

**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 year ended December 31, 2019

- 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:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
None	N/A	N/A

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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2019, the aggregate market value of the issued and outstanding common stock held by non-affiliates of the registrant was \$10,907,281 based on the closing sale price as reported on the OTC Markets.

As of March 25, 2020, there were 27,076,762 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE - None.

CELL SOURCE, INC.

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

INDEX

	<u>Page</u>
<u>PART I</u>	
<u>Item 1. Business.</u>	4
<u>Item 1A. Risk Factors.</u>	37
<u>Item 1B. Unresolved Staff Comments.</u>	49
<u>Item 2. Properties.</u>	49
<u>Item 3. Legal Proceedings.</u>	49
<u>Item 4. Mine Safety Disclosures.</u>	49
<u>PART II</u>	
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	50
<u>Item 6. Selected Financial Data.</u>	51
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	51
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk.</u>	54
<u>Item 8. Financial Statements and Supplementary Data.</u>	55
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	55
<u>Item 9A. Controls and Procedures.</u>	55
<u>Item 9B. Other Information.</u>	56
<u>PART III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance.</u>	57
<u>Item 11. Executive Compensation.</u>	59
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	60
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence.</u>	61
<u>Item 14. Principal Accounting Fees and Services.</u>	62
<u>PART IV</u>	
<u>Item 15. Exhibits, Financial Statement Schedules.</u>	63
<u>Signatures</u>	66

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 Science (“Weizmann Institute”) in Israel. We have recently shifted the focus of our Research and Development efforts to MD Anderson Cancer Center (“MD Anderson”) in Houston, Texas.

This technology addresses 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, a number of potentially life-saving treatments have limited effectiveness today because the patient’s immune system rejects them. For example, while HSCT - hematopoietic stem cell transplantation (e.g. bone marrow transplantation) has become a preferred therapeutic approach for treating blood cell cancer, most patients do not have a matched family donor. Although matched unrelated donors and cord blood can each provide an option for such patients, haploidentical stem cell transplants (sourced from partially mismatched family members) are rapidly gaining favor as a treatment of choice. This is still 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 HSCT while the compromised new immune system works to reconstitute itself by using the transplanted stem cells. Today, rejection is partially overcome using aggressive immune suppression treatments that leave the patient exposed to many dangers by compromising their immune system.

The unique advantage of Cell Source technology lies in the ability to induce sustained tolerance of transplanted cells (or organs) by the recipient’s immune system in a setting that requires only mild immune suppression, while avoiding the most common post-transplant complications. The scientific term for inducing such tolerance in a transplantation setting is chimerism, where the recipient’s immune system tolerates the co-existence of the (genetically different) donor type and host (recipient) type cells. Attaining sustained chimerism is an important prerequisite to achieving the intrinsic GvL (graft versus leukemia) effect of HSCT and supporting the reconstitution of normal hematopoiesis (generation of blood cells, including those that protect healthy patients from cancer) in blood cancer patients. Preclinical data show that Cell Source’s Veto Cell technology (currently in clinical trials in the US) can provide superior results in allogeneic (donor-derived) HSCT by allowing for haploidentical stem cell transplants under a mild conditioning regimen, while avoiding the most common post-transplant complications. Combining this with CAR (Chimeric Antigen Receptor) T cell therapy as a unified VETO CAR-T treatment, we will be able to treat patients in relapse as well as those in remission and use the cancer killing power of CAR-T to protect the patient while their immune system fully reconstitutes, thus providing an end-to-end solution for blood cancer treatment by potentially delivering a fundamentally safer and more effective allogeneic HSCT: prevention of relapse; avoidance of graft versus host disease (GvHD); prevention of viral infections; and enhanced persistence of GvL effect. This means that the majority of patients will be able to find a donor, and will have access to a potentially safer procedure with higher long term survival rates than what either donor-derived HSCT or autologous CAR-T each on their own currently provide.

The ability to induce permanent chimerism (and thus sustained tolerance) in patients – which allows the transplantation 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, in addition to blood cancers, which are characterized by this need. These include:

- The broader set of cancers, including solid tumors, that can potentially be treated effectively using genetically modified cells such as CAR-T cell therapy, 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). Inducing sustained tolerance to CAR-T cells may bring reduced cost and increased efficacy by allowing for off-the-shelf (vs. patient-derived) treatments with more persistent cancer

killing capability.

- 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. Haploidentical organ transplants, with sustained chimerism, have the potential to make life saving transplants accessible to the majority of patients, with the prospect of improved life quality and expectancy.
- Non-malignant hematological conditions (such as type one diabetes and sickle cell anemia) which could, in many cases, also be more effectively treated by stem cell transplantation if the procedure could be made safer and more accessible by inducing sustained tolerance in the stem cell transplant recipient.

[Table of Contents](#)

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. 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, March, 2018, August 2019 and, most recently, in December 2019 (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 HSCT. To the best of our knowledge, over 1,500,000 HSCT have been performed worldwide with the annual number of procedures approaching 100,000 (table below). Our technology has immediate relevance for, at a minimum, the roughly 40,000 worldwide stem cell transplants that are allogeneic (using cells taken from another individual, not the patient). According to the Center for International Blood and Marrow Transplant Research ("CIBMTR"), there were 9,028 allogeneic stem cell transplants in the US in 2018.

