: a) \$0.75 per share, or b) 70% of the pricing of a qualified financing or 70% of the closing price for a period immediately before such conversions.

We are in default of payment obligations under certain promissory notes.

As of December 31, 2018, \$2,673,000 of indebtedness represented by outstanding promissory notes was past due. Although only one holder of a note with the principal amount of \$250,000 has elected to pursue remedies against us, no assurance can be given that the other holders will not do so in the future. The institution of collection actions could have a material adverse effect on our business and could force us to seek relief through insolvency or other proceedings.

As an issuer of "penny stock," the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

Our issuance of Common Stock upon exercise of warrants or options may depress the price of our Common Stock.

As of December 31, 2018, we had 26,077,611 shares of Common Stock issued and outstanding and outstanding warrants to purchase 13,458,653 shares of Common Stock. The issuance of shares of Common Stock upon exercise of outstanding warrants or options could result in substantial dilution to our stockholders, which may have a negative effect on the price of our Common Stock.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. Since we are subject to the filing requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, we file reports with the Securities and Exchange Commission. As a result, we file annual, quarterly and current reports with respect to our business and financial condition and establish and maintain effective disclosure and financial controls and corporate governance practices. Compliance with the Exchange Act and the rules and regulations under the Exchange Act have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. Our management and other personnel devote a substantial amount of time to these compliance initiatives. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We estimate that we will incur between \$1 million and \$2.5 million annually in expenses in response to these requirements.

If we take advantage of specified reduced disclosure requirements applicable to a "smaller reporting company", the information that we provide to stockholders may be different than they might receive from other public companies.

As a company with less than \$100 million in revenue during our last fiscal year and a public float of less than \$250 million, we qualify as a "smaller reporting company". As a smaller reporting company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- Reduced disclosure about our executive compensation arrangements;
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

As a result of our status as a "smaller reporting company," the information that we provide stockholders may be different than you might get from other public companies in which you hold stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Due to a lack of financial resources, we were unable to file our annual reports on Form 10-K for the years ended December 31, 2017 and December 31, 2016 and the quarterly reports on Form 10-Q for the periods ended March 31, 2017, June 30, 2017, September 30, 2017 and March 31, 2018 on a timely basis. Management evaluated the lack of financial resources on our assessment of our reporting controls and procedures and concluded that the control deficiency represented a material weakness as of the end of each of such periods.

Management's efforts to remediate the material weakness included raising funds and seeking new resources to alleviate this material weakness and filing all necessary regulatory reports on a timely basis. Although management concluded that our internal controls over financial reporting were effective as of December 31, 2018, there can be no assurance that we will have the necessary resources to maintain effective controls in future periods.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are a "smaller reporting company", our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

Our corporate headquarters is located at 57 West 57th Street, New York, NY 10019 under a lease which expires in June 2019. The telephone number at such address is (646) 416-7896. We believe that our facilities are adequate and suitable for our current operations. To the extent that other office space is required, we believe that such space is readily available.

ITEM 3. LEGAL PROCEEDINGS.

Except as described below, we are not involved in any pending legal proceeding or litigations and, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on us.

In January 2019, the holder of a promissory note in the principal amount of \$250,000 due on March 16, 2016 instituted a collection action in the Supreme Court of the State of New York, County of New York. A motion for summary judgement was heard on March 7, 2019 and the Company did not oppose the motion. The Company has had discussion with respect to entering into an agreement providing for a payment plan with the holder of the note, but no agreement has yet been reached.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is currently quoted under the symbol "CLCS" on the OTCQB. From in or about April 2017 until January 2019, our common stock was quoted on the OTCBK.

There was no reported trading in our common stock prior to March 13, 2014. Since March 13, 2014, there has been limited trading in our common stock. The following table sets forth the range of high and low bid prices of our common stock as reported and summarized on the OTCQB for the periods indicated. These prices are based on inter-dealer bid and asked prices, without markup, markdown, commissions, or adjustments and may not represent actual transactions.

2018 Fiscal Year

	<u>High</u>	<u>Low</u>
First Quarter ended March 31, 2018	\$ 0.43	\$ 0.25
Second Quarter ended June 30, 2018	\$ 0.85	\$ 0.42
Third Quarter ended September 30, 2018	\$ 1.09	\$ 0.55
Fourth Quarter ended December 31, 2018	\$ 0.75	\$ 0.45

2017 Fiscal Year

	<u>High</u>	<u>Low</u>
First Quarter ended March 31, 2017	\$ 0.53	\$ 0.35
Second Quarter ended June 30, 2017	\$ 0.45	\$ 0.25
Third Quarter ended September 30, 2017	\$ 0.40	\$ 0.30
Fourth Quarter ended December 31, 2017	\$ 0.45	\$ 0.20

Transfer Agent

Our transfer agent is Globex Transfer, LLC, 780 Deltona Blvd., Suite 202, Deltona, FL 32725.

Holdings

As of March 27, 2019, there were 108 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Warrants

As of December 31, 2018, we had outstanding warrants to purchase an aggregate of 13,458,653 shares of common stock with a weighted average exercise price of \$0.64 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

As of the date of the filing of this Annual Report on Form 10-K, we do not have any equity compensation plan.

Sales of Unregistered Securities

In February 2018, the Company issued five-year warrants to purchase 300,000 shares of common stock to three purchasers of notes in the aggregate principal amount of \$500,000. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with these transactions.

In March 2018, the Company sold 6,667 shares of Series A Preferred Stock to one investor for \$50,000. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with this transaction.

In November 2018, the Company sold 133,334 shares of Series A Preferred Stock to one investor for \$1,000,000. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with this transaction.

In December 2018, the Company issued warrants to purchase 218,000 shares of common stock with an exercise price of \$0.75 per share in satisfaction of \$109,000 of fees due to members of its Scientific Advisory Board. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with this transaction.

In December 2018, the Company issued 76,500 shares of Series A Preferred Stock in exchange for the surrender of notes payable with a total outstanding principal amount and accrued interest of \$382,500. The Company relied upon the exemption provided by Section 3(a)(9) of the Securities Act in connection with this transaction.

The Company issued a total of 728,375 shares of common stock as a payment in kind dividend to holders of its Series A Preferred Stock in 2018. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with this transaction.

Between January 4, 2019 and February 28, 2019, the Company sold 43,333 shares of Series A Convertible Preferred Stock at an aggregate purchase price of \$325,000. The Company relied upon the exemption provided by Section 4(2) of the Securities Act in connection with this transaction.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This Management Discussion and Analysis ("MD&A") contains "forward-looking statements," which represent our projections, estimates, expectations or beliefs concerning among other things, financial items that relate to management's future plans or objectives or to our future economic and financial performance. In some cases, you can identify these statements by terminology such as "may," "should," "plans," "believe," "will," "anticipate," "estimate," "expect," "project" or "intend," including their opposites or similar phrases or expressions.

You should be aware that these statements are projections or estimates as to future events and are subject to a number of factors that may tend to influence the accuracy of the statements. These forward-looking statements should not be regarded as a representation by the Company or any other person that the events or plans of the Company will be achieved. You should not unduly rely on these forward-looking statements, which speak only as of the date of this MD&A. Except as may be required under applicable securities laws, we undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this MD&A or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe under "Risk Factors" in this Annual Report on Form 10-K. Actual results may differ materially from any forward-looking statement.

Overview

We are a cell therapy company focused on immunotherapy. Since our inception, we have been involved with the development of proprietary immune system management technology licensed from Yeda Research & Development Company Limited (Yeda), the commercial arm of the Weizmann Institute of Technology, Israel.

This technology seeks to address one of the most fundamental challenges within human immunology: *how to tune the immune response such that it tolerates selected desirable foreign cells, but continues to attack all other (undesirable) targets.* In simpler terms, many potentially life-saving treatments have limited effectiveness today because the patient's immune system rejects them. Today, rejection is partially overcome using aggressive immune suppression treatments that leave the patient exposed to many dangers by compromising their immune system. The ability to overcome rejection without having to compromise the rest of the immune system may open the door to effective treatment of a number of severe medical conditions which are characterized by this need. These include:

- Hematological malignancies (leukemias, lymphomas, etc.). One of the most effective treatments for these conditions is SCT - stem cell transplantation (e.g. bone marrow transplantation). While the challenge finding donors for allogeneic (donor vs. patient derived) SCT can be addressed through haploidentical (partially mismatched donor) transplants, is a risky and difficult procedure primarily because of potential conflicts between host and donor immune systems and also due to viral infections that often follow even successful SCT while the compromised new immune system works to reconstitute itself by using the transplanted stem cells.
- The broader set of cancers, including solid tumors, that can potentially be treated effectively using genetically modified cells such as CAR-T cells, but also face efficacy and economic constraints due to limited persistence based on immune system issues (i.e., the need to be able to safely and efficiently deliver allogeneic CAR-T therapy).
- Organ failure and transplantation. A variety of conditions can be treated by the transplantation of vital organs. However, transplantation is limited both by the insufficient supply of available donor organs and the need for lifelong, daily anti-reject treatments post-transplant.
- Non-malignant hematological conditions (such as sickle cell anemia) which could, in many cases, also be effectively treated by stem cell transplantation if the procedure could be made safer and more accessible by addressing conflicts between host and donor immune systems.

Recent Developments

On November 28, 2018, we entered into a Sponsored Research Agreement with The University of Texas M.D. Anderson Cancer Center (“MD Anderson”) for a research study in the area of stem cells. The Sponsored Research Agreement shall be for three years and can be extended by mutual written agreement. We are committed to engage MD Anderson to perform research services in the amount of approximately \$1,500,000 from January 1, 2019 to December 31, 2021.

On February 7, 2019, MD Anderson submitted an IND application with respect to the Anti-Rejection, Anti-Viral Veto Cell to the FDA.

On February 19, 2019, we entered into an agreement with MD Andersen for the latter to perform cell production and conduct Phase I/II human clinical trials. In connection with that agreement, we committed to fund such work in the amount of approximately \$2,000,000 over a two-year period beginning that same date.

Consolidated Results of Operations

Year Ended December 31, 2018 Compared with the Year Ended December 31, 2017

Research and Development

Research and development expense was \$725,088 and \$1,476,856 for the years ended December 31, 2018 and 2017, respectively. Research and development expense decreased by \$751,768, or 51%, in 2018, primarily due to a decrease of approximately \$389,000 in fees related to our agreement with Yeda and a decrease of approximately \$362,000 in patent-related expenses.

Selling, General and Administrative

Selling, general and administrative expense was \$1,281,055 and \$815,947 for the years ended December 31, 2018 and 2017, respectively. Selling, general and administrative expense increased by \$465,108, or 57%, in 2018, primarily due to increases of approximately \$226,000 of external accounting and professional fees, which was due in part by our financing activities in 2017 which allowed us to increase operations and file our delinquent SEC reports in 2018, approximately \$162,000 of consulting expenses and approximately \$105,000 of external expenses.

Change in Fair Value of Derivative Liabilities

The change in fair value of derivative liabilities for the years ended December 31, 2018 and 2017 was a gain of \$485,500 and \$590,173, respectively, which represents the change in fair value of the warrants and conversion options that were deemed to be derivative liabilities.

Interest Expense

Interest expense for the years ended December 31, 2018 and 2017 was \$268,997 and \$177,970, respectively, an increase of \$91,027, or 51%, in 2018, due to an increase in notes payable outstanding during 2018 as well as interest and penalties associated with certain notes payable that became past due in 2018.

Amortization of Debt Discount

Amortization of debt discount was \$209,655 and \$438,162 for the years ended December 31, 2018 and 2017, respectively, a decrease of \$228,507, or 52%, which is associated with warrants and conversion options issued in connection with notes payable.

Loss on Exchange of Notes Payable for Series A Convertible Preferred Stock

The loss on exchange of notes payable for Series A Convertible preferred stock for the years ended December 31, 2018 and 2017 was \$191,251 and \$725,335, respectively, which represents the excess value of the preferred shares as compared to the carrying value of the notes payable.

Loss on Exchange of Warrants for Common Stock

During the year ended December 31, 2017, we recognized \$38,393 of loss on exchange of warrants for common stock related to outstanding warrants exchanged in connection with a note extension during the period.

Gain on Exchange of Accrued Liabilities for Warrants

During the year ended December 31, 2018, we recognized a \$73,100 gain on exchange of accrued liabilities for warrants related to accrued Scientific Advisory Board fees, which represents the excess value of the warrants as compared to the carrying value of the accrued liabilities.

Liquidity and Going Concern

We measure our liquidity in a number of ways, including the following:

	December 31,	
	2018	2017
Cash	\$ 18,934	\$ 371,048
Working capital deficiency	\$ (4,920,171)	\$ (4,557,374)

We have not generated any revenues since our inception, we have recurring net losses, we have a working capital deficiency as of December 31, 2018 and 2017 of approximately \$4,920,000 and \$4,557,000, respectively. We have used cash in operations of approximately \$2,002,000 and \$2,288,000 during the years ended December 31, 2018 and 2017, respectively. Subsequent to December 31, 2018, the Company received proceeds of approximately \$325,000 through the sale of 43,333 shares of Series A Convertible Preferred Stock at \$7.50 per share. These conditions raise substantial doubt about our ability to continue as a going concern within twelve months from the date these financial statements are issued. We are currently funding our operations on a month-to-month basis. While there can be no assurance that we will be successful, we are in active negotiations to raise additional capital.

Our ability to continue our operations is dependent on the execution of management's plans, which include the raising of capital through the debt and/or equity markets, until such time that funds provided by operations are sufficient to fund working capital requirements. We may need to incur additional liabilities with certain related parties to sustain our existence. If we were not to continue as a going concern, we would likely not be able to realize our assets at values comparable to the carrying value or the fair value estimates reflected in the balances set out in the preparation of our financial statements.

There can be no assurances that we will be successful in generating additional cash from equity or debt financings or other sources to be used for operations. Should we not be successful in obtaining the necessary financing to fund our operations, we would need to curtail certain or all operational activities and/or contemplate the sale of our assets, if necessary.

During the years ended December 31, 2018 and 2017, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

We experienced negative cash flows from operating activities for the years ended December 31, 2018 and 2017 in the amounts of \$2,002,114 and \$2,287,814, respectively. The net cash used in operating activities for the year ended December 31, 2018 was primarily due to cash used to fund a net loss of \$2,117,446, reduced by net non-cash expenses in the aggregate amount of \$176,809 and by \$292,141 of net cash provided due to changes in the levels of operating assets and liabilities. The net cash used in operating activities for the year ended December 31, 2017 was primarily due to cash used to fund a net loss of \$3,082,510, adjusted for net non-cash expenses in the aggregate amount of \$656,863 and by \$137,833 of net cash provided due to changes in the levels of operating assets and liabilities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the years ended December 31, 2018 and 2017 was \$1,650,000 and \$2,655,127, respectively. The net cash provided by financing activities during the year ended December 31, 2018 was attributable to \$1,050,000 of proceeds from the issuance of Series A preferred stock, \$500,000 of proceeds from the issuance of notes payable and \$100,000 of proceeds from a related party advance. The net cash provided by financing activities during the year ended December 31, 2017 was attributable to \$2,295,127 of proceeds from the issuance of Series A preferred stock, \$135,000 of proceeds from the issuance of notes payable and \$225,000 of proceeds from the issuance of notes payable – related party.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

For a description of our critical accounting policies, see Note 3 – Summary of Significant Accounting Policies of our financial statements included within this Annual Report.