Source: American Society of Hematology

HSCT often has a curative effect when successful. However, it is very risky. HSCT typically 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, 43% die from either infections (associated with a compromised immune system) or GvHD (Graft Versus Host Disease).

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

Another very important treatment protocol for blood cancers is CAR-T cell therapy. This novel approach uses the patient's own immune system cells to directly attack cancer cells. CAR-T cells are made by removing a specific set of cells from the blood, genetically modifying them in order to intensify the immune system's natural response to cancer, and re-injecting them into the patient. This form of cellular therapy has produced exceptional near term results in blood cancer patients and is currently being tested against a variety of different cancer types.

CAR T-cell therapy has been approved by the U.S. Food and Drug Administration as standard therapy for some patients with aggressive, relapsed and/or refractory diffuse large B cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma, and transformed follicular lymphoma (drug names Yescarta and Kymriah); and patients age 25 and under with relapsed or refractory B-cell acute lymphoblastic leukemia (drug name Kymriah).

These approved treatments use the patient's own cells in order to create CAR-T cells, which involves high cost (up to \$475,000 per infusion) and significant safety risks (e.g. high rate of relapse, significant incidence of Cytokine Release Syndrome (CRS)). While a number of companies are attempting to develop allogeneic or "off-the-shelf" CAR-T, they face several challenges including rejection by the host's immune system and GvHD. The currently approved CAR-T treatments, while showing high early response rates, have not shown long term survival results for blood cancer that exceed those of allogeneic HSCT.

This means that:

- a) many blood cancer patients are not candidates for the primary treatment (HSCT) that represents a potential cure;
- b) there is high mortality among those patients who are candidates for HSCT and do undergo the procedure;
- c) CAR-T cell therapy, which is currently used in limited indications and has had relatively slow adoption, has yet to demonstrate long term survival that substantively exceeds that of HSCT.

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.

There is also a strong awareness for the need of an off-the-shelf approach to CAR-T that overcomes rejection, avoids GvHD, and has increased persistence so as to deliver longer-term efficacy.

We aspire to use VETO CAR-T, combining Veto Cell technology with allogeneic CAR-T cell therapy, 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 or CAR-T, as the firm's tolerizing technology could potentially make allogeneic transplantation and off-the-shelf CAR-T an option for a much larger proportion of the diseased population. The following table shows the incidence 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 HSCT
Lymphoma	216,621	15,301
Leukemia	157,588	15,481
Multiple Myeloma	81,058	21,691
Total	455,267	52,473

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

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).

Table of Contents

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 an 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 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 treatment 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 is support of organ transplantations (kidney, liver, etc.). Approximately 70,000 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 and life expectancy 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 can make this treatment available to a broader set of sickle cell anemia sufferers. Preclinical data have also shown the potential effectiveness of Veto Cells in preventing the development of Type 1 Diabetes.

[Table of Contents](#)

[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. There are roughly 100 centers in the US today that provide CAR-T cell therapy treatments.

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 \$84 billion for 2018 and projected to grow to over \$243 billion by 2026, according to Reports and Data.

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 treatment 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 VETO CAR-T cell therapy, this will initially be combined with HSCT, but a more generic “off the shelf” modality offering is planned, which would eventually be marketed as a pre-packaged suspension of cells and medium, prepared and stored in advance.

[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. We are currently at the stage of human trials (testing both safety and 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 validated 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 emended 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.

[Table of Contents](#)

We commenced human clinical trials for approval for the Veto Cell based treatments in the United States in late 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 both leverage the priority of the already granted patents and extend the protection period for more advanced versions. We have commenced our first human clinical trial. If such 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 under a mild conditioning regimen, with a reduction in GvHD, 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 14 patent “families” (i.e. grouping of similar patent applications in different territorial jurisdictions) which currently include: 43 granted patents; 5 allowed/accepted patents; and a further 47 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 March 2020.

Professor Yair Reisner, the inventor of Veto Cell technology, left the Weizmann Institute and relocated to 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 850 transplantations per year. Cell Source has commenced a human clinical trial for its Anti-Rejection Anti-Viral Veto Cell at MD Anderson. Professor Richard Champlin (who Chairs their Department of Stem Cell Transplantation and Cellular Therapy and is a longtime associate and collaborator of Professor Reisner) serves as Principal Investigator for this trial.

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.

[Table of Contents](#)

Our licensed technology portfolio consists of 14 patent families, 43 granted patents, 5 allowed/accepted patents and a further 47 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 (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	9,738,872	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	285832	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.

[Table of Contents](#)

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	5,977,2388	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.
Canada	2,810,632	08-Sep-2011	08-Sep-2031	Allowed	Yeda Research and Development Co. Ltd.
China	ZL201180053858.9	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	10-1788826	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	HK1187528	08-Sep-2011	08-Sep-2031	Granted	Yeda Research and Development Co. Ltd.

[Table of Contents](#)

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 (Divisional)	2018-0193384-A1	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	HK1200099	06-Sep-2012	06-Sep-2032	Granted	Yeda Research and Development Co. Ltd.
Japan	6,196,620	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	ZL201280054739.X	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	10-2073901	06-Sep-2012	06-Sep-2032	Granted	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	2636503	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	CN 108135938 A	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	1255063A	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.

[Table of Contents](#)

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	2019-0316087-A1	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	3475414	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.
Hong Kong	19130758.6	27-Jun-2017	27-Jun-2037	Pending	Yeda Research and Development Co. Ltd.

[Table of Contents](#)

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
Europe	3571295	18-Jan-2018	18-Jan-2038	Pending	Yeda Research and Development Co. Ltd.
Israel	268126	18-Jan-2018	18-Jan-2038	Pending	Yeda Research and Development Co. Ltd.
China	CN 110392736 A	18-Jan-2018	18-Jan-2038	Pending	Yeda Research and Development Co. Ltd.

Name: ANTI-VIRAL CENTRAL MEMORY CD8 VETO CELLS IN HAPLOIDENTICAL STEM CELL TRANSPLANTATION

Country	Patent Number	Filed	Expires	Status	Assignee
USA	62/883,164	06-Aug-2019	06-Aug-2039	Pending	Yeda Research and Development Co. Ltd.

Name: USE OF VETO CELLS IN TREATMENT OF T CELL MEDIATED AUTOIMMUNE DISEASES

Country	Patent Number	Filed	Expires	Status	Assignee
USA	62/930,621	05-Nov-2019	05-Nov-2039	Pending	Yeda Research and Development Co. Ltd.

Name: USE OF VETO CELLS FOR THE TREATMENT OF SICKLE CELL DISEASE

Country	Patent Number	Filed	Expires	Status	Assignee
USA	62/930,634	05-Nov-2019	05-Nov-2039	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 (Divisional)	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	Allowed	Yeda Research and Development Co. Ltd.
Russian Federation	2657758	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.
USA (Continuation)	2019-0328793-A1	20-Dec- 2012	20-Dec- 2032	Pending	Yeda Research and Development Co. Ltd.
New Zealand	627272	20-Dec- 2012	20-Dec- 2032	Granted	Yeda Research and Development Co. Ltd.
Republic Korea	of 10-2014-7020449	20-Dec- 2012	20-Dec- 2032	Accepted	Yeda Research and Development Co. Ltd.
Australia	2012355990	20-Dec- 2012	20-Dec- 2032	Granted	Yeda Research and Development Co. Ltd.
Europe	2793914	20-Dec- 2012	20-Dec- 2032	Pending	Yeda Research and Development Co. Ltd.
USA	10,369,172	20-Dec- 2012	20-Dec- 2032	Granted	Yeda Research and Development Co. Ltd.
Hong Kong	1202810A	20-Dec- 2012	20-Dec- 2032	Pending	Yeda Research and Development Co. Ltd.

[Table of Contents](#)

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

<u>Country</u>	<u>Patent Number</u>	<u>Filed</u>	<u>Expires</u>	<u>Status</u>	<u>Assignee</u>
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	Accepted	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	2648354	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Israel	233302	20-Dec-2012	20-Dec-2032	Allowed	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	Accepted	Yeda Research and Development Co. Ltd.
USA	10,434,121	20-Dec-2012	20-Dec-2032	Granted	Yeda Research and Development Co. Ltd.
Hong Kong	1202775A	20-Dec-	20-Dec-	Pending	Yeda Research and Development

Veto Cell Technology Platform

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 possible 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 32, 2018; 1038-1040.* If it succeeds in human clinical trials, we believe that it may have meaningful and potentially broad impact on the field of stem cell 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. Furthermore, by adding CAR-T to the HSCT protocol, we can bridge between the initial transplantation and the conclusion of immune reconstitution, thus providing both short-term and ongoing protection against remission. This has the potential to significantly improve efficacy beyond that of the current outcomes of either CAR-T or HSCT on their own.
- 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 the near term in treating blood cancer.

[Table of Contents](#)

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 GvHD in an allogeneic 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 have 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.
- In the case of blood cancer treatment, we believe that a VETO CAR-T combined treatment will provide sustained protection for patients in relapse as well as a fundamentally superior approach for those in remission.

Cell Source is near the completion of 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 will 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 introduce allogeneic VETO CAR-T HSCT combined cell treatment for lymphoma and leukemia and, eventually, off the shelf VETO CAR-T for these and other cancers, including solid tumors.

Furthermore, Yeda has filed a patent application, licensed to Cell Source, which is now in the national phase, as well as a provisional patent based on more advanced data, 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, where the donor bone marrow rejects the host or recipient), and infections, which collectively are responsible for over 40% 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, as well as allowing for a reduced intensity conditioning (RIC) regimen. 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, under a mild conditioning regimen, as well as virus prevention, Veto Cell could potentially significantly increase survival rates post-transplant. Further adding the short-term cancer killing of CAR-T can combine to deliver even better long term survival outcomes,
- 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 commenced human clinical trials in the US in 2019.