Recent Accounting Standards

For a description of our recently issued and adopted accounting pronouncements, see in Note 3 – Summary of Significant Accounting Policies of our financial statements included within this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements are presented following the signature page to this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Exchange Act, such as this Annual Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the Principal Executive and Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Internal controls are procedures which are designed with the objective of providing reasonable assurance that (1) our transactions are properly authorized, recorded and reported; and (2) our assets are safeguarded against unauthorized or improper use, to permit the preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles.

In connection with the preparation of this Annual Report, management, with the participation of our Principal Executive and Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)). Based upon that evaluation, our Principal Executive and Financial Officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive and Financial Officer, and effected by the Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and Board of Directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013 Framework). Based on this evaluation under the 2013 Framework, our principal executive officer and principal financial officer have concluded that our internal control over financial reporting was effective as of December 31, 2018.

As previously reported, we identified the following material weakness in internal control over financial reporting as of December 31, 2017 that continued to exist through September 30, 2018:

- (1) Due to a lack of financial resources, we were unable to file our annual reports on Form 10-K for the years ended December 31, 2017 and December 31, 2016 and the quarterly reports on Form 10-Q for the periods ended March 31, 2017, June 30, 2017, September 30, 2017, March 31, 2018 and June 30, 2018 on a timely basis. Management evaluated the lack of financial resources in its assessment of our reporting controls and procedures and has concluded that the control deficiency represented a material weakness.

A material weakness is a deficiency, or a combination of deficiencies, within the meaning of Public Company Accounting Oversight Board ("PCAOB") Auditing Standard AS 2201, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

During the year ended December 31, 2018, we completed our remediation of the material weakness in our internal control over financial reporting by filing our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and our Annual Report on Form 10-K for the year ended December 31, 2018 on a timely basis.

Changes in Internal Controls

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as noted above as it relates to our successful remediation of our material weakness in internal control over financial reporting.

Limitations of the Effectiveness of Control

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations of any control system, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

Attestation Report of Registered Public Accounting Firm

This Annual Report does not contain an attestation report of our independent registered public accounting firm regarding internal control over financial reporting since the rules for smaller reporting companies provide for this exemption.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Below are the names and certain information regarding the Company's executive officers and directors:

Name	Age	Title(s)
Dennis Brown	69	Director (Chairman)
Itamar Shimrat	59	Chief Executive Officer, Chief Financial Officer and Director
Yoram Drucker	53	Director
David Zolty	69	Director
Ben Friedman	60	Director

Dr. Dennis M. Brown, PhD, was elected Director of the Company on June 30, 2014 and as Chairman of the Board on May 18, 2015. Dr. Brown became the Chair of our Audit Committee in September 2015. Dr. Brown is a founder and Chief Scientific Officer and director of Del Mar Pharmaceuticals (BC) Ltd. a subsidiary of DelMar Pharmaceuticals, Inc. (OTCQB: DMPI) to which he serves as a director and Chief Scientific Officer. Dr. Brown has more than thirty years of drug discovery and development experience. Since 2000 to the present, Dr. Brown has served as Chairman of Mountain View Pharmaceutical's Board of Directors and is the President of Valent. Dr. Brown has focused over the past 5 years on the development of DelMar Pharmaceuticals, serving as its Chief Scientific Officer since January 25, 2013 and Director since February 11, 2013. His extensive technical expertise, successful track record as an inventor, executive and director in the field of medical technology position him as an authoritative voice on the scientific, intellectual property, finance and commercialization and well as general management issues for Cell Source both now and in the future. In 1999 he founded ChemGenex Therapeutics, which merged with a publicly traded Australian company in 2004 to become ChemGenex Pharmaceuticals (ASX: CXS/NASDAQ: CXSP), of which he served as President and a Director until 2009. He was previously a co-founder of Matrix Pharmaceutical, Inc., where he served as Vice President (VP) of Scientific Affairs from 1985-1995 and as VP, Discovery Research, from 1995-1999. He also previously served as an Assistant Professor of Radiology at Harvard University Medical School and as a Research Associate in Radiology at Stanford University Medical School. He received his B.A. in Biology and Chemistry (1971), M.S. in Cell Biology (1975) and Ph.D. in Radiation and Cancer Biology (1979), all from New York University. Dr. Brown is an inventor of about 34 issued U.S. patents and applications, many with foreign counterparts. Dr. Brown's scientific knowledge and experience qualifies him to serve on our Board of Directors.

Itamar Shimrat, CEO, CFO and Director, is a Canadian businessman and a founding member of Cell Source Israel. Since Cell Source Israel's inception, Mr. Shimrat served as a Director, Chief Financial Officer and, in October 2013, he was appointed Chief Executive Officer. From March 2009 through September 2011, Mr. Shimrat served as Chief Financial Officer and Director of Rainbow Energy Ltd. From September 2011 through October 2013, Mr. Shimrat served as Chief Financial Officer and Director of Cell Source Ltd. From August 2012 to present, Mr. Shimrat served as Director of Step Up - OlimMadrega Inc. From October 2013 to present, Mr. Shimrat served as Chief Executive Officer and Director of Cell Source Ltd.. Previously, Mr. Shimrat served as an Executive Vice President at First International Bank of Israel from March 2005 until April, 2008. Prior to 2008, he served as a senior manager at McKinsey& Company's Tel Aviv office after having being elected Partner at Mitchell Madison Group and consulting for Bain & Co. Mr. Shimrat led major profit improvement programs for leading corporations ranging from American Express and Barclays to El Al Airlines. He has been a Director of two private companies: Rainbow Energy Ltd., a company in the renewable energy industry, and Step Up - OlimMadrega Ltd., a company in the wheelchair industry, and also was on the Allocations Committee of Matan, a leading Israeli philanthropic organization. He holds an MBA with Distinction from the Ivey Business School of the University of Western Ontario in Canada. Itamar brings to Cell Source significant knowledge and experience in the area of corporate finance. He also has extensive experience working in foreign environments and cultures and possesses distinctive oral and written presentation skills. This positions him to be effective in both financing and corporate development both domestically and internationally.

David Zolty has been a Director of Cell Source Israel since November 2011 and of our Board of Directors since June 30, 2014, and is a Canadian businessman who has owned and managed various Canadian enterprises since 1968. From more than five years prior through the present, Mr. Zolty served as Director of Management and Administration for Hightower Investments. In the mid 1970's David was one of the founders of TNT Appliances, a coin laundry and appliance sales and service company, primarily serving the Canadian burgeoning multi-family apartment industry. The company grew to be the second largest coin laundry in Canada and was sold in and about 2002. While owning and managing TNT, David was also involved in many real estate acquisitions both through TNT and the Zolty family real estate portfolio. Upon David's father Morris Zolty's retirement, David took a larger role in the Zolty family business where David currently holds a 12% ownership interest and has served in various roles therein for more than 5 years. David has received an honors BA and has done his post graduate work at the University of Toronto in the field of Religious Studies. He is also involved in a number of local charities and is a long standing board member of Camp Agudah Toronto, a children's summer camp which have facilities at Port Carling, Ontario. His extensive business experience and community involvement are an asset to Cell Source.

Ben Friedman, BBA, BGS, LLB, has been a Director of Cell Source Israel since November 2011 and of our Board of Directors since June 30, 2014, and is a Canadian business executive with over 25 years' experience in real estate and commerce. From more than five years prior through the present, Mr. Friedman served as Director and Vice President of Rancee Management. Since 1985, he has served as Owner and CEO of Saucham Holdings Ltd., a private real estate holding and development company active throughout Canada. He is, and has been for more than five years, a managing partner and Director of The Zolty Group, a private company specializing in the development and ownership of high rise multi-unit residential buildings in Canada and the United States. He continues to act as Director of numerous private business related enterprises in the high tech, medical, and laser technology fields, and is a Director of an array of non-profit educational and vocational institutions. Mr. Friedman's experience as both an executive, along with his degrees in both business and law, position him well to help guide Cell Source through its development.

Yoram Drucker, a Director, is an Israeli entrepreneur who has previously been involved in the development of two successful cell therapy technology firms. Mr. Drucker became a member of our Audit Committee in September 2015 and is the audit committee financial expert. From March 2009 through September 2011, Mr. Drucker served as Chief Executive Officer and Chairman of Rainbow Energy Ltd. From September 2011 through October 2013, Mr. Drucker served as Chief Executive Officer until October 2013 and Chairman of Cell Source Ltd. From October 2013 until May 2015, Mr. Drucker served as Chairman of Cell Source Ltd. He was a founding member of the cell stem therapy company Brainstorm (NASDAQ: BCLI). He served as COO in 2004 and CEO from 2005 to 2007. He was also among the founders of Pluristem (listed on the NASDAQ), also a cell therapy company, and was a Director in 2004 and 2005. In 2007 he was a seed investor and VP Business Development in a renewable energy technology firm called Millennium Electric TOU Ltd. Since March 2008 he was a Director of a private renewable energy company called Rainbow Energy, where he actively served as CEO from then until November of 2011. From 1996 to 2003 he served as business and marketing consulting and campaign execution in varied industries ranging from real estate development to insurance. He is an honors graduate of the Abudi College of Advertising and Marketing. Yoram brings significant experience in capital markets in the US and in developing Israeli based cell therapy companies from inception through financing over-the-counter and commencing clinical trials. His understanding of both the financial and the technical side of early stage corporate development has and will continue to be of great value to Cell Source.

The Company's directors are elected at the annual meeting of shareholders to hold office until the annual meeting of shareholders for the ensuing year or until their successors have been duly elected and qualified. Officers are elected annually by the Board of Directors and serve at the discretion of the Board.

Board Leadership Structure and Role in Risk Oversight

Due to the small size and early stage of the Company, we have not adopted a formal policy on whether the Chairman and Chief Executive Officer positions should be separate or combined. Dr. Brown serves as the Chairman whereas Mr. Shimrat will serve as the Chief Executive Officer.

Our Board of Directors ("Board") is primarily responsible for overseeing our risk management processes on behalf of the Company. The Board receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding our company's assessment of risks. In addition, the Board focuses on the most significant risks facing our company and our company's general risk management strategy, and also ensures that risks undertaken by our Company are consistent with the board's appetite for risk. While the Board oversees our company's risk management, management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing our company and that our board leadership structure supports this approach.

Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;
4. being found by a court of competent jurisdiction in a civil action, the SEC or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
5. being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
6. being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Code of Ethics

We have not adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions because of the small number of persons involved in the management of the Company.

Board Meetings and Attendance

During the year ended December 31, 2018, the Company's Board of Directors held seven meetings and acted by written consent on eight occasions. All of our Directors were present at the meetings.

Nominating Committee

We have not adopted any procedures by which security holders may recommend nominees to our Board of Directors.

Audit Committee

In September 2015, the Board of Directors approved the formation of the Audit Committee of the Board of Directors that operates under a charter that has been approved by the Board of Directors. The Audit Committee of the Board of Directors is responsible for overseeing our accounting and financial reporting processes and the audits of our financial statements. The members of the Audit Committee are Messrs. Brown (Chair) and Drucker.

The Board of Directors has determined that Mr. Drucker is an "audit committee financial expert," as that is defined in Item 407(d)(5) of Regulation S-K. Mr. Drucker is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who own more than 10% of the issued and outstanding shares of our common stock to file reports of initial ownership of common stock and other equity securities and subsequent changes in that ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. To our knowledge, during the fiscal year ended December 31, 2018 all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with, except that David Zolty did not file a Form 4 to report his receipt of warrants to purchase 60,000 shares of common stock in 2018.

ITEM 11. EXECUTIVE COMPENSATION.

Summary Compensation Table

The following table sets forth all compensation earned in respect of the Company's principal executive officer ("PEO") for 2018 and 2017:

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Itamar Shimrat	2018	\$ 165,625	\$ -	\$ -	\$ -	\$ -	\$ 165,625
Chief Executive Officer	2017	\$ 179,064	\$ -	\$ -	\$ -	\$ -	\$ 179,064

Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2018 to the Named Executive Officers:

Name	Option Awards					Stock Awards			
	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options	Option exercise price	Option expiration date	Number of shares or units of stock that have not vested	Market value of shares of units that have not vested	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
Itamar Shimrat	750,000	-	-	\$ 0.75	11/10/2019	-	\$ -	-	\$ -

Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2018:

Year	Fees Earned or Paid In Salary	Stock Awards	Option Awards	Change in Present Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Dennis Brown	2018	\$ -	\$ -	\$ -	\$ -	\$ -
Yoram Drucker	2018	\$ -	\$ -	\$ -	\$ -	\$ -
David Zolty	2018	\$ -	\$ -	\$ -	\$ -	\$ -
Ben Friedman	2018	\$ -	\$ -	\$ -	\$ -	\$ -

Risk Management

The Company does not believe risks arising from its compensation policies and practices for its employees are reasonably likely to have a material adverse effect on the Company.

Compensation Committee Interlocks and Insider Participation

Currently, the Board of Directors does not have a standing compensation committee, or a committee performing similar functions. During the fiscal year ended 2018, the entire Board of Directors deliberated with respect to executive compensation.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information, as of the date set forth below, with respect to the beneficial ownership of the outstanding Common Stock by (i) any holder of more than five (5%) percent; (ii) each of the Company's executive officers and directors; and (iii) the Company's directors and executive officers as a group. Except as otherwise indicated, each of the stockholders listed below has sole voting and investment power over the shares beneficially owned.

Name and Address of Beneficial Owner (10)	As of March 27, 2019	
	Amount and Nature of Beneficial Ownership (1)	Percentage of Class (2)
Directors and Officers:		
Yoram Drucker, Director	1,125,004 (3)	4.22%
Itamar Shimrat, Chief Executive Officer, Chief Financial Officer and Director	1,337,311 (4)	4.99%
David Zolty, Director	1,168,318 (5)	4.47%
Ben Friedman, Director (6)	4,383,344 (7)	16.80%
Dennis Brown, Director (Executive Chairman)	200,000 (8)	*
All directors and executive officers as a group (5 persons)	8,213,977	29.80%
Yeda Research & Development Co. Ltd. P.O. Box 95 Rehovot, 76100, Israel	1,308,684 (9)	4.99%

* less than 1%

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of March 27, 2019 are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.
- (2) Based on 26,077,611 shares issued and outstanding as of March 27, 2019.
- (3) Includes a five-year warrant to purchase 550,000 shares of common stock with an exercise price of \$0.75 per share.
- (4) Includes 762,307 shares of a five-year warrant to purchase 750,000 shares of common stock with an exercise price of \$0.75 per share, which warrant is subject to a 4.99% conversion limitation.
- (5) Includes warrants to purchase a total of 72,500 shares of common stock with an exercise price of \$0.75 per share.
- (6) Mr. Friedman's beneficial ownership includes shares beneficially owned by his wife, Phyllis Friedman.
- (7) Excludes a five-year warrant to purchase 50,000 shares of common stock with an exercise price of \$0.75 per share, which warrant is subject to a 4.99% conversion limitation.
- (8) Includes a five-year warrant to purchase 100,000 shares of common stock with an exercise price of \$0.75 per share.
- (9) Includes 148,722 shares of a five-year warrant to purchase 1,995,376 shares of common stock with an exercise price of \$0.001 per share, which warrant is subject to a 4.99% conversion limitation.
- (10) Except as otherwise indicated, the address of each beneficial owner is c/o Cell Source, Inc., 57 West 57th Street, Suite 400, New York, New York 10019.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.Certain Relationships and Related Transactions

The Company maintains an exclusive worldwide license to certain intellectual property of Yeda, the commercial arm of the Weizmann Institute, which currently owns 1,159,972 shares of Company common stock and warrants to purchase 1,995,376 shares of Company common stock at \$0.001 per share. Dr. Reisner, who leads a team at the Weizmann Institute, holds 1,159,972 shares of Company common stock and warrants to purchase 48,459 shares of Company common stock at \$0.001 per share. See the section entitled "Intellectual Property" in this Annual Report on Form 10-K.