Table of Contents

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), or a set of viral peptides, 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 stem 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 stem cell 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.

Table of Contents

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.
- 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 stem cells when they are transplanted. This population is created by identifying donor cells with Veto Cell properties, exposing them to simulated 3rd party cells (e.g., selecting only those that react to a third person and therefore by definition will not react to either host or donor) or to viral peptides, 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 attack 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, and in 2019 a further provisional patent application based on additional data, also licensed by Cell Source, which show the ability of Veto Cells to be directed against these types of viruses that 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. VETO CAR-T combined therapy

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.

CAR-T cell therapy has shown strong cancer killing efficacy in the near term, mainly in an autologous setting. Longer term efficacy to date has been significantly lower, and to date there has been little success in establishing a successful approach to allogeneic CAR-T therapy. Having worked with Zelig Eshhar, the inventor of CAR-T therapy, to combine the CAR-T cell and the Veto Cell in to single cell which both directly attacks cancer cells and facilitates T cell depleted HSCT under RIC, Cell Source intends to combine Veto Cell powered HSCT with CAR-T cell therapy for blood cell cancers into a single treatment, thus providing a comprehensive end-to-end solution which addresses both short-term cancer killing (via CAR-T) and long term relapse prevention (through a more safely delivered reconstituted immune system).

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 CAR-T or similar treatment (e.g. combining Veto with NK cells) 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 (stem cell 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. Yeda has recently filed provisional patent applications, licensed to Cell Source, based on preclinical data that show Veto Cells' effectiveness in reversing Sickle Cell Disease and their use in the treatment of T-cell mediated auto immune diseases such as preventing the development of Type 1 Diabetes.

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 procedures involved with stem cell transplantations. Blood will be taken from the donor. The 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

Cell Source's CD8 TcM (central memory T-cells) Veto Cell, are protected by granted patents in the US, Mexico, Europe, China, Japan, Hong Kong, Korea, Singapore, Israel, India and the Russian Federation as well as Canada, Australia, New Zealand and South Africa. More recent patent applications, including those 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.

<u>Offering</u>	<u>Objective</u>	<u>Major Activities</u>	<u>Estimated timing</u>
VETO CAR-T HSCT	Validate and introduce new commercial treatment to deliver safer and more successful haploidentical HSCT combined with CAR-T cell therapy	1. Establish initial safety and efficacy for Anti-viral Veto Cell, then augment existing trial protocol with CAR-T 2. Commence multi-center registration study 3. Introduce approved product to high profile US HSCT centers	<ul style="list-style-type: none">• 2022• 2024-2025• 2026-2028
Veto Cell Organ Transplantation	Validate efficacy of Veto Cells in attaining engraftment and educing need for ongoing post-transplant anti-rejection treatment for haploidentical kidney transplants	1. Finalize treatment protocol and commence Phase 1/2 study 2. Show sustained tolerance post- transplant without need for daily anti-rejection therapy	<ul style="list-style-type: none">• 2021-2022• 2023-2024

[Table of Contents](#)

[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. *VETO CAR-T HSCT cell therapy for donor mismatched allogeneic stem cell transplantations for treatment of blood cancer.*

This is our flagship (as an initial platform for increasing transplantation success) and is focused on haploidentical allogeneic stem cell transplantations. Treatment will comprise infusion of VETO CAR-T 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. *Veto Cell based haploidentical organ transplantation initially for kidney and then also for liver transplants.*

This therapy will involve a partially mismatched donor organ transplant combined with an Anti-Viral Veto powered HSCT using stem cells derived from the same donor.

3. *Off the shelf VETO CAR-T cell therapy.*

This treatment would be use Veto Cells to increase persistence and hence efficacy of CAR-T cell therapy, without the use of HSCT, for blood cancers and eventually solid tumors as well.

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, possibly including preventing the development of Type 1 Diabetes in Diabetes prone or early onset Diabetes patients.

[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 1 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 2 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 3 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)

[Table of Contents](#)

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 1 and 2 (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 2, foregoing the requirement for Phase 3 data prior to commencing commercial treatments.

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’s 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 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 five 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 RIC 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. In February of 2019, we executed a second agreement with MD Anderson for the production of Veto Cells and the conducting of a Phase 1/2 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, and approved by, 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 commenced a Phase 1/2 human clinical trial at MD Anderson in 2019. Cell Source anticipates that the US Phase 1/2 trial, once augmented with CAR-T cancer killing capability in the anticipated VETO CAR-T cell HSTC combined therapy, will last through 2023 or 2024. This would be followed by completion of a Phase 2 trial and Phase 3 trial, which could each last another 2-3 years. While under a fast track FDA program such as RMAT initial marketing approval could potentially be attained after a Phase 2 registration study as early as in 2025 or 2026, full approval, if successful, may not be attained until 2027 or later. By late 2019, Cell Source was moving to towards the conclusion of an initial proof-of-concept collaboration with Professor Zelig Eshhar, the inventor of CAR-T cell therapy, with respect to combining CAR-T cell therapy with Veto Cells. This is expected to lead to the augmentation of the existing Veto Cell treatment protocol at MD Anderson to include VETO CAR-T cells in 2022 or 2023, which may lead to fast track approval by 2025 or 2026 but may last until 2027 or 2028.

As referenced above, 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 at least \$5 million over the coming two years and overall company financing requirements of at least \$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.

[Table of Contents](#)

The following table summarizes the development plan through 2026:

Competition

In the area of allogeneic HSCT and related GvHD and virus management, our competitors include: the so-called “Baltimore” protocol, which employs a T-cell replete approach under RIC; companies who are working to reduce GvHD in a T-cell depleted setting, with high intensity conditioning (e.g. Kiadis, Molmed, Bellicum and Fate); companies working to treat GvHD or viral infections after they occur (e.g. Abbvie, Incyte and Kadmon); and finally cell therapy companies developing anti-viral treatments (e.g. Atara, Allovir). In the area of CAR-T cell therapy, our competitors include allogeneic CAR-T companies (e.g. Allogene, Cellectis, Precision) and autologous CAR-T players (e.g. Novartis, Gilead (KITE), BMS/Celgene (JUNO), Bluebird).

Haploidentical HSCT is gaining popularity in the US, outflanking UCB (umbilical cord blood) and growing more quickly than MUD (matched unrelated donor) based transplants. In the US, the majority of haploidentical HSCT are performed under RIC, mostly using T-cell replete transplants with post-transplant cyclophosphamide treatment. While this “Baltimore” RIC approach has gained popularity (mainly due to safety reasons) – as a **T-cell replete** approach it carries the risk of marked GvHD. Although Kiadis, Molmed and Bellicum’s **T-cell depleted** products have all shown reductions in GvHD, they have each reported setbacks with respect to their lead products candidates in this area in 2019. Similarly, while currently approved CAR-T therapy for blood cancer has shown compelling short term efficacy, the initial longer term data have shown a marked drop off in overall survival rates. Cell Source’s planned distinctive combination of a **T-cell depleted HSCT with RIC**, complemented by anti-viral activity and enhanced by CAR-T short-term cancer killing, aims to provide the “best of both worlds” with safer, more effective HSTC leading to a reconstituted immune system, supported by “bridging” CAR-T remission induction and relapse prevention during the immune reconstitution period.

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.

Table of Contents

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, kidney disease) and products (VETO CAR-T and Veto Organ Transplants).

Subsequently, we plan to broaden the segmentation strategy to include, stand-alone cancer treatments without HSCT (e.g. for solid tumors) and additional HSCT indications (e.g. selected genetic non-malignant diseases).

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• Kidney disease	<ul style="list-style-type: none">• Same as before plus solid tumor cancer targets, liver failure, sickle cell anemia beta thalassemia, diabetes and other non-malignant hematological disorders;
Product Rollout	<ul style="list-style-type: none">• VETO CAR-T HSCT for B-cell malignancies• Veto Cell Kidney transplants	<ul style="list-style-type: none">• VETO CAR-T for solid tumors• Veto Cell liver transplants• Veto HSCT for non-malignant disorders
Customer/ Geographic Focus	<ul style="list-style-type: none">• United States• Western Europe• China	<ul style="list-style-type: none">• Major markets worldwide
Channels/Go to Market	<ul style="list-style-type: none">• Direct relationships with leading transplantation centers• Partnerships with global pharma players	<ul style="list-style-type: none">• Out-licensing to, or outright acquisition by, global pharma players
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 outright or JV with partners

[Table of Contents](#)

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., blood cancers, kidney failure). 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 first-in-human Phase 1/2 trial in the US, which could be concluded by 2023 or 2024, 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 2025 or 2026. Full approval by the FDA in the U.S. can take as long as 8 years, or until 2028.

Future products may include VETO CAR-T HSCT combined cell therapy for allogeneic stem cell transplantations as well as Veto Cell based organ transplantation. 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 activities in these 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, and possibly Russia and India.

Marketing Strategy

The initial target market is concentrated and networked. It comprises the approximately 100 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.

[Table of Contents](#)

The broader provider community will be addressed both through a presence in leading peer-reviewed publications and by attending conferences where research and best clinical practices are shared, seminars are conducted, and networking opportunities are provided for the physicians. Furthermore, a dedicated sales force will approach leading bone marrow transplant physicians in the United States, as well as other key points of contact at the leading HSCT centers in the US as referenced above.

[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 as MD Anderson in Texas. 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 post regulatory approval phase, 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 commenced our first Phase 1/2 clinical trial in late 2019. This trial combines traditional Phase 1 safety with Phase 2 efficacy inasmuch as it is a safety trial conducted on sick patients, so as 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.

[Table of Contents](#)

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 current initial 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 augment the current clinical trial protocol for blood cell cancer to include VETO CAR-T cells. 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 commenced human clinical trials for Anti-Viral Veto Cells, our lead product candidate, in the US in late 2019.

[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.

Table of Contents

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 March 2020. Should the Company elect to curtail such funding, it would have to pay a \$50,000 annual license fee until such time 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 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 2019, Cell Source extended the research period, which was scheduled to have been terminated in 2019, through March of 2020.