On March 29, 2016, the Company exercised its option pursuant to an October 3, 2011 exclusive option agreement with Yeda, as amended, such that the Company attempted to negotiate an agreement with Yeda whereby the Company would exclusively license certain organ regeneration technology from Yeda. On September 22, 2016, the Company notified Yeda of its decision to not exclusively license certain organ regeneration technology from Yeda.

On November 28, 2016, the Company and Yeda executed an amendment to the research and license agreement. Under the terms of the amended research and license agreement, Yeda granted the Company an exclusive worldwide license for the licensed information and the patents for the development, manufacture and sale of the products derived therefrom. In consideration for the grant of the license, the Company committed to engage Yeda to perform research services in the amount of \$800,000 per annum through October 3, 2018. In addition, the Company is obliged to pay Yeda an annual license fee of \$50,000 until the end of the research period and a royalty of four percent (4%) of net future sales by the Company or any sublicensees. Prior to the November 28, 2016 amendment, the Company was required to make a \$200,000 payment to Yeda within seven (7) days of the achievement of the Company of the receipt of an aggregate total equity capital investment in the Company of more than \$10,000,000, (the "Amended Additional Research Payment"). As a result of this amendment, the Company no longer has an obligation to Yeda for the Amended Additional Research Payment.

In March 2018, the License Agreement was amended to reduce the Company's funding obligation for the period from October 2017 through September 2018 to \$500,000 and \$100,000 for the period from October 2018 through June 2019. In addition, the License Agreement was amended to provide that the Company would fund an additional \$100,000 of research during 2018 and the Company's obligation to fund the original research was reduced by \$50,000. The Company funded the additional \$100,000 of additional research in April 2018 and \$50,000 was credited against the amount that would have otherwise been funded by the Company for the period from July 2018 through September 2018. After giving effect to these amendments and this credit, the Company was required to fund \$100,000 for the three-month period ended June 30, 2018, \$50,000 for the three month period ended December 2018, and is required to fund \$25,000 for the three month period ending March 2019 and \$25,000 for the three month period ending June 2019. In addition, the amendments amended the milestones and related completion dates. If the Company fails to achieve any of the milestones by the dates set forth in the agreement, Yeda is entitled to terminate the license upon written notice to the Company. To date, the Company has been deemed to have met all of the milestones and the next milestone in the agreement is January 1, 2022. Either Yeda or the Company may terminate the agreement and the license after the commitment of a material breach by the other party and in certain other instances as detailed in the agreement.

For the years ended December 31, 2018 and 2017, the Company recorded expenses in operations of approximately \$450,000 and \$840,000, respectively, related to its research and license agreement with Yeda. At December 31, 2018, there was no liability to Yeda.

On July 20, 2015, the Company issued a one-year note payable in the principal amount of \$100,000 to David Zolty, a member of its Board of Directors. The note is non-interest bearing. The note must be prepaid in whole from the proceeds of any closing after the issuance date, of any offering or offerings pursuant to which the Company receives aggregate gross proceeds greater than or equal to \$3,000,000. In consideration of the loan, a four-year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.75 per share was issued by the Company to Mr. Zolty. The warrant contains an exercise limitation such that at no time may the warrant be exercised if the shares of common stock to be issued upon such exercise would exceed, when aggregated with all other shares of common stock owned by the holder (or his permitted successors or assigns), 4.99% of the issued and outstanding shares of the common stock of the Company. Because the principal amount of the note was not paid by the Company on or before July 20, 2016, the Company is required under the terms of the note to (i) pay to Mr. Zolty a one-time cash penalty payment of five percent (5%) of the principal amount of the note due and unpaid on such date, and (ii) issue to Mr. Zolty a warrant to purchase, at an exercise price of \$0.75 per share, the number of shares the Company's common stock equal to the product of (a) the principal amount of the note due and unpaid on July 20, 2015 and (b) ten percent (10%). As a result of the Company's failure to make the required payments and Mr. Zolty's agreement to extend the maturity date from July 20, 2016 to January 24, 2017, the Company issued Mr. Zolty a three-year warrant to purchase 60,000 shares of common stock at an exercise price of \$0.75 per share. The Company owes Mr. Zolty a \$5,000 late fee as a result of the payment failure.

In May 2017, the Company received a loan of \$180,000 from an entity owned by Ben Friedman and a loan of \$45,000 from an entity owned by David Zolty. Each of Mr. Friedman and Mr. Zolty is a director of the Company. The loans are non-interest bearing and became due on May 18, 2018.

In December 2018, the Company received a non-interest-bearing short-term advance in the amount of \$100,000 from David Zolty. As of December 31, 2018, the entire amount of the advance was outstanding.

Director Independence

None of our directors are independent, as that term is defined under the Nasdaq Marketplace Rules.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following is a summary of fees for professional services rendered by our independent registered public accounting firm for the years ended December 31, 2018 and 2017:

	<u>2018</u>	<u>2017</u>
Audit Fees	\$ 185,900	\$ 73,000
Tax fees	--	--
All other fees	--	--
	<u>\$ 185,900</u>	<u>\$ 73,000</u>

Audit fees represent fees for professional services performed for the audit of our annual financial statements and the review of our quarterly financial statements, as well as services that are normally provided in connection with statutory and regulatory filings or engagements.

All other fees consist of fees billed for all other services.

The Audit Committee is responsible for the appointment, compensation and oversight of the work of the independent registered public accountants and approves in advance any services to be performed by the independent registered public accountants, whether audit-related or not. The Audit Committee reviews each proposed engagement to determine whether the provision of services is compatible with maintaining the independence of the independent registered public accountants. The fees shown above were pre-approved either by our Board or our Audit Committee.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

Financial Statements

See Index to Financial Statements immediately following the signature page of this Annual Report.

Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Exhibits

The following exhibits are included as part of this Annual Report:

Exhibit Number	Description
2.1 (1)	Share Exchange Agreement, dated June 30, 2014, by and between Cell Source, Ltd., and Ticket to See, Inc.
3.1 (1)	Articles of Association of Cell Source Limited, dated August 14, 2011, as amended on November 11, 2013
3.2 (2)	Articles of Incorporation of Ticket to See, Inc., dated June 6, 2012
3.3 (3)	Certificate of Amendment to Articles of Incorporation of Ticket to See, Inc., dated June 23, 2014
3.3 (4)	Certificate of Amendment to Articles of Incorporation of Ticket to See, Inc., dated May 20, 2014
3.4 (2)	Bylaws of Cell Source, Inc., dated June 6, 2012
3.5 (18)	Certificate of Designation with respect to Series A Preferred Stock dated November 14, 2016
10.1 (1)	Form of Subscription Agreement
10.2 (1)	Form of Registration Rights Agreement
10.3 (1)	Form of Investor Warrant
10.4 (1)	Form of Consultant Warrant(8)
10.5 (1)	Form of Researcher Company Warrant
10.6 (1)	Form of Company Warrant
10.7 (1)	Form of Lockup Agreement (included in Exhibit 2.1)
10.8 (1)	Research and License Agreement by and between Yeda Research and Development Company Limited and Cell Source Limited, dated October 3, 2011
10.9 (1)	Amendment to Research and License Agreement
10.10 (1)	Evaluation and Exclusive Option Agreement by and between Yeda Research and Development Company Limited and Cell Source Limited, dated Oct. 3, 2011 (included in Exhibit 10.7)
10.11 (1)	Amendment dated April 1, 2014 to Evaluation and Exclusive Option Agreement by and between Yeda Research and Development Company Limited and Cell Source Limited
10.12 (1)	Second Amendment dated June 22, 2014 to Evaluation and Exclusive Option Agreement by and between Yeda Research and Development Company Limited and Cell Source Limited
10.13 (1)	Consulting Agreement by and between Cell Source Limited and Professor Yair Reisner
10.14 (6)	Form of Amendment No. 1 to Registration Rights Agreement
10.15 (7)	Bridge Funding Agreement
10.16 (5)	Third Amendment dated June 22, 2014 to Evaluation and Exclusive Option Agreement by and between Yeda Research and Development Company Limited and Cell Source Limited
10.17 (8)	Form of Consulting Agreement pursuant to which the Company issued warrants to purchase an aggregate of 2,000,000 shares of the Company's common stock
10.18 (9)	Form of Promissory Note issued to the Company's Chief Executive Officer
10.19(10)	Form of March 2015 Promissory Note
10.20(10)	Form of March 2015 Warrant
10.21(11)	Form of Note Amendment Letter Agreement
10.22(11)	Form of May 2015 Note
10.23(11)	Form of May 2015 Warrant
10.24(12)	Form of Advisory/Consulting Agreement
10.25(13)	Zolty Promissory Note
10.26(13)	Zolty Warrant
10.27(13)	Form of July 2015 Convertible Promissory Note
10.28(13)	Form of July 2015 Warrant

10.29(15)	Form of Bridge Note Subscription Agreement
10.30(15)	Form of Convertible Note
10.31(15)	Form of March 2016 Note
10.32(15)	Form of March 2016 Warrant
10.33(18)	Form of July 2016 Warrants
10.34(18)	Second Amendment to Research and License Agreement dated as of November 28, 2016 between the Company and Yeda Research and Development Company Limited
10.35(18)	Third Amendment to Research and License Agreement dated as of March 29, 2018 between the Company and Yeda Research and Development Company Limited
10.36(18)	Fourth Amendment to Research and License Agreement dated as of March 30, 2018 between the Company and Yeda Research and Development Company Limited
10.37(16)	Convertible Note due July 27, 2016
10.38(17)	Promissory Note dated May 10, 2016
10.39(19) *	Sponsored Research Agreement dated November 28, 2018 between The University of Texas M.D. Anderson Cancer Center and Cell Source Limited
10.40(19) *	Agreement for Veto Cell Production and Clinical Trial Program dated February 19, 2019 between The University of Texas M.D. Anderson Cancer Center and Cell Source Limited
16.1(1)	Letter from Paritz & Company, P.A.
21(14)	Subsidiaries
31.1 *	Certification of principal executive and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 *	Certification of principal executive and principal financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS *	XBRL Instance Document
101.SCH *	XBRL Taxonomy Extension Schema Document
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document

- (1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 1, 2014.
 - (2) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 6, 2012.
 - (3) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on June 26, 2014.
 - (4) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on June 6, 2014.
 - (5) Incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 19, 2014.
 - (6) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 8, 2014.
 - (7) Incorporated by reference to the Company's Registration Statement Form S-1/A filed with the Securities and Exchange Commission on September 23, 2014.
 - (8) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on June 30, 2014.
 - (9) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on December 2, 2014.
 - (10) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on April 1, 2015.
 - (11) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on June 3, 2015.
 - (12) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on June 10, 2015.
 - (13) Incorporated by reference to the Company's Form 8-K filed with the Securities and Exchange Commission on July 28, 2015.
 - (14) Incorporated by reference to the Company's Form 10-K filed with the Securities and Exchange Commission on March 13, 2015.
 - (15) Incorporated by reference to the Company's Form 10-K filed with the Securities and Exchange Commission on April 14, 2016.
 - (16) Incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 13, 2016.
 - (17) Incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 15, 2016.
 - (18) Incorporated by reference to the Company's Form 10-K filed with the Securities and Exchange Commission on July 25, 2018.
 - (19) Certain portions of this exhibit have been omitted based upon a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission.
- * Filed Herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELL SOURCE, INC.

Dated: March 29, 2019

By: /s/ Itamar Shimrat

Name: Itamar Shimrat

Title: Chief Executive Officer and
Chief Financial Officer

(Principal Executive, Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
By: <u>/s/ Dennis Brown</u> Dennis Brown	Chairman	March 29, 2019
By: <u>/s/ Itamar Shimrat</u> Itamar Shimrat	Chief Executive Officer, Chief Financial Officer and Director (Principal Executive, Financial and Accounting Officer)	March 29, 2019
By: <u>/s/ Ben Friedman</u> Ben Friedman	Director	March 29, 2019
By: <u>/s/ Yoram Drucker</u> Yoram Drucker	Director	March 29, 2019
By: <u>/s/ David Zolty</u> David Zolty	Director	March 29, 2019

CELL SOURCE, INC. AND SUBSIDIARY
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Cell Source, Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cell Source, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' deficiency and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum Ilp

Marcum Ilp

We have served as the Company's auditor since 2014.

New York, NY
March 29, 2019

CELL SOURCE, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2018	2017
Assets		
Current Assets:		
Cash	\$ 18,934	\$ 371,048
Prepaid expenses	38,926	124,693
Other current assets	7,932	35,936
Total Assets	<u>\$ 65,792</u>	<u>\$ 531,677</u>
Liabilities and Stockholders' Deficiency		
Current Liabilities:		
Accounts payable	\$ 277,786	\$ 201,824
Accrued expenses	532,790	749,244
Accrued expenses - related party	72,000	72,000
Accrued interest	345,948	248,746
Accrued interest - related parties	27,559	13,310
Accrued compensation	587,734	626,758
Accrued compensation - related party	55,083	19,262
Advances payable	100,000	100,000
Advances payable - related party	100,000	-
Notes payable, net of debt discount of \$0 and \$89,326, as of December 31, 2018 and 2017, respectively	1,463,000	1,173,674
Notes payable - related parties	150,000	150,000
Convertible notes payable, net of debt discount of \$0 and \$34,173 as of December 31, 2018 and 2017, respectively	835,000	800,827
Convertible notes payable - related parties, net of debt discount of \$0 and \$28,356 as of December 31, 2018 and 2017, respectively	225,000	196,644
Derivative liabilities	200,500	628,200
Accrued dividend payable	13,563	108,562
Total Liabilities	<u>4,985,963</u>	<u>5,089,051</u>
Commitments and contingencies (Note 11)	-	-
Stockholders' Deficiency:		
Convertible Preferred Stock, \$0.001 par value, 10,000,000 shares authorized; Series A Convertible Preferred Stock, 1,335,000 shares designated, 860,291 and 643,790 shares issued and outstanding as of December 31, 2018 and 2017, respectively; liquidation preference of \$6,465,745 and \$4,936,987 as of December 31, 2018 and 2017, respectively	860	644
Common Stock, \$0.001 par value, 200,000,000 shares authorized, 26,077,611 and 25,349,236 shares issued and outstanding as of December 31, 2018 and 2017, respectively	26,078	25,349
Additional paid-in capital	11,723,224	9,969,520
Accumulated deficit	<u>(16,670,333)</u>	<u>(14,552,887)</u>
Total Stockholders' Deficiency	<u>(4,920,171)</u>	<u>(4,557,374)</u>
Total Liabilities and Stockholders' Deficiency	<u>\$ 65,792</u>	<u>\$ 531,677</u>

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

CELL SOURCE, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2018	2017
Operating Expenses:		
Research and development	\$ 274,937	\$ 637,318
Research and development - related party	450,151	839,538
General and administrative	1,281,055	815,947
Total Operating Expenses	<u>2,006,143</u>	<u>2,292,803</u>
Loss From Operations	<u>(2,006,143)</u>	<u>(2,292,803)</u>
Other (Expense) Income:		
Interest expense	(219,122)	(174,970)
Interest expense - related parties	(49,875)	(3,000)
Amortization of debt discount	(181,299)	(389,218)
Amortization of debt discount - related parties	(28,356)	(48,944)
Change in fair value of derivative liabilities	485,500	590,173
Gain on exchange of accrued liabilities for warrants	73,100	-
Loss on exchange of notes payable for Series A Convertible Preferred Stock	(191,251)	(725,355)
Loss on exchange of warrants for common stock	-	(38,393)
Total Other Expense	<u>(111,303)</u>	<u>(789,707)</u>
Net Loss	(2,117,446)	(3,082,510)
Dividend attributable to Series A Convertible Preferred Stockholders	<u>(451,283)</u>	<u>(240,559)</u>
Net Loss Applicable to Common Stockholders	<u>\$ (2,568,729)</u>	<u>\$ (3,323,069)</u>
Net Loss Per Common Share - Basic and Diluted	<u>\$ (0.09)</u>	<u>\$ (0.12)</u>
Weighted Average Common Shares Outstanding - Basic and Diluted	<u>27,549,867</u>	<u>26,774,860</u>

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

CELL SOURCE, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficiency
	Shares	Amount	Shares	Amount			
Balance, December 31, 2016	-	\$ -	24,679,256	\$ 24,679	\$ 5,202,749	\$ (11,470,377)	\$ (6,242,949)
Issuance of Series A Convertible Preferred Stock for cash, net of offering expenses of \$54,543	306,759	307	-	-	2,240,277	-	2,240,584
Issuance of Series A Convertible Preferred Stock in exchange for advances payable	23,834	24	-	-	178,722	-	178,746
Issuance of Series A Convertible Preferred Stock in exchange for notes payable	281,697	282	-	-	2,112,452	-	2,112,734
Issuance of Series A Convertible Preferred Stock as debt discount in connection with the issuance of notes payable	24,000	24	-	-	119,976	-	120,000
Issuance of Series A Convertible Preferred and Common Stock in connection with the extension of notes payable	7,500	7	243,750	244	116,937	-	117,188
Series A Convertible Preferred Stock dividends:							
Accrual of earned dividends	-	-	-	-	(240,559)	-	(240,559)
Payment of dividends in-kind	-	-	176,230	176	131,997	-	132,173
Issuance of Common Stock in exchange for surrender of warrants	-	-	250,000	250	62,250	-	62,500
Stock-based compensation:							
Warrants	-	-	-	-	44,719	-	44,719
Net loss	-	-	-	-	-	(3,082,510)	(3,082,510)
Balance, December 31, 2017	<u>643,790</u>	<u>\$ 644</u>	<u>25,349,236</u>	<u>\$ 25,349</u>	<u>\$ 9,969,520</u>	<u>\$ (14,552,887)</u>	<u>\$ (4,557,374)</u>
Issuance of Series A Convertible Preferred Stock for cash	140,001	140	-	-	1,049,860	-	1,050,000
Issuance of Series A Convertible Preferred Stock in exchange for notes payable	76,500	76	-	-	573,675	-	573,751
Series A Convertible Preferred Stock dividends:							
Accrual of earned dividends	-	-	-	-	(451,283)	-	(451,283)
Payment of dividends in-kind	-	-	728,375	729	545,552	-	546,281
Issuance of warrants in satisfaction of accrued liabilities	-	-	-	-	35,900	-	35,900
Net loss	-	-	-	-	-	(2,117,446)	(2,117,446)
Balance, December 31, 2018	<u>860,291</u>	<u>\$ 860</u>	<u>26,077,611</u>	<u>\$ 26,078</u>	<u>\$ 11,723,224</u>	<u>\$ (16,670,333)</u>	<u>\$ (4,920,171)</u>

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

CELL SOURCE, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For The Years Ended December 31,	
	2018	2017
Cash Flows From Operating Activities:		
Net loss	\$ (2,117,446)	\$ (3,082,510)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	(485,500)	(590,173)
Amortization of debt discount	209,655	438,162
Loss on exchange of notes payable for Series A Convertible Preferred Stock	191,251	725,355
Loss on exchange of warrants for common shares	-	38,393
Gain on exchange of accrued liabilities for warrants	(73,100)	-
Depreciation	-	407
Stock-based compensation:		
Common stock	(22,500)	-
Warrants	3,385	44,719
Changes in operating assets and liabilities:		
Prepaid expenses	85,767	(23,105)
Other current assets	28,004	34,394
Accounts payable	75,962	(17,270)
Accrued expenses	(24,955)	(134,671)
Accrued interest	97,202	155,804
Accrued interest - related parties	14,249	3,000
Accrued compensation	15,912	119,681
Net Cash Used In Operating Activities	(2,002,114)	(2,287,814)
Cash Flows From Financing Activities:		
Proceeds from issuance of notes payable	500,000	135,000
Proceeds from issuance of notes payable - related party	-	225,000
Proceeds from issuance of Series A Convertible Preferred Stock	1,050,000	2,295,127
Proceeds from cash advance - related party	100,000	-
Net Cash Provided By Financing Activities	1,650,000	2,655,127
Net (Decrease) Increase In Cash	(352,114)	367,313
Cash - Beginning of Period	371,048	3,735
Cash - End of Period	\$ 18,934	\$ 371,048
Supplemental Disclosures of Cash Flow Information:		
Cash paid for:		
Interest	\$ 18,030	\$ -
Non-cash investing and financing activities:		
Preferred stock issued in exchange for notes and advances payable	\$ 573,751	\$ 2,291,480
Reduction of additional paid-in capital for public offering issuance costs that were previously paid	\$ -	\$ 54,543
Accrual of earned preferred stock dividends	\$ 451,283	\$ 240,559
Common stock issued in connection with exchange of warrants	\$ -	\$ 62,500
Common stock issued in connection with payment of Series A Convertible Preferred Stock dividends in-kind	\$ 546,281	\$ 132,173
Stock issued in connection with issuances and extensions of notes payable	\$ -	\$ 237,188
Warrants issued in satisfaction of accrued liabilities	\$ 35,900	\$ -
Warrants and conversion options issued in connection with issuance and extension of notes payable	\$ 57,800	\$ 67,080

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

CELL SOURCE, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Business Organization and Nature of Operations

Cell Source, Inc. (“Cell Source”, “CSI” or the “Company”) is a Nevada corporation formed on June 6, 2012 that is the parent company of Cell Source Limited (“CSL”), a wholly owned subsidiary which was founded in Israel in 2011 in order to commercialize a suite of inventions relating to certain cancer treatments. The Company is a biotechnology company focused on developing cell therapy treatments based on the management of immune tolerance. The Company’s lead prospective product is its patented Veto Cell immune system management technology, which is an immune tolerance biotechnology that enables the selective blocking of immune responses. CSL’s Veto Cell immune system management technology is based on technologies patented, owned, and licensed to CSL by Yeda Research and Development Company Limited, an Israeli corporation (“Yeda”) (see Note 11, *Commitments and Contingencies*). The Company’s target indications include: lymphoma, leukemia and multiple myeloma through the facilitation of safer and more accessible stem cell (e.g. bone marrow) transplantation acceptance, treatment of end stage kidney disease and other non-malignant organ diseases through improved organ transplantation (broadened donor pool, reduced dependence on post-transplant anti-rejection therapy), and ultimately treating a variety of cancers and non-malignant diseases.

Note 2 – Going Concern and Management’s Plans

During the years ended December 31, 2018 and 2017, the Company had not generated any revenues, had recurring net losses of approximately \$2,117,000 and \$3,083,000, respectively, and used cash in operations of approximately \$2,002,000 and \$2,288,000, respectively. As of December 31, 2018, the Company had a working capital deficiency of \$4,920,000 and an accumulated deficit of approximately \$16,670,000. Subsequent to December 31, 2018 and as more fully described in Note 13, *Subsequent Events*, the Company received proceeds of \$325,000 through the sale of 43,333 shares of Series A Convertible Preferred Stock at \$7.50 per share. These conditions raise substantial doubt about the Company’s ability to continue as a going concern within twelve months from the date these financial statements are issued.

The Company is currently funding its operations on a month-to-month basis. While there can be no assurance that it will be successful, the Company is in active negotiations to raise additional capital. The Company’s primary source of operating funds since inception has been equity and debt financings. Management’s plans include continued efforts to raise additional capital through debt and equity financings. There is no assurance that these funds will be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such additional financing on a timely basis or, notwithstanding any request the Company may make, if the Company’s debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company’s business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Note 3 – Summary of Significant Accounting Policies

Principles of Consolidation

The Company’s financial statements are consolidated and include the accounts of CSI and CSL. All significant intercompany transactions have been eliminated in the consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. Management bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, establishment of valuation allowances for deferred tax assets, stock-based compensation, contingencies and the recoverability and useful lives of long-lived assets. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates. Estimates and assumptions are periodically reviewed and the effects of any material revisions are reflected in the consolidated financial statements in the period that they are determined to be necessary. See the *Stock-Based Compensation* section of this footnote for additional discussion of the use of estimates in estimating the fair value of the Company's common stock.

Cash and Cash Equivalents

The Company considers all highly-liquid instruments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2018 and 2017, the Company did not have any cash equivalents. The Company maintains cash in bank accounts, which, at times, may exceed Federal Deposit Insurance Corporation ("FDIC") insured limits. The Company has not experienced any losses in such accounts, periodically evaluates the creditworthiness of the financial institutions and has determined the credit exposure to be negligible. As of December 31, 2018, the Company does not have domestic cash balances in excess of FDIC insured limits. The Company's foreign bank accounts are not subject to FDIC insurance.

Property and Equipment

Property and equipment is stated at cost, net of accumulated depreciation which is recorded using the straight-line method at a rate sufficient to charge the cost of depreciable assets to operations over the estimated useful life, which is three years. Maintenance and repairs are charged to operations as incurred. As of December 31, 2018 and 2017, accumulated depreciation was \$2,582 and \$2,582, respectively. During the years ended December 31, 2018 and 2017, depreciation expense was \$0 and \$407, respectively.

Convertible Instruments

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). The accounting treatment of derivative financial instruments requires that the Company record embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options and any related freestanding instruments are recorded as a discount to the host instrument.

If the instrument is determined to not be a derivative liability, the Company then evaluates for the existence of a beneficial conversion feature by comparing the commitment date fair value to the effective conversion price of the instrument.

The Black-Scholes option pricing model was used to estimate the fair value of the Company's warrants and embedded conversion options. The Black-Scholes option pricing model includes subjective input assumptions that can materially affect the fair value estimates. The Company determined the fair value under the Binomial Lattice model and the Black-Scholes option pricing model to be materially the same.

Embedded conversion options within notes payable are recorded as a debt discount and are amortized as interest expense over the term of the related debt instrument.

Sequencing Policy

On October 28, 2013, as a result of entering into warrant agreements which contained a variable conversion feature with no floor, the Company adopted a sequencing policy in accordance with ASC 815-40-35-12 whereby all instruments issued subsequent to that date were classified as a derivative liability with the exception of instruments related to share-based compensation issued to employees or directors. Any warrants granted after this date were determined to be and were recorded as derivative liabilities.

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities;

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable; and

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

The carrying amounts of the Company's financial instruments, such as cash, other current assets, accounts payable, accrued expenses and other current liabilities approximate fair values due to the short-term nature of these instruments. The carrying amounts of Company's credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates, are comparable to rates of returns for instruments of similar credit risk.

Income Taxes

CSI is the parent of CSL. CSI and CSL file tax returns in the United States and Israel, respectively.

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

The Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2018 and 2017. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

The Company's policy is to classify assessments, if any, for tax-related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations.

Research and Development

Research and development expenses are recognized to operations as they are incurred and consist of fees paid to consultants, clinical trials and related clinical manufacturing costs, license and milestone fees. The Company records prepaid expenses on its balance sheet for the payment of research and development expenses in advance of services being provided.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period the services are required to be provided in exchange for the award, usually the vesting period. Awards granted to directors are treated on the same basis as awards granted to employees. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

Because the Company's common stock historically was not actively traded on a public market, the fair value of the Company's restricted equity instruments is estimated by management based on observations of the sales prices of both restricted and freely tradable common stock, or instruments convertible into common stock. The Company obtained a third-party valuation of its common stock as of December 31, 2017, which was also considered in management's estimation of fair value during the years ended December 31, 2018 and 2017. The Company, in estimating the fair value of its common stock as of December 31, 2018, concluded that it did not need to obtain a third-party valuation as of such date as (a) the nature of the Company's operations has not significantly changed during the year ended December 31, 2018 and (b) the Company continued to raise capital during the year ended December 31, 2018 at the same valuation as the capital raised during the year ended December 31, 2017. The third-party valuation was performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The estimates used by management are considered highly complex and subjective. The Company anticipates that once its shares become more actively traded, the use of such estimates will no longer be necessary to determine the fair value of its common stock.

Foreign Currency Translation

The Company's functional and reporting currency is the United States Dollar. The functional currency of the Company's operating subsidiary is their local currency (The New Israeli Shekel). Assets and liabilities are translated based on the exchange rates at the balance sheet date, while revenue and expense accounts are translated at the actual exchange rates in the effect of the date of the transaction during the year. Equity accounts are translated at historical exchange rates. The resulting translation gain and loss adjustments are accumulated as a component of other comprehensive income. Foreign currency gains and losses resulting from transactions denominated in foreign currencies, including intercompany transactions, are included in results of operations.

The Company recorded approximately \$3,000 and \$18,000 of transaction losses for the years ended December 31, 2018 and 2017, respectively. Such amounts have been classified within general and administrative expenses in the accompanying consolidated statements of operations.

Net Loss Per Common Share

The Company computes basic net loss per share by dividing net loss by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share includes the dilution that would occur upon the exercise or conversion of all dilutive securities into common stock using the "treasury stock" and/or "if converted" methods, as applicable. Weighted average shares outstanding for the years ended December 31, 2018 and 2017 includes the weighted average impact of warrants to purchase an aggregate of 2,043,835 shares of common stock because their exercise price was determined to be nominal.