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 March 31, 2020 is \$185,000. 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 2 clinical trials with respect to a Product;
- b. by January 1, 2025, to have either commenced Phase 3 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:

- o **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.
- o **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.

- o **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.

- o **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.

Table of Contents

The Company may grant a Sublicense only with Yeda's 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.

- o **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.

[Table of Contents](#)

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 commenced a human clinical trial, conducted on its behalf by MD Anderson, in 2019 to show initial safety, and possibly efficacy, results in the US.

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 1, 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 2 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 2 evaluations, Phase 3 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 1 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 1 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 2 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 1 studies, further submissions to regulatory authorities are necessary in relation to Phase 2 and 3 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.

[Table of Contents](#)

By leveraging existing pre-clinical and clinical data, we are seeking to 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 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.

[Table of Contents](#)

In various countries, animal rights activism has led to either formal or informal boycotting of certain types of animal trials. This may have an adverse impact on our business 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. We are currently conducting research and development activities in order to facilitate the continued transition of the patented 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 a net loss of \$4,475,495 for the year ended December 31, 2019. 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. As of December 31, 2019, we had cash in the amount of \$27,908. 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.

[Table of Contents](#)

There is substantial doubt about our ability to continue as a going concern.

As of December 31, 2019, we had a working capital deficit and accumulated deficit of \$5,596,941 and \$21,145,828, respectively. During the year ended December 31, 2019, we had a net loss and used cash in operations of \$4,475,495 and \$2,587,212, respectively. We have historically incurred operating losses and may continue to incur operating losses for the foreseeable future. We believe that 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. This may hinder our future ability to obtain financing or may force us to obtain financing on less favorable terms than would otherwise be available. We have not generated revenues to-date. Our primary source of operating funds since inception has been equity and debt financings. Our 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 us to fully complete our development activities or attain profitable operations. If we are unable to obtain such additional financing on a timely basis or, notwithstanding any request we may make, if our debt holders do not agree to convert their notes into equity or extend the maturity dates of their notes, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate. There can be no assurance that we will be able to continue as a going concern.

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 commercial 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 any future 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;

Table of Contents

- 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 3 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 underway (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.

[Table of Contents](#)

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.

Table of Contents

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.

[Table of Contents](#)

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 Israeli Shekels, 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 Israeli Shekel. In order to minimize our exposure to foreign exchange fluctuations we may hold sufficient Israeli Shekels to cover our expected Israeli Shekel 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. As we move forward with our own clinical trials, 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. As Cell Source continues 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 direct participation in clinical trials, above and beyond whatever insurance coverage is already held by the institutions and facilities providing services with respect to such clinical trials, as may be required.

[Table of Contents](#)

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 this person, 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 and since 2019, 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.

Capital markets and certain businesses and institutions may experience periods of disruption and instability and we cannot predict when these conditions will occur. Such market conditions could materially and adversely affect debt and equity capital markets in the United States and abroad, which could have a negative impact on our ability to raise capital. In addition, the closing or reduction of activities at research facilities could interfere with the ability of our research and development partners to conduct research and clinical trials

Recently, the outbreak of the novel coronavirus, or COVID-19, in many countries has adversely impacted global commercial activity, particularly in China, and has contributed to significant volatility in financial markets and disrupted normal business operations. The global impact of the outbreak has been rapidly evolving, and as cases of the virus have continued to be identified in additional countries, many countries have reacted by instituting quarantines and restrictions on travel, and many businesses and other institutions have temporarily closed or reduced work activities at their facilities. Such actions are creating disruption in global supply chains, and adversely impacting a number of industries, such as transportation, hospitality and entertainment. The outbreak could have a continued adverse impact on economic and market conditions and trigger a period of global economic slowdown. The rapid development and fluidity of this situation precludes any prediction as to the ultimate adverse impact of the novel coronavirus. Nevertheless, the novel coronavirus presents material uncertainty and its disruption of the capital markets may have a material adverse impact on our ability to raise additional capital and may slow down the pace at which

research and clinical trials may be conducted on our behalf.

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 1,335,000 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.

[Table of Contents](#)

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-2-07 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.

[Table of Contents](#)

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 we fail to maintain effective internal controls over financial reporting, the price of our common stock may be adversely affected.

In the past, our management identified weaknesses in our internal controls and although our management believes such weaknesses have been remediated, our internal control over financial reporting may still or could in the future have weaknesses and conditions that could require correction or remediation, the disclosure of which may have an adverse impact on the price of our common stock. We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

We are required to comply with certain provisions of Section 404 of the Sarbanes-Oxley Act of 2002 and if we fail to comply in a timely manner, our business could be harmed and our stock price could decline.

Rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 require an annual assessment of internal controls over financial reporting, and for certain issuers an attestation of this assessment by the issuer's independent registered public accounting firm. The standards that must be met for management to assess the internal controls over financial reporting as effective are evolving and complex, and require significant documentation, testing, and possible remediation to meet the detailed standards. We expect to incur significant expenses and to devote resources to Section 404 compliance on an ongoing basis. It is difficult for us to predict how long it will take or how costly it will be to complete the assessment of the effectiveness of our internal control over financial reporting for each year and to remediate any deficiencies in our internal control over financial reporting. As a result, we may not be able to complete the assessment and remediation process on a timely basis. In addition, although attestation requirements by our independent registered public accounting firm are not presently applicable to us, we could become subject to these requirements in the future and we may encounter problems or delays in completing the implementation of any resulting changes to internal controls over financial reporting. In the event that our principal executive and financial officer determines that our internal control over financial reporting is not effective as defined under Section 404, we cannot predict how regulators will react or how the market prices of our shares will be affected; however, we believe that there is a risk that investor confidence and share value may be negatively affected.

Voting power of our shareholders is highly concentrated by insiders.

Our officers, directors and affiliates currently own approximately 23% 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.

[Table of Contents](#)

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.

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 will 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.

Below is a summary of the notes issued and outstanding as of December 31, 2019:

- Ten notes payable with principal amounts totaling \$1,263,000; and
- Fourteen convertible notes payable with principal amounts totaling \$1,338,000.

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, 2019, \$1,983,000 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.

[Table of Contents](#)

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

As of December 31, 2019, we had 27,076,762 shares of Common Stock issued and outstanding and outstanding warrants to purchase 4,059,157 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.

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.

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 2020. 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 July 12 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.

Market for Common Equity and Related Stockholder Matters

Our common stock is currently quoted under the symbol "CLCS" on the OTCQB.

As of March 25, 2020, there were 126 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, 2019, we had outstanding warrants to purchase an aggregate of 4,059,157 shares of common stock with a weighted average exercise price of \$0.75 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

Our Board of Directors adopted the 2019 Equity Incentive Plan in August 2019. A total of 7,900,000 shares of common stock are reserved for issuance under the Plan, which permits the Board of Directors to issue stock options, stock appreciation rights, restricted stock, restricted stock units, performance and other awards to employees, consultants and directors of the Company. As of the date of filing, the Company's shareholders have not approved the Plan. The number of stock options outstanding under the Equity Incentive Plan, the weighted-average exercise price of the outstanding options, and the number of securities remaining available for issuance, as of December 31, 2019 were as follows:

EQUITY COMPENSATION PLAN TABLE

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	---	---	---
Equity compensation plans not approved by security holders	3,782,004	\$ 0.75	4,117,996
Total	3,782,004	\$ 0.75	4,117,996

Sales of Unregistered Securities

In October 2019, we issued a convertible note payable in the principal amount of \$1,500,000 and received proceeds of \$500,000. An additional \$500,000 was received in March 2020 and we expect to receive the remaining \$500,000 during the quarter ending June 30, 2020. The note accrues interest at 8% per annum and matures on October 31, 2020. If we create and sell shares of Series B Convertible Preferred Stock (“Series B Preferred Stock”), the note will be convertible in Series B Preferred Stock at a conversion price equal to the price paid by investors in the offering of the Series B Preferred Stock. The note provides that in the event that we are awarded a grant by the Cancer Prevention and Research Institute of Texas (a “CPRIT Grant”) and the holder of the note has converted all or a portion of the note into Series B Preferred Stock, the holder will have the right, but not the obligation, to purchase at an exercise price of \$1.25 per share, a number of shares of our common stock that shall be determined by multiplying 7,400,000 by a fraction, the numerator of which shall be the number of shares of Series B Preferred Stock owned by the holder of the note and the denominator of which shall be 666,666. We relied upon the exemption provided by Section 4(2) of the Securities Act of 1933, as amended (the “Securities Act”) in connection with this transaction.

During the year ended December 31, 2019, we issued 991,651 shares of common stock as payment of in-kind dividends to holders of Series A Convertible Preferred Stock. We relied upon the exemption provided by Section 4(2) of the Securities Act in connection with these transactions.

During January 2020, we sold 13,333 shares of Series A Convertible Preferred Stock to accredited investors at a price of \$7.50 per share for gross proceeds of \$100,000. We relied upon the exemption provided by Rule 506 and Section 4(2) of the Securities Act in connection with these transactions.

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. We have recently shifted the focus of our Research and Development efforts to MD Anderson.

This technology addresses 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, a number of potentially life-saving treatments have limited effectiveness today because the patient's immune system rejects them. For example, while HSCT - hematopoietic stem cell transplantation (e.g. bone marrow transplantation) has become a preferred therapeutic approach for treating blood cell cancer, most patients do not have a matched family donor. Although matched unrelated donors and cord blood can each provide an option for such patients, haploidentical stem cell transplants (sourced from partially mismatched family members) are rapidly gaining favor as a treatment of choice. This is still 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 HSCT while the compromised new immune system works to reconstitute itself by using the transplanted stem cells. Today, rejection is partially overcome using aggressive immune suppression treatments that leave the patient exposed to many dangers by compromising their immune system.