The common stock equivalents associated with the following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Warrants	11,414,818	11,615,481
Convertible notes	1,564,110	1,530,433
Convertible preferred stock	8,602,910	6,437,900
Total	<u>21,581,838</u>	<u>19,583,814</u>

Convertible notes are assumed to be converted at the rate of \$0.75 per common share which is the conversion price as of December 31, 2018. However, as further described in Note 8, Notes Payable, such conversion rates are subject to adjustment under certain circumstances, which may result in the issuance of common shares greater than the amount indicated.

Comprehensive Income (Loss)

The Company reports comprehensive income (loss) and its components in its consolidated financial statements. Comprehensive income (loss) consists of net loss and foreign currency translation adjustments affecting stockholders' deficiency that, under U.S. GAAP, are excluded from net loss. The differences between net loss as reported and comprehensive income (loss) have historically been immaterial. As of December 31, 2018, the exchange rate between the U.S. Dollar and the New Israeli Shekel was 1 to 3.76 and the weighted average exchange rate for the year then ended was 1 to 3.59. As of December 31, 2017, the exchange rate between the U.S. Dollar and the New Israeli Shekel was 1 to 3.48 and the weighted average exchange rate for the year then ended was 1 to 3.60.

Reclassifications

Certain prior period accrued liabilities have been reclassified from non-related party to related party to conform to the fiscal 2018 presentation. These reclassifications have no impact on the previously reported net loss.

Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before these financial statements are issued. Based upon that evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the consolidated financial statements except as disclosed in Note 13, *Subsequent Events*.

Recent Accounting Standards

In February 2016, FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is required to adopt ASU 2016-02 effective January 1, 2019. The Company does not expect the adoption of the new standard will have a material impact on its consolidated statements of operations and cash flows.

In August 2016, the FASB issued Accounting Standards Update ("ASU") 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments" ("ASU 2016-15"). ASU 2016-15 makes eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017. ASU 2016-15 requires adoption on a retrospective basis unless it is impracticable to apply, in which case the Company would be required to apply the amendments prospectively as of the earliest date practicable. The Company adopted this standard on January 1, 2018 and its adoption did not have a material impact on the Company's financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718)" ("ASU 2017-09"). ASU 2017-09 provides clarity on the accounting for modifications of stock-based awards. ASU 2017-09 requires adoption on a prospective basis in the annual and interim periods beginning after December 15, 2017. The Company adopted this standard on January 1, 2018 and its adoption did not have a material impact on the Company's financial position, results of operations or cash flows.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260) and Derivatives and Hedging (Topic 815) - Accounting for Certain Financial Instruments with Down Round Features" ("ASU 2017-11"). Equity-linked instruments, such as warrants and convertible instruments may contain down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under ASU 2017-11, a down round feature will no longer require a freestanding equity-linked instrument (or embedded conversion option) to be classified as a liability that is remeasured at fair value through the income statement (i.e. marked-to-market). However, other features of the equity-linked instrument (or embedded conversion option) must still be evaluated to determine whether liability or equity classification is appropriate. Equity classified instruments are not marked-to-market. For earnings per share ("EPS") reporting, the ASU requires companies to recognize the effect of the down round feature only when it is triggered by treating it as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in any interim period. The Company will adopt this standard on January 1, 2019 and its adoption will not have a material impact on the Company's financial position, results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation — Stock Compensation (Topic 718)," ("ASU 2018-07"). ASU 2018-07 is intended to reduce cost and complexity of financial reporting for non-employee share-based payments. Currently, the accounting requirements for non-employee and employee share-based payments are significantly different. ASU 2018-07 expands the scope of Topic 718, which currently only includes share-based payments to employees, to include share-based payments to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, "Equity — Equity-Based Payments to Nonemployees". The amendments to ASU 2018 - 07 are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of ASU No. 2014-09, (Topic 606), "Revenue from Contracts with Customers". The Company is currently evaluating ASU 2018-07 and its impact on its financial position, results of operations or cash flows.

In July 2018, the FASB issued ASU No. 2018-09, “Codification Improvements” (“ASU 2018-09”). These amendments provide clarifications and corrections to certain ASC subtopics including the following: Income Statement - Reporting Comprehensive Income – Overall (Topic 220-10), Debt - Modifications and Extinguishments (Topic 470-50), Distinguishing Liabilities from Equity – Overall (Topic 480-10), Compensation - Stock Compensation - Income Taxes (Topic 718-740), Business Combinations - Income Taxes (Topic 805-740), Derivatives and Hedging – Overall (Topic 815-10), and Fair Value Measurement – Overall (Topic 820-10). The majority of the amendments in ASU 2018-09 will be effective in annual periods beginning after December 15, 2018. The Company is currently evaluating the impact this guidance will have on its financial position, results of operations or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2020. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2018-13 and its impact on its financial position, results of operations and cash flows.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, “Disclosure Update and Simplification,” amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company anticipates its first presentation of changes in stockholders’ deficiency will be included in its Form 10-Q for the quarter ended March 31, 2019.

Note 4 – Fair Value

The following table summarizes the Company’s instruments recorded at fair value as of December 31, 2018 and 2017:

	Total	Quoted Prices In Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Accrued compensation - common stock	\$ 37,500	\$ -	\$ -	\$ 37,500
Accrued compensation - warrants	24,741	-	-	24,741
Accrued compensation - warrants - related party	55,083	-	-	55,083
Derivative liabilities	200,500	-	-	200,500
Balance - December 31, 2018	\$ 317,824	\$ -	\$ -	\$ 317,824
Accrued compensation - common stock	\$ 60,000	\$ -	\$ -	\$ 60,000
Accrued compensation - warrants	19,262	-	-	19,262
Derivative liabilities	628,200	-	-	628,200
Balance - December 31, 2017	\$ 707,462	\$ -	\$ -	\$ 707,462

See Note 6, *Accrued Compensation* for additional details.

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The Company’s Level 3 liabilities shown in the above table consist of warrants with “down-round protection”, as the Company is unable to determine if it will have sufficient authorized common stock to settle such arrangements, warrants deemed to be derivative liabilities according to the Company’s sequencing policy in accordance with ASC 815-40-35-12, the embedded conversion options within its convertible notes payable and an accrued obligation to issue warrants and common stock.

Assumptions utilized in the valuation of Level 3 liabilities as follows:

	For the Years Ended December 31,	
	2018	2017
Risk-free interest rate	1.73% - 2.91%	1.04% - 2.09%
Expected term (years)	0.08 - 5.00	0.25 - 4.00
Expected volatility	110%	110%
Expected dividends	0.00%	0.00%

The expected term used is the contractual life of the instrument being valued. Since the Company's stock has not been publicly traded for a sufficiently long period of time or with significant volume, the Company is utilizing an expected volatility based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of all Level 3 liabilities measured at fair value on a recurring basis using unobservable inputs during the years ended December 31, 2018 and 2017:

	<u>Accrued Compensation</u>	<u>Derivative Liability</u>	<u>Total</u>
Balance - December 31, 2016	\$ 79,178	\$ 1,175,400	\$ 1,254,578
Issuance of warrants and conversion options	-	67,080	67,080
Exchange of warrant for common stock	-	(24,107)	(24,107)
Change in fair value	<u>85</u>	<u>(590,173)</u>	<u>(590,088)</u>
Balance - December 31, 2017	79,262	628,200	707,462
Issuance of warrants	-	57,800	57,800
Accrued compensation - warrants	24,300	-	24,300
Accrued compensation - warrants - related party	36,000	-	36,000
Change in fair value	<u>(22,238)</u>	<u>(485,500)</u>	<u>(507,738)</u>
Balance - December 31, 2018	<u>\$ 117,324</u>	<u>\$ 200,500</u>	<u>\$ 317,824</u>

On December 28, 2017, the Company exchanged warrants for the purchase of up to 250,000 shares of common stock with a value of \$24,107 for the issuance of 250,000 shares of common stock a value of \$62,500, as more fully described in Note 10, *Stockholder's Deficiency*.

As of December 31, 2018 and 2017, the Company had an obligation to issue 150,000 shares of common stock to a service provider. The shares had a fair value of \$37,500 and \$60,000, respectively, which was a component of accrued compensation on the consolidated balance sheets and the reduction in fair value of \$22,500 was included within stock-based compensation expense during the year ended December 31, 2018.

See Note 8, *Notes Payable* and Note 11, *Commitments and Contingencies* for additional details associated with the issuance of warrants which were deemed to be derivative liabilities.

Note 5 – Accrued Expenses

Accrued expenses consisted of the following:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Accrued research and development	\$ 302,433	\$ 430,504
Accrued legal fees	122,351	119,216
Accrued other professional fees	70,399	50,731
Accrued director compensation	12,000	12,000
Accrued Scientific Advisory Board compensation	-	109,000
Other accrued expenses	<u>25,607</u>	<u>27,793</u>
Total accrued expenses	<u>\$ 532,790</u>	<u>\$ 749,244</u>

See Note 10, *Stockholders' Deficiency – Stock Warrants* for details associated with the extinguishment of accrued compensation to the Company's Scientific Advisory Board.

Note 6 – Accrued Compensation

Accrued compensation consisted of the following:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Withholding tax	\$ 116,401	\$ 147,082
Social security	34,825	54,218
Stock-based compensation - common stock	37,500	60,000
Stock-based compensation - warrants	24,741	-
Pension insurance	117,897	97,221
Accrued payroll	98,505	132,366
Vacation	46,808	38,059
Severance	<u>111,057</u>	<u>97,812</u>
	<u>\$ 587,734</u>	<u>\$ 626,758</u>

Note 7 – Advances Payable

Advances payable and advances payable – related party represent cash received from lenders in advance of closing. See Note 12, *Related Party Transactions*.

Note 8 – Notes Payable

The Company has a variety of outstanding debt instruments consisting of: a) notes payable, b) notes payable due to related parties, c) convertible notes payable, and d) convertible notes payable due to related parties. The notes within each of those groups are described in the sections below.

As of December 31, 2018 and through the date of this filing, notes payable with principal amounts totaling \$2,673,000 were past due and are classified as current liabilities on the consolidated balance sheet as of December 31, 2018. Such notes continue to accrue interest and all relevant penalties have been accrued as of December 31, 2018. Of such past due notes payable, a holder of a note with principal amount of \$250,000 issued a notice of default. See Note 11, *Commitments and Contingencies – Litigation* for additional details. The Company is in negotiations with all holders of notes payable to extend the maturity dates of such notes or to convert the principal and accrued interest into equity.

During the years ended December 31, 2018 and 2017, the Company recorded interest expense of \$268,997 and \$177,970, respectively, and amortization of debt discount of \$209,655 and \$438,162, respectively. As of December 31, 2018, the Company had \$373,507 of accrued interest, which includes \$80,177 of penalties related to past due notes payable.

a) Notes payable consist of the following:

	December 31,	
	2018	2017
i) Notes issued on March 26, 2015	\$ 500,000	\$ 500,000
ii) Note issued on May 15, 2015, net of debt discount of \$0 and \$66,532 as of December 31, 2018 and 2017, respectively	250,000	183,468
iii) Notes issued on March 8, 2016	-	300,000
iv) Note issued on May 10, 2016	53,000	53,000
v) Notes issued on various dates from July 20, 2016 to October 13, 2016, net of debt discounts of \$0 and \$22,794 as of December 31, 2018 and 2017, respectively	160,000	137,206
vi) Note issued on December 5, 2017	-	-
vii) Notes issued on February 21, 2018	400,000	-
viii) Note issued on February 26, 2018	100,000	-
	<u>\$ 1,463,000</u>	<u>\$ 1,173,674</u>

Details regarding certain of these notes are as follows (which numbering corresponds to the above table):

- i) As of December 31, 2018 and through the date of this filing, the Company is not in compliance with the terms of these notes due to non-payment of principal. On December 21, 2018, the holder of one of those notes issued a notice of default and demanded repayment. See Note 11, *Commitments and Contingencies - Litigation*, for additional disclosure regarding this matter. The holder of the other note has not issued a notice of default.
- ii) On December 28, 2017, the maturity date of the note was extended from its original maturity date of September 15, 2015 to March 31, 2018. In connection with that extension, the Company issued 125,000 shares of common stock. Those shares were valued at a total of \$31,250 on the date of issuance and was recorded as a debt discount. Such discount was amortized to expense over the term of the extension period.
- iii) On March 8, 2017, the holder of one of these notes with a principal amount of \$300,000 and accrued interest of \$30,000 exchanged that note for 66,000 shares of the Company's Series A Convertible Preferred Stock. The value of the shares issued exceeded the carrying value of the debt and accrued interest and, as more fully discussed in Note 10, *Stockholders' Deficiency - Series A Convertible Preferred Stock*, the difference of \$165,000 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

On December 12, 2018, the holder of the remaining note with a principal amount of \$300,000 and accrued interest of \$82,500 exchanged that note for 76,500 shares of the Company's Series A Convertible Preferred Stock. The value of the shares issued exceeded the carrying value of the debt and accrued interest and, as more fully discussed in Note 10, *Stockholders' Deficiency - Series A Convertible Preferred Stock*, this difference of \$191,251 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.
- v) On March 8, 2017, the holders of three of these notes with total principal amount of \$300,000 and accrued interest of \$19,167 exchanged those notes for 63,833 shares of the Company's Series A Convertible Preferred Stock. The value of the shares issued exceeded the carrying value of the debt and accrued interest and, as more fully discussed in Note 10, *Stockholders' Deficiency - Series A Convertible Preferred Stock*, this difference of \$159,585 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

On December 28, 2017, the maturity date of one of these notes with the principal amount of \$100,000 was extended from its original maturity date of February 4, 2017 to January 31, 2018. In connection with that extension, the Company issued a total of 25,000 shares of common stock and 2,500 shares of Series A Convertible Preferred Stock. Those shares were valued at a total of \$6,250 and \$18,750, respectively, on the date of issuance and were recorded as debt discounts. Such discounts were amortized to expense over the terms of those extension periods.

- vi) On December 5, 2017, the Company issued a note payable in the aggregate principal amount of \$100,000 and a warrant for the purchase of a total of 50,000 shares of common stock at \$0.75 per share for a period of five years. The note did not accrue interest, matured on December 15, 2017 and was repaid on that date. The warrant was 100% vested upon issuance, valued at \$8,200 on the date of issuance, and recorded as a debt discount. The discount was amortized to expense over the term of the note.
- vii) On February 21, 2018, the Company issued two notes payable in the aggregate principal amount of \$400,000 and warrants for the purchase of a total of 240,000 shares of common stock at \$0.75 per share for a period of five years. These notes did not accrue interest, matured on May 21, 2018, and had an effective interest rate of 40% per annum. The warrants were 100% vested upon issuance, valued at \$39,700 on the date of issuance, and recorded as a debt discount. The discount was amortized to expense over the term of those notes.
- viii) On February 26, 2018, the Company issued a note payable in the aggregate principal amount of \$100,000 and a warrant for the purchase of a total of 60,000 shares of common stock at \$0.75 per share for a period of five years. The note did not accrue interest, matured on May 26, 2018, and had an effective interest rate of 40% per annum. The warrant was 100% vested upon issuance, valued at \$9,900 on the date of issuance, and recorded as a debt discount. The discount was amortized to expense over the term of the note.

b) Notes payable due to related parties consist of the following:

	December 31,	
	2018	2017
i) Note issued on November 26, 2014	\$ 50,000	\$ 50,000
ii) Note issued on July 20, 2015	100,000	100,000
	<u>\$ 150,000</u>	<u>\$ 150,000</u>

c) Convertible notes payable consist of the following:

	December 31,	
	2018	2017
i) Convertible notes issued on July 24, 2015, net of debt discounts of \$0 and \$17,159 as of December 31, 2018 and 2017, respectively	\$ 145,000	\$ 127,841
ii) Convertible notes issued on October 7, 2015	265,000	265,000
iii) Convertible notes issued on November 9 and 17, 2015	-	-
iv) Convertible notes issued on various dates from January 6, 2016 to March 15, 2016	290,000	290,000
v) Convertible note issued on January 14, 2016	-	-
vi) Convertible notes issued on May 18, 2017, net of debt discounts of \$0 and \$17,014 as of December 31, 2018 and 2017, respectively	135,000	117,986
	<u>\$ 835,000</u>	<u>\$ 800,827</u>

Details regarding certain of these notes are as follows (which numbering corresponds to the above table):

- i) On August 15, 2017, the maturity dates of two of these notes were extended to February 15, 2018. In connection with that extension, the Company issued 93,750 common shares. The shares were valued at \$23,438 on the date of issuance and recorded as a debt discount. These discounts were amortized to expense over the remaining term of the notes.
- iii) On May 18 and 24, 2017, the holders exchanged these notes with total principal and interest of \$332,500 and \$49,875, respectively, for 76,475 shares of Series A Convertible Preferred Stock. The value of the shares issued exceeded the carrying value of the debt and accrued interest and, as more fully discussed in Note 10 - *Stockholders' Deficiency - Series A Convertible Preferred Stock*, this difference of \$191,190 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

- iv) On October 3, 2017, the holder of one of these notes with the principal amount of \$100,000 and accrued interest of \$15,417 exchanged that note for 15,389 shares of the Company's Series A Convertible Preferred Stock. There was no gain or loss in connection with this exchange.
- v) On January 19, 2017, the holder exchanged the note with total principal and interest of \$250,000 and \$50,000, respectively, for 60,000 shares of Series A Convertible Preferred Stock. The value of the shares issued exceeded the carrying value of the debt and accrued interest and, as more fully discussed in Note 10, Stockholders' Deficiency - Series A Convertible Preferred Stock, this difference of \$150,000 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.
- vi) On May 18, 2017, the Company issued three convertible notes payable in the total principal amount of \$135,000 and a total of 9,000 shares of Series A Convertible Preferred Stock. These notes did not accrue interest and matured on May 18, 2018. Proceeds from the issuance of such notes were allocated proportionately to the value of the notes and the shares. Consequently, those shares were allocated \$45,000 on the date of issuance and recorded as debt discounts. Such discounts were amortized to expense over the term of those notes.

d) Convertible notes payable due to related parties consist of the following:

	December 31,	
	2018	2017
Convertible notes issued on May 18, 2017, net of debt discounts of \$0 and \$28,356 as of December 31, 2018 and 2017, respectively	\$ 225,000	\$ 196,644

On May 18, 2017, the Company issued to two entities individually controlled by two members of the Company's Board of Directors convertible notes payable in the total principal amount of \$225,000 and a total of 15,000 shares of Series A Convertible Preferred Stock. These notes did not accrue interest and matured on May 1, 2018. Proceeds from the issuance of such notes were allocated proportionately to the value of the notes and the shares. Consequently, those shares were allocated \$75,000 on the date of issuance and recorded as debt discounts. Such discounts were amortized to expense over the term of those notes. As of December 31, 2018, principal of \$225,000 is due to these related parties.

Note 9 – Income Taxes

In December 2017, the U.S. Congress enacted The Tax Cuts and Jobs Act (the "Act"). The primary provisions of the Act impacting the Company is the reduction to the U.S. corporate income tax rate from 35% to 21%, eliminating certain deductions, and imposing a mandatory one-time transition tax on accumulated earnings of foreign subsidiaries. The change in tax law required the Company to remeasure existing net deferred tax assets using the lower rate in the period of enactment resulting in an income tax expense of approximately \$430,000 which was fully offset by a corresponding tax benefit of \$430,000 which related to the corresponding reduction in the valuation allowance for the year ended December 31, 2017. There were no specific impacts of Tax Reform that could not be reasonably estimated which the Company accounted for under prior tax law.

The Israeli and U.S. components of income before income taxes were as follows:

	For the Years Ended December 31,	
	2018	2017
Israel	\$ (983,695)	\$ (1,793,483)
United States	(1,133,751)	(1,289,027)
Income before income taxes	\$ (2,117,446)	\$ (3,082,510)

The tax effects of temporary differences that give rise to deferred tax assets are presented below:

	For the Years Ended December 31,	
	2018	2017
Net operating loss carryforwards	\$ 4,536,000	\$ 3,712,000
Foreign deferred research and development costs	224,000	331,000
Stocked-based compensation expense	26,000	26,000
Deferred tax assets	<u>4,786,000</u>	<u>4,069,000</u>
Valuation allowance	(4,786,000)	(4,069,000)
Deferred tax assets, net	<u>\$ -</u>	<u>\$ -</u>

The income tax provision (benefit) for the years ended December 31, 2018 and 2017 consists of the following:

	For the Years Ended December 31,	
	2018	2017
Current		
Foreign	\$ -	\$ -
Federal	-	-
U.S State and local	-	-
Deferred		
Foreign	(226,000)	(357,000)
Federal	(403,587)	110,000
U.S State and local	(87,413)	(161,000)
Change in valuation allowance	(717,000)	(408,000)
Income tax provision (benefit)	<u>\$ 717,000</u>	<u>\$ 408,000</u>

The reconciliation of the expected tax expense (benefit) based on the U.S. federal statutory rates for 2018 and 2017, respectively, with the actual expense is as follows:

	For The Years Ended December 31,	
	2018	2017
Expected federal statutory rate	(21.0%)	(34.0%)
State and local taxes, net of federal tax benefit	(11.3%)	(9.4%)
Statutory rate differential - domestic vs. foreign	4.3%	11.3%
Permanent differences - change in fair value of derivatives	(7.4%)	(8.3%)
Permanent differences - loss on exchange of notes for preferred stock	2.9%	10.2%
Permanent differences - tax rate changes	-	17.4%
Permanent differences - other	(0.2%)	1.2%
Other	(1.2%)	(1.6%)
Change in valuation allowance	33.9%	13.2%
Income tax provision (benefit)	<u>0.0%</u>	<u>0.0%</u>

At December 31, 2018 and 2017, the Company had approximately \$12,206,000 and \$10,758,000, respectively, of foreign net operating losses (“NOLs”) that may be available to offset future taxable income indefinitely. At December 31, 2018 and 2017, the Company had approximately \$5,352,000 and \$3,832,000, respectively, of domestic federal and state NOLs that may be available to offset future taxable income. Domestic Federal NOLs of \$1,520,000 generated in 2018 have no expiration date while the remainder will expire for domestic federal purposes between 2034 and 2038. In accordance with Section 382 of the U.S. Internal Revenue Code, the usage of the Company’s domestic federal NOLs may be subject to annual limitations following greater than 50% ownership changes. There were no ownership changes greater than 50% impacting post-reverse merger NOLs.

The Company assesses the likelihood that deferred tax assets will be realized. ASC 740, “Income Taxes” requires that a valuation allowance be established when it is “more likely than not” that all, or a portion of, deferred tax assets will not be realized. A review of all available positive and negative evidence needs to be considered, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After consideration of all the information available, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of December 31, 2018 and 2017. For the years ended December 31, 2018 and 2017, the increase in the valuation allowance was approximately \$717,000 and \$408,000, respectively.

Cell Source, Inc. files income tax returns in the U.S. federal jurisdiction and the state and city of New York which remain subject to examination by such various taxing authorities beginning with the tax year ended December 31, 2014 and is in the process of preparing returns for the tax years ended December 31, 2016 through 2018. Cell Source Limited, a wholly owned Israeli subsidiary, files income tax returns with the government of the State of Israel and is in the process of preparing returns for the tax years ended December 31, 2014 through 2018. No tax audits were commenced or were in process during the years ended December 31, 2018 and 2017.

Note 10 – Stockholders’ Deficiency

Authorized Capital

As of December 31, 2018, the Company was authorized to issue 200,000,000 shares of common stock, par value of \$0.001 per share, and 10,000,000 shares of preferred stock, par value of \$0.001 per share. The holders of the Company’s common stock are entitled to one vote per share. The preferred stock was designated as 1,335,000 shares of Series A Convertible Preferred Stock.

Common Stock

On August 15, 2017, November 25, 2017, and December 28, 2017, the Company issued a total of 243,750 shares of common stock as follows:

- 93,750 shares of common stock valued at \$0.25 per share in connection with the extension of convertible notes payable, as more fully described in Note 8(c)(i), *Notes Payable*;
- 25,000 shares of common stock valued at \$0.25 per share in connection with the extension of a note payable, as more fully described in Note 8(a)(v), *Notes Payable*; and
- 125,000 shares of common stock valued at \$0.25 per share in connection with the extension of a notes payable, as more fully described in Note 8(a)(ii), *Notes Payable*.

On December 4, 2017, the Company issued 176,230 shares of common stock valued at \$0.75 per share, pursuant to the terms of the Series A Convertible Preferred Stock Certificate of Designation, in connection with the partial payment of accrued dividends for Series A Convertible Preferred Stock, as more fully described in the Series A Convertible Preferred Stock section of this footnote.

On December 28, 2017, the Company issued 250,000 shares of common stock valued at \$0.25 per share with a total value of \$62,500 in connection with the exchange of warrants for the purchase of up to 250,000 shares of common stock at \$0.75 per share with a total value of \$24,107. The difference of \$38,393 was recorded in the consolidated statements of operations as a loss on exchange of warrants for common shares.

See Note 10 – Stockholders’ Deficiency – Series A Convertible Preferred Stock for details associated with the issuance of common stock in satisfaction of preferred stock dividends.

Series A Convertible Preferred Stock

On various dates from January 1, 2017 to December 7, 2017, the Company raised \$2,295,127 through the sale of 306,759 shares of Series A Convertible Preferred Stock at \$7.50 per share and, after transaction costs of \$54,543, received net proceeds of \$2,240,584.

On January 11, 2017, in connection with the exchange of advances payable, the Company issued an aggregate of 23,834 shares of Series A Convertible Preferred Stock under the terms of the PPM with a total value of \$178,746.

On various dates from January 19, 2017 to October 3, 2017, in connection with the extension certain convertible notes payable and convertible notes payable to related parties, the Company issued 281,697 shares of Series A Convertible Preferred Stock under the terms of the PPM with a total value of \$2,112,734 as more fully described in Note 8, *Notes Payable*.

During the year ended December 31, 2017, in connection with the issuances of 23,834 shares (as described above) and 281,697 shares (as described above and in Note 8) of Series A Convertible Preferred Stock, the value of the shares issued often exceeded the carrying value of the debt and accrued interest. This difference of \$725,355 was recorded in the consolidated statements of operations during the year ended December 31, 2017 as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

On May 18, 2017, in connection with the issuance of a series of convertible notes payable and convertible notes payable due to related parties, the Company issued 24,000 shares of Series A Convertible Preferred Stock under the terms of the PPM, (9,000 and 15,000 shares, respectively), with a total value of \$180,000, as more fully described in Notes 8(c)(vi) and 8(d), *Notes Payable*. As the proceeds from the issuance of such notes was allocated proportionately to the value of the notes and the shares, the amount allocated to these shares totaled \$120,000.

On January 19, 2017, in connection with exchange of a convertible note payable with the principal amount and interest of \$250,000 and \$50,000, respectively, the Company issued 60,000 shares of Series A Convertible Preferred Stock as more fully described in Note 8(c)(v), *Notes Payable*.

On December 28, 2017 and in connection with the extension of two notes payable, the Company issued 7,500 shares of Series A Convertible Preferred Stock (5,000 and 2,500) under the terms of the PPM with a total value of \$56,250, as more fully described in Notes 8, *Notes Payable*, sections (a)(ii) and 8(a)(v), respectively.

During the year ended December 31, 2017, the Company accrued preferred dividends of \$240,559 and on December 4, 2017 partially satisfied \$132,173 of that obligation by issuing 176,230 shares of common stock at \$0.75 per share pursuant to the terms of the Series A Convertible Preferred Stock Certificate of Designation. The net effect of these actions resulted in an accrued dividend payable as of December 31, 2017 of \$108,562.

On March 3, 2018 and November 6, 2018, the Company raised \$1,050,000 through the sale of 140,001 shares of Series A Convertible Preferred Stock at \$7.50 per share and incurred no transaction costs.

On December 12, 2018, in connection with the exchange of a note payable and accrued interest totaling \$382,500, the Company issued 76,500 shares of Series A Convertible Preferred Stock under the terms of the PPM with a total value of \$573,751 as more fully described in Note 8, *Notes Payable*, sections (a)(iii). As the value of those shares exceeded the carrying value of the note payable and accrued interest, the difference of \$191,251 was recorded in the consolidated statements of operations during the year ended December 31, 2018 as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

During the year ended December 31, 2018, the Company accrued preferred dividends of \$451,283 and satisfied \$546,281 of its obligation by issuing 728,375 shares of common stock at \$0.75 per share pursuant to the terms of the Series A Convertible Preferred Stock Certificate of Designation. The net effect of these actions resulted in an accrued dividend payable as of December 31, 2018 of \$13,563.

Stock-Based Compensation

During the years ended December 31, 2018 and 2017, the Company recognized a benefit of \$18,938 and an expense of \$44,719 respectively, of stock-based compensation related to warrants and common stock. As of December 31, 2018, there was no unrecognized stock-based compensation expense related to warrants and common stock.

Stock Warrants

See Note 4, *Fair Value* and Note 8, *Notes Payable* for details associated with warrants.

A summary of the warrant activity during the years ended December 31, 2018 and 2017 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2016	13,909,316	\$ 0.64		
Granted	50,000	0.75		
Exercised	-	-		
Exchanged	(250,000)	0.75		
Forfeited	-	-		
Outstanding, December 31, 2017	13,709,316	\$ 0.64		
Granted	518,000	0.75		
Exercised	-	-		
Exchanged	-	-		
Expired	(768,663)	0.75		
Outstanding, December 31, 2018	<u>13,458,653</u>	<u>\$ 0.64</u>	<u>0.9</u>	<u>\$ 508,915</u>
Exercisable, December 31, 2018	<u>13,458,653</u>	<u>\$ 0.64</u>	<u>0.9</u>	<u>\$ 508,915</u>

On December 5, 2017, the Company issued warrants for the purchase of up to 50,000 shares of common stock at \$0.75 per share for a period of five years in connection with the issuance of a note payable in the principal amount of \$100,000 as more fully described in Note 8(a)(vi), Notes Payable.

On December 28, 2017, the Company exchanged warrants for the purchase of up to 250,000 shares of common stock at \$0.75 per share for the issuance of 250,000 shares of common stock as more fully described within the Common Stock section of this footnote.

On February 21, 2018, the Company issued five-year warrants for the purchase of up to 240,000 shares of common stock at \$0.75 per share in connection with the issuance of two notes payable in the aggregate principal amount of \$400,000 as more fully described in Note 8(a)(vii), Notes Payable.

On February 26, 2018, the Company issued warrants for the purchase of up to 60,000 shares of common stock at \$0.75 per share for a period of five years in connection with the issuance of a note payable in the principal amount of \$100,000 as more fully described in Note 8(a)(viii), Notes Payable.

On December 28, 2018, the Company issued warrants for the purchase of up to 218,000 shares of common stock at \$0.75 per share valued at \$35,900 in exchange for accrued liabilities of \$109,000 due to members of the Scientific Advisory Board. The difference of \$73,100 was recorded in the consolidated statements of operations as a gain on exchange of accrued liabilities for warrants.

Information regarding outstanding and exercisable warrants at December 31, 2018 is as follows:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$ 0.001	2,043,835	1.9	2,043,835
\$ 0.750	11,414,818	0.7	11,414,818
	<u>13,458,653</u>	0.9	<u>13,458,653</u>

Note 11 – Commitments and Contingencies

Research and License Agreement

On October 3, 2011, the Company entered into a Research and License Agreement (the "Agreement") with Yeda Research and Development Company Limited ("Yeda") for Veto Cell technology and an exclusive option to negotiate an additional license for organ regeneration technology.

Yeda is the technology transfer and commercial arm of the Weizmann Institute of Science, for research conducted at the Weizmann Institute of Science for an invention comprising methods of bone marrow transplantation and cell therapy utilizing Veto-Cells. As Yeda is a founder and a significant shareholder of the Company, it is a related party.

In connection with certain March 2018 amendments to the agreement, the provision for the payment of \$200,000 in connection with reaching an equity financing threshold was permanently eliminated and the research budget was reduced such that the agreement now requires the following payments by the Company:

Three Months Ending:	Total
March 31, 2018	\$ 200,000
June 30, 2018	150,000
September 30, 2018	50,000
December 31, 2018	50,000
March 31, 2019	25,000
June 30, 2019	25,000
	<u>\$ 500,000</u>

In addition, the parties amended the milestones and related completion dates. If the Company fails to achieve any of the milestones by the dates set forth in the agreement, Yeda is entitled to terminate the license upon written notice to the Company. To date, the Company has been deemed to have met all of the milestones and the next milestone in the agreement is January 1, 2022. Either Yeda or the Company may terminate the agreement and the license after the commitment of a material breach by the other party and in certain other instances as detailed in the agreement. Through December 31, 2018, the Company has made all required payments under the terms of the amended agreement.

During the years ended December 31, 2018 and 2017, the Company recorded research and development expenses of approximately \$450,000 and \$840,000, respectively, related to this Agreement.

Research Agreement With University Hospital

On December 8, 2016, the Company entered into a one-year research agreement with a university hospital in Germany. In exchange for the university's performance of the specified research and development, the Company agreed to pay a fee of \$50,000 per quarter, provided that certain specified milestones were met by the university. The Company recognized \$0 and \$200,000 of research and development expenses during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, the Company accrued \$150,000 pursuant to the agreement.

Sponsored Research Agreement

On November 28, 2018, the Company entered into a Sponsored Research Agreement with The University of Texas M.D. Anderson Cancer Center ("MD Anderson") for a research study in the area of stem cells. The Sponsored Research Agreement shall be for three years and can be extended by mutual written agreement. The Company committed to engage MD Anderson to perform research services in the amount of approximately \$1,500,000 from January 1, 2019 to December 31, 2021.

The Sponsored Research Agreement may be terminated: (a) immediately by the written agreement of both parties; (b) by the Company at the end of each twelve month period following the commencement of the study, with sixty days' notice to MD Anderson; (c) by MD Anderson for health, safety or regulatory reasons or if the Company breaches this Agreement and fails to cure such breach within fifteen business days of notice of such breach by MD Anderson; or (d) immediately by either party if at any time the Principal Investigator becomes unable to conduct the study, and the parties cannot agree upon a mutually acceptable successor to the Principal Investigator.

Litigation

Certain conditions may exist as of the date the consolidated financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company, or unasserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or unasserted claims, as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's consolidated financial statements. If the assessment indicates that a potential material loss contingency is not probable, but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability and an estimate of the range of possible losses, if determinable and material, would be disclosed.

On January 15, 2019, a noteholder of the Company filed a motion for summary judgement in New York County with respect to a default under an outstanding note and advance in the aggregate of \$250,000. The motion was heard on March 7, 2019 and the Company did not oppose the motion. The Company has had discussion with respect to entering into an agreement providing for a payment plan with the holder of the note, but no agreement has yet been reached.

Loss contingencies considered remote are generally not disclosed, unless they involve guarantees, in which case the guarantees would be disclosed. There can be no assurance that such matters will not materially and adversely affect the Company's business, financial position, and results of operations or cash flows. As of December 31, 2018 and 2017, the Company has not accrued any amounts for contingencies.

Note 12 – Related Party Transactions

See Note 11, *Commitments and Contingencies* for details associated with the Company's Agreement with Yeda.

On May 18, 2017, as more fully described in Note 8(d), Notes Payable, the Company issued to two entities individually controlled by two members of the Company's Board of Directors convertible notes payable in the total principal amount of \$225,000 and a total of 15,000 shares of Series A Convertible Preferred Stock.

On December 20, 2018, the Company received a non-interest-bearing short-term advance in the amount of \$100,000 from a director of the Company which was included within advances payable – related party on the consolidated balance sheet as of December 31, 2018.

Note 13 – Subsequent Events

Series A Convertible Preferred Stock

On January 27, 2019, the Board of Directors extended the expiration date of the Private Placement Memorandum ("PPM") to March 31, 2019 and has authorized two sixty-day extensions beyond that date at management's discretion, under which the Company continues to raise up to \$7,500,000 via the sale of up to 1,000,000 shares of Series A Convertible Preferred Stock at \$7.50 per share.

On March 27, 2019, the Board of Directors extended the expiration date of the PPM to May 30, 2019.

On various dates from January 7, 2019 through March 13, 2019, the Company received proceeds of \$325,000 through the sale of 43,333 shares of Series A Convertible Preferred Stock at \$7.50 per share.

Agreement for Veto Cell Production and Clinical Trial Program

On February 19, 2019, the Company entered into an agreement with MD Andersen for the latter to perform cell production and conduct Phase I/II human clinical trials. In connection with that agreement, the Company committed to fund such work in the amount of approximately \$2,000,000 over a two-year period beginning that same date.

Veto Cell Production and Clinical Trial Program

This agreement is entered into between
 The University of Texas M. D. Anderson Cancer Center
 located at 1515 Holcombe Blvd, Houston, TX 77030, USA

Hereunder called MD Anderson

and

Cell Source Limited

a company duly registered under the laws of the State of Israel, Company Number 514669761 having its principal place of business at 5 Kineret Street, Bnei Brak 5126237

- hereinafter called Cell Source –

This Veto Cell Production and Clinical Trial Sponsorship Agreement ("Agreement"), is effective as of the 19th day of February, 2019 (the "Effective Date").

§ 1 – Subject matter

- (1) Subject to MD Anderson receiving the necessary approvals, including without limitation, the approval of the applicable institutional review board ("IRB") overseeing the Program, MD Anderson will use reasonable efforts to undertake to implement the protocol "Anti-viral central memory CD8 veto cells in haploidentical HSCT" (attached hereto as Exhibit A), such protocol as may be further revised pending approval by the applicable IRB (the "Program").
 - (2) As outlined in the initial budget, MDA undertakes to perform 4 production validation runs and a Phase I/II clinical trial using veto cells in * patients. Based on the assessment of results in the first * patients further continuation of the study in up to * patients will be considered.
 - (3) MD Anderson, under the supervision of its Principal Investigator Richard Champlin, M.D., shall perform the Program in close co-operation with Cell Source and shall keep Cell Source informed of the Program's progress and all major developments concerning the Program.
 - (4) Upon completion of each quarter MDA shall submit a written report to Cell Source describing the results of the Program.
 - (5) Cell Source represents and warrants that it exclusively licenses proprietary scientific knowledge developed at the Weizmann Institute of Science by a team headed by Prof. Yair Reisner, including without limitation, the Anti-viral central memory CD8 veto cells, from Yeda Research and Development Limited ("Yeda"). The Program will be conducted in cooperation with Prof. Riesner.
 - (6) The rights to any outcomes of the treatments performed on behalf of Cell Source, to the extent that they may be protected by patent laws, will belong exclusively to Yeda and fall under the existing exclusive license that Cell Source has from the Weizmann Institute through its agreement with Yeda, provided, however, MD Anderson shall have the right to use such outcomes for MD Anderson's internal academic, research and patient care purposes.
 - (7) MD Anderson and Cell Source will promptly notify each other upon identifying any aspect of the protocol for the Program or the Program results that may adversely affect the safety, well-being, or medical care of Program subjects, or that may affect the willingness of subjects to continue participation of the Program, influence the conduct of the Program, or may alter the IRB's approval to continue the Program; when possible, such findings shall be submitted to MD Anderson electronically. MD Anderson shall promptly notify the IRB of any such events. When Program subject safety or medical care could be directly affected by Program results, then notwithstanding any other provision of this Agreement, MD Anderson will send Program subjects a written communication about the results.
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§ 2 – Payment

In support of MD Anderson's participation in the Program hereunder, Cell Source shall pay to MD Anderson the sums as described in the attached budget (attached hereto as Exhibit B).

§ 3 – Confidentiality

- (1) Any Confidential Information that will be exchanged between the Parties, whether orally, in writing or by any other medium, during the course of the Program under this agreement, shall be treated confidential by the receiving Party. The receiving Party shall not use such Confidential Information for any purpose other than performance of this agreement, and shall not make available such Confidential Information to any third party.
- (2) For the purposes of this agreement, "Confidential Information" shall mean any information that is expressly marked as confidential by appropriate means, or clearly identifiable as being confidential by its nature. However, "Confidential Information" shall not include any information that
 - was known to the receiving Party prior to its disclosure, or
 - was known to the public or was generally available prior to its disclosure, or
 - became known to the public or became generally available after disclosure through no wrongful act or omission of the receiving Party, or
 - essentially corresponds to information that was disclosed or made available to the receiving Party at any time by a third party, who, to the knowledge of the receiving Party, had the legal right to disclose the information to the receiving Party (it is agreed that Prof. Reisner, his team or anyone from the Weizmann Institute deriving its information from the technology developed by Prof. Reisner while at the Weizmann Institute are not considered third party to this matter),
 - was developed independently by the receiving Party without knowledge of the Confidential Information,
 - is required to be disclosed in order to obtain the informed consent from subjects who may wish to enroll in the Program, provided, however, that the Confidential Information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Program candidates,
 - is disclosed to a Program subject for the safety or well-being of the Program subject.
- (3) Notwithstanding the foregoing, each receiving Party will be permitted to disclose Confidential Information as required by law or regulation, provided to the extent practicable, prior to such disclosure, the receiving Party will provide reasonable advance notice to the disclosing Party to allow the disclosing Party an opportunity to obtain a protective order.
- (4) Each Party shall ensure that its respective employees will be bound by these confidentiality obligations.

§ 4 – Publications

- (1) Notwithstanding anything to the contrary herein, Cell Source acknowledges that MDA has the first right to publish the results of Program. Any publication in whatever form on the data and results of the Program by MD Anderson, shall be submitted to Cell Source in advance. Cell Source will review the manuscript and provide comments within 30 days. If Cell Source does not react within such 30 days, Cell Source shall be deemed to not have any comments on the publication. Cell Source will also have the right to publish press releases regarding the Program, provided, however, all press releases including the name of MD Anderson requires prior written approval from MD Anderson's Department of External Communications. All such publication and press releases shall be in accordance with generally acceptable scientific research and/or academic standards.
- (2) Cell Source may request a delay of the publication for a period not to exceed sixty (60) days, or changes to its content, only insofar as necessary to avoid undue disclosure of Cell Source's Confidential Information, provided, in no case shall MD Anderson be required to remove any data or results of the Program. Should Cell Source or Yeda elect to file a patent regarding a new invention that results from this Program, Cell Source may request a delay of the publication for a period not to exceed sixty (60) days if the publication discloses the content of such patent application.

§ 5 – Liability

- (1) MDA shall perform the Program hereunder with its usual care and on the basis of the current state of the art in science and technology research and in accordance with all relevant laws and regulations required in the MDA's domicile. With respect to the Results, no warranty of any kind is given, neither express nor implied, as to the Results' fitness for any particular purpose or to the non-infringement of any third party's rights by the Results.
- (2) Any liability among the contracting parties shall be limited to gross negligence and willful misconduct. Except in cases of willful misconduct, neither party shall be liable for any remote or incidental damage or loss (such as loss of profit or loss of contract).
- (3) This Agreement does not obligate any of the contracting parties to provide medical treatment, except to the extent required by applicable law, nor does this Agreement obligate either party to provide reimbursement for medical treatment if a Program subject requires medical treatment for physical illness or injury sustained as a direct result of the treatment of such Program subject in accordance with this Agreement and the protocol for the Program.

§ 6 – Term

- (1) This agreement shall enter into force upon signature by both parties.
- (2) This agreement may not be terminated prematurely by either Party, except in case of "good cause for termination" as per the pertinent regulations in MDA's domicile.

§ 7 – Miscellaneous

- (1) This agreement may only be amended by written agreement of the Parties.

Signatures

THE UNIVERSITY OF TEXAS
M.D. ANDERSON CANCER CENTER
Houston, Texas

Name
Title

Read and Understood:

Principal Investigator
Richard Champlin

CELL SOURCE LIMITED
Israel

Itamar Shimrat
Chief Executive Officer

* Information has been redacted and is subject to a request for confidential treatment

* Information has been redacted and is subject to a request for confidential treatment

EXHIBIT B- BUDGET

Funding Agency: Cell Source Limited
Principal Investigator: Champlin, Richard
Title: Role of Veto Cells in Haploidentical Transplantation for Myeloma
Project Dates: TBD
Protocol(s): 2018-0221
Total Patients *

*

	Year 1	Year 2	Grand Total
Total Costs	\$ 1,162,760.38	\$ 889,624.93	\$ 2,052,385.31

PAYMENT SCHEDULE
Payment Plan

Milestone/Deliverable	Payment (USD)
*	\$29,375.00
*	\$177,668.45
*	\$245,766.09
*	\$245,766.09
*	\$245,766.10
Total	\$944,341.73

* Information has been redacted and is subject to a request for confidential treatment

SPONSORED RESEARCH AGREEMENT

This Sponsored Research Agreement ("Agreement"), effective as of the 28th day of November, 2018 (the "Effective Date") is made by and between The University of Texas M. D. Anderson Cancer Center, ("MD Anderson"), a member institution of The University of Texas System ("System"), with a place of business at 1515 Holcombe Blvd., Houston, Texas, 77030, and Cell Source, a corporation with a place of business at 57 West 57th Street, Suite 400, New York, NY 10019. ("Sponsor"). MD Anderson and Sponsor hereinafter may be referred to each as a "Party" and collectively as the "Parties."

RECITALS

- A. MD Anderson and Sponsor are interested in pursuing research in the area of stem cells.
- B. Sponsor desires to collaborate with MD Anderson and is willing to sponsor MD Anderson's research study entitled "Tolerance Induction by Veto Cells" ("Study"), as described in Exhibit A, attached hereto.
- C. Sponsor and MD Anderson are entering into this Agreement to set forth the rights and obligations of the Parties with respect to the Study.

NOW THEREFORE, in consideration of the mutual covenants and promises herein contained, MD Anderson and Sponsor agree as follows:

1. TERM

This Agreement shall be effective as of the Effective Date, and shall continue in effect for a period of three (3) years following the Effective Date ("Term") unless such Term is extended by mutual written agreement of the Parties, or the Agreement is earlier terminated in accordance with Section 11 of this Agreement.

2. STUDY CONDUCT

2.1 MD Anderson will use its own facilities and its reasonable best efforts to conduct the Study under the direction of Dr. Yair Reisner, or his/her successor as mutually agreed to by the Parties (the "Principal Investigator") in accordance with Exhibit A and applicable laws and regulations. In the event of any conflict between Exhibit A and this Agreement, this Agreement shall control. Unless expressly set forth herein, MD Anderson shall provide all necessary personnel, equipment, supplies, facilities and resources to perform the Study, and shall be fully responsible for the activities of any MD Anderson personnel to whom Study activities are delegated.

2.2 Sponsor understands and acknowledges that MD Anderson's primary mission is the development and dissemination of scientific knowledge, and that MD Anderson makes no representations, warranties, or guarantees with respect to any specific results of the Study.

2.3 Sponsor understands and acknowledges that MD Anderson may be involved in similar research through other researchers on behalf of itself and others. Nothing in this Agreement will limit or prohibit MD Anderson or any of its personnel, including the Principal Investigator, from conducting any research or for performing research for or with any entity or person, including any other outside sponsors. Sponsor acknowledges that this provision is intended to preserve the academic freedom and integrity of MD Anderson and its faculty and to ensure that MD Anderson and its faculty are not regarded as captive researchers for Sponsor. Despite the above, it is agreed that if the Principal Investigator conducts any research or if any other research is conducted at MD Anderson that breaches this agreement inasmuch as such research uses confidential materials or information as defined below as "Confidential Information" in Paragraph 6.1 of this agreement that is provided by Sponsor and that is associated with the Study outside of the Study without Sponsor's written permission, Sponsor shall then be entitled to all the rights it has under this agreement with respect to the results of such research.

2.4 . MD Anderson will provide a written report every * months to the Sponsor in terms of progress in the Research being conducted. Furthermore, MD Anderson will provide a current annual advance work plan * for each annual period which must be approved in advanced in writing by the Sponsor. In the event that MD Anderson wishes to propose curtailing or modifying an existing research stream between update periods, any change of this kind must be pre-approved in writing by the Sponsor.

3. STUDY BUDGET

3.1 Sponsor agrees to pay MD Anderson an amount equal to its expenditures and reasonable overhead in conducting the Study in the amount of US\$,507,352.33 ("Budget"). The schedule and procedure of payments under the Budget shall be made as set forth in Exhibit B, attached hereto. In the event of any conflict between Exhibit B and this Agreement, this Agreement shall control.

4. DATA

4.1 MD Anderson shall own all data and results generated in the conduct of the Study ("Data"), and shall have the right to use such Data for any purpose, and to publish such Data as set forth in Section 5 hereunder.

4.2 MD Anderson shall provide Data to Sponsor in the form of Study reports as described in section 2.4 above. Sponsor shall have the right to use Data for its own purposes, provided that Sponsor shall maintain such Data in confidence until the earlier of: (a) publication or public disclosure of such Data by MD Anderson and/or Principal Investigator; or (b) twelve (12) months following the completion of the Study; or (c) under non-disclosure agreements with business associates or regulatory bodies as needed.

5. PUBLICATION AND PUBLICITY

5.1 MD Anderson and Principal Investigator shall have the right to publish or present Data in scientific journals and/or at scientific meetings at MD Anderson's and/or the Principal Investigator's sole discretion, and to submit Data to a public data registry. MD Anderson and Principal Investigator shall provide Sponsor with a copy of a proposed publication or presentation for review and comment sixty (60) days prior to publication by the publishing source or at least forty (40) days prior to presentation at a scientific meeting or conference. MD Anderson and Principal Investigator shall have the final authority to determine the scope and content of any presentation and/or publication of Data. At Sponsor's request, MD Anderson will delay the publication or presentation for up to sixty (60) additional days in order to allow Sponsor to protect its proprietary interests.

5.2 Except for MD Anderson's right to publish the Data as set forth in Section 5.1 and subject to applicable law and regulations, neither Party will reference the other party's name or disclose the results (including interim findings) of the Study in a press release or any written statement except as agreed in advance by both parties. In the event that the Sponsor wishes to issue a press release sharing findings and/or status of the Study, a draft press release will be circulated to MD Anderson for approval or editorial comments and MD Anderson will respond promptly. In any permitted statements, the Parties shall describe the scope and nature of their participation accurately and appropriately.

6. CONFIDENTIAL INFORMATION

6.1 In conjunction with the Study, the Parties may wish to disclose certain of their respective confidential and/or proprietary information ("Confidential Information") to each other. Each Party will use Confidential Information of the other Party solely for the purpose of conducting the Study, and shall use reasonable efforts to prevent the disclosure of such other Party's Confidential Information to third parties during the Term and for a period of three (3) years after expiration or termination of this Agreement, provided that the receiving Party's obligation of confidentiality and nonuse hereunder shall not apply to information that: (a) is already in the receiving Party's possession at the time of disclosure; (b) is or later becomes part of the public domain through no fault of the receiving Party; (c) is received from a third party having no obligations of confidentiality or nonuse to the disclosing Party; (d) independently developed by the receiving Party; (e) is required by law or regulation to be disclosed; (f) is published in accordance with Section 5 of this Agreement; (g) is necessary to disclose in order to file a patent application or enforce a patent related to this Agreement; or (h) is communicated to MD Anderson's scientific and/or institutional review committees.

6.2 In the event that information is required to be disclosed pursuant to Section 6.1(e), the Party required to make disclosure shall notify the other Party to allow the other Party to assert whatever exclusions or exemptions may be available to such Party under applicable law or regulation.

6.3 In the event that Sponsor shall come into contact with any "Protected Health Information" (as such term is defined under HIPAA) of MD Anderson or any information which could be used to identify any of MD Anderson's patients or research subjects, Sponsor shall maintain any such Protected Health Information or other information confidential in accordance with laws and regulations as applicable to MD Anderson, including without limitation HIPAA, and shall not use or disclose any such Protected Health Information or other information in any manner that would constitute a violation of any applicable law or regulation if such use or disclosure was made by MD Anderson.

7. INTELLECTUAL PROPERTY

7.1 Sponsor and MD Anderson understand and agree that the performance of the Study may require use of information and/or materials that may be protected by patents or other proprietary rights owned by or licensed to either Party ("Background Intellectual Property"). Nothing in this Agreement will be deemed or construed to convey or transfer to either Party any rights or license with respect to the Background Intellectual Property of the other Party except insofar as contemplated by this Agreement.

7.2 Title to any inventions or discoveries arising from the performance of the Study ("Inventions") and conceived and reduced to practice solely by MD Anderson employees shall be owned by MD Anderson and shall be disclosed in writing to Sponsor. Title to any Inventions conceived and reduced to practice jointly by MD Anderson and Sponsor shall be owned jointly by MD Anderson and Sponsor. MD Anderson, consistent with the MD Anderson's patent policy, will offer to grant the Sponsor an exclusive royalty-bearing license for MD Anderson's rights in Inventions. *

8. INDEMNIFICATION

8.1 Sponsor agrees to indemnify, hold harmless, and subject to the statutory duties of the Texas State Attorney General defend MD Anderson, System, their Regents, officers, agents and employees ("MD Anderson Indemnitees") from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of Sponsor's rights and obligations under this Agreement, including but not limited to Sponsor's use of Data; provided, however, that Sponsor shall not be obligated to hold harmless any MD Anderson Indemnitee from claims arising out of the negligence or willful malfeasance of any MD Anderson Indemnitee.

8.2 To the extent authorized by the constitution and laws of the State of Texas, MD Anderson agrees to indemnify and hold harmless Sponsor, its officers, agents and employees ("Sponsor Indemnitees") from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of MD Anderson's negligence in conducting the Study, provided, however, that MD Anderson shall not be obligated to hold harmless any Sponsor Indemnitee from claims arising out of the negligence or willful malfeasance of any Sponsor Indemnitee.

8.3 Both Parties agree that upon receipt of a notice of claim or action arising out of the Study, the Party receiving such notice will notify the other Party promptly.

9. INDEPENDENT CONTRACTOR

For the purposes of this Agreement and the Study, the Parties shall be, and shall be deemed to be, independent contractors and not agents or employees of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be expressly provided for herein or authorized in writing.

10. TERMINATION

10.1 This Agreement may be terminated: (a) immediately by the written agreement of both Parties; (b) by the Sponsor at the end of each twelve month period following the commencement of the Study, with sixty (60) days' notice to MD Anderson; (c) by MD Anderson for health, safety or regulatory reasons or if Sponsor breaches this Agreement and fails to cure such breach within fifteen (15) business days of notice of such breach by MD Anderson; or (d) immediately by either Party if at any time Principal Investigator becomes unable to conduct the Study, and the Parties cannot agree upon a mutually acceptable successor to the Principal Investigator.

10.2 In the event that either Party shall be in default of its material obligations under this Agreement and shall fail to remedy such default within thirty (30) days after receipt of written notice thereof, this Agreement shall terminate upon expiration of the thirty (30) day period.

10.3 Termination or cancellation of this Agreement shall not affect the rights and obligations of the Parties accrued prior to termination. Upon termination: (a) Sponsor shall pay MD Anderson for all reasonable expenses incurred or committed to be expended as of the effective termination date, including salaries for appointees for the remainder of the current quarter, for the proportion of their appointment allocated to the Sponsor as applicable; and (b) each Party shall return to the other Party or destroy any Confidential Information of such other Party remaining in the Party's possession, provided that such Party may retain one (1) copy of such Confidential Information for purposes of compliance with this Agreement and with applicable laws and regulations.

10.4 Any provisions of this Agreement which by their nature extend beyond expiration or termination of the Agreement shall survive such termination.

11. MISCELLANEOUS PROVISIONS

11.1 This Agreement may not be assigned by either Party without the prior written consent of the other Party.

11.2 This Agreement constitutes the entire and only agreement between the Parties relating to the Study, and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of the Parties.

11.3 Principal Investigator and Sponsor may be parties to a consulting agreement or other outside agreement to which MD Anderson is not a party. Sponsor acknowledges and agrees that MD Anderson has no involvement with or responsibility for these consulting or outside agreements.

11.4 Any notice required by this Agreement shall be given by prepaid, first class, certified mail, return receipt requested, addressed in the case of MD Anderson to:

The University of Texas
M. D. Anderson Cancer Center
1515 Holcombe Blvd., Unit 1436
Office of Research Administration
Attn: Executive Director, Research Administration
Houston, TX 77030

With a copy to:
The University of Texas System
M. D. Anderson Cancer Center
1515 Holcombe Blvd., 1674
Legal Services
ATTN: Chief Legal Officer
Houston, TX 77030

or in the case of Sponsor to:

Cell Source, Inc.
57 West 57th Street, Suite 400
New York, NY 10019
ATTN: ITAMAR SHIMRAT, Chief Executive Officer)
FAX: 1 646 416-8006
PHONE: 1 646 416-7896

or at such other addresses as may be given from time to time in accordance with the terms of this notice provision.

11.5 This Agreement shall be governed by, construed, and enforced in accordance with the laws of the State of Texas.

11.6 MD Anderson is an agency of the State of Texas and under the Constitution and laws of the State of Texas possesses certain rights and privileges and only such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing herein is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this agreement as they pertain to MD Anderson are enforceable only to the extent authorized by the Constitution and laws of the State of Texas.

11.7 Neither MD Anderson nor Sponsor will be required to perform any act or to refrain from any act or be bound to any act that would violate any state or federal law applicable to it. In this regard, this Agreement is subject to, and MD Anderson and Sponsor agree to comply with, all applicable local, state, federal, national and international laws, statutes, rules and regulations. Any provision of any law, statute, rule or regulation that invalidates any provision of this Agreement, that is inconsistent with any provision of this Agreement, or that would cause one or any of the Parties hereto to be in violation of law will be deemed to have superseded the terms of this Agreement. MD Anderson and Sponsor, however, will use all reasonable efforts to accommodate the terms and intent of this Agreement to the greatest extent possible consistent with the requirements of the law and negotiate in good faith toward amendment of this Agreement in such respect. If the Parties cannot reach agreement on an appropriate amendment, then this Agreement may be immediately terminated by either Party.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

SPONSOR

**THE UNIVERSITY OF TEXAS
M. D. ANDERSON CANCER CENTER**

By
Name: Itamar Shimrat
Title: Chief Executive Officer

By
Name: Jaime Farias
Title: Assistant Director of Sponsored Programs

READ AND UNDERSTOOD BY:

Dr. Yair Reisner
Principal Investigator

* Information has been redacted and is subject to a request for confidential treatment

EXHIBIT A

*

* Information has been redacted and is subject to a request for confidential treatment

EXHIBIT B

STUDY BUDGET

Funding Agency: Cell Source
Principal Investigator: Yari Reisner
Title:
Project Dates: TBD
Protocol(s): N/A
Total Patients: N/A

*

Total Costs	Year 1	Year 2	Year 3	Grand Total
	\$ 499,673.60	\$ 499,703.81	\$ 507,974.92	\$ 1,507,352.33

PAYMENT PLAN (Effective 01/01/2019)

	YEAR 01	YEAR 02	YEAR 03
Quarterly payments*	\$ 124,918.40	\$ 124,925.95	\$ 126,993.73
Total	\$ 499,673.60	\$ 499,703.81	\$ 507,974.95

*Payments to be made quarterly by first of each quarter

* Information has been redacted and is subject to a request for confidential treatment

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Itamar Shimrat, certify that:

1. I have reviewed this report on Form 10-K of Cell Source, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 29, 2019

By: /s/ Itamar Shimrat
Itamar Shimrat
Chief Executive Officer and Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Cell Source, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Itamar Shimrat, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2019

By: /s/ Itamar Shimrat
Itamar Shimrat
Chief Executive Officer and Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)