Table of Contents

The unique advantage of Cell Source technology lies in the ability to induce sustained tolerance of transplanted cells (or organs) by the recipient's immune system in a setting that requires only mild immune suppression, while avoiding the most common post-transplant complications. The scientific term for inducing such tolerance in a transplantation setting is chimerism, where the recipient's immune system tolerates the co-existence of the (genetically different) donor type and host (recipient) type cells. Attaining sustained chimerism is an important prerequisite to achieving the intrinsic GvL (graft versus leukemia) effect of HSCT and supporting the reconstitution of normal hematopoiesis (generation of blood cells, including those that protect healthy patients from cancer) in blood cancer patients. Preclinical data show that Cell Source's Veto Cell technology (currently in clinical trials in the US) can provide superior results in allogeneic (donor-derived) HSCT by allowing for haploidentical stem cell transplants under a mild conditioning regimen, while avoiding the most common post-transplant complications. Combining this with CAR (Chimeric Antigen Receptor) T cell therapy as a unified VETO CAR-T treatment, we will be able to treat patients in relapse as well as those in remission and use the cancer killing power of CAR-T to protect the patient while their immune system fully reconstitutes, thus providing an end-to-end solution for blood cancer treatment by potentially delivering a fundamentally safer and more effective allogeneic HSCT: prevention of relapse; avoidance GvHD; prevention of viral infections; and enhanced persistence of GvL effect. This means that the majority of patients will be able to find a donor, and will have access to a potentially safer procedure with higher long term survival rates than what either donor-derived HSCT or autologous CAR-T each on their own currently provide.

The ability to induce permanent chimerism (and thus sustained tolerance) in patients – which allows the transplantation 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, in addition to blood cancers, which are characterized by this need. These include:

- The broader set of cancers, including solid tumors, that can potentially be treated effectively using genetically modified cells such as CAR-T cell therapy, 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). Inducing sustained tolerance to CAR-T cells may bring reduced cost and increased efficacy by allowing for off-the-shelf (vs. patient-derived) treatments with more persistent cancer killing capability.
- 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. Haploidentical organ transplants, with sustained chimerism, have the potential to make life saving transplants accessible to the majority of patients, with the prospect of improved life quality and expectancy.
- Non-malignant hematological conditions (such as type one diabetes and sickle cell anemia) which could, in many cases, also be more effectively treated by stem cell transplantation if the procedure could be made safer and more accessible by inducing sustained tolerance in the stem cell transplant recipient.

Recent Developments

After two years of intensive collaboration with Professor Zelig Eshhar, the inventor of CAR-T cell therapy, interim data confirm that Veto Cells can markedly extend persistence of genetically modified T cells from the same donor and that genetically modified Veto Cells can effectively inhibit tumors expressing an antigen recognized by the transgenic T cell receptor. Furthermore, human Veto Cells transfected with CAR exhibit anti-tumor activity in-vitro without losing their veto activity. These preclinical results will form the basis of the development of a clinical protocol for allogeneic VETO CAR-T HSCT combined therapy for blood cancer treatment. Cell Source plans to submit this protocol for approval in the second quarter of 2021.

Consolidated Results of Operations

Year Ended December 31, 2019 Compared with the Year Ended December 31, 2018

Research and Development

Research and development expense was \$2,630,385 and \$725,088 for the years ended December 31, 2019 and 2018, respectively, an increase of \$1,905,297, or 263%, primarily related to approximately \$1,335,000 associated with the commencement of research by MD Anderson and approximately \$825,000 of stock-based compensation expense associated with a stock option grant to Dr. Reisner, who Chairs the Company's Scientific Advisory Board and leads the Reisner Laboratory at MD Anderson, offset by a decrease of approximately \$277,000 in fees related to our agreement with Yeda.

[Table of Contents](#)

General and Administrative

General and administrative expense, which is associated with external consulting and professional fees, payroll and stock-based compensation expenses, was \$1,174,816 and \$1,281,055 for the years ended December 31, 2019 and 2018, respectively, a decrease of \$106,239, or 8%.

Change in Fair Value of Derivative Liabilities

The change in fair value of derivative liabilities for the years ended December 31, 2019 and 2018 was a gain of \$146,700 and a gain of \$485,500, respectively, primarily due to the warrants and conversion options, which are deemed to be derivative liabilities, either drawing closer to their expiration dates or were no longer outstanding.

Interest Expense

Interest expense for the years ended December 31, 2019 and 2018 was \$292,977 and \$268,997, respectively, a decrease of \$23,980, or 9%, due to a decrease in notes payable outstanding during 2019 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 \$14,970 and \$209,655 for the years ended December 31, 2019 and 2018, respectively, a decrease of \$194,685, or 93%, which is primarily related to warrants, conversion options and original issuance discounts drawing closer to their expiration dates or which were no longer outstanding.

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.

Warrant Modification Expense

During the year ended December 31, 2019, we recognized \$283,500 of warrant modification expense on the extension of an expiration date of certain warrants.

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

During the years ended December 31, 2019 and 2018, we recognized a loss on exchange of notes payable for Series A Convertible Preferred Stock of \$262,470 and \$191,251, respectively, which represents the value of the preferred shares in excess of the carrying value of notes payable.

Loss on Extinguishment of Debt

During the year ended December 31, 2019, we recognized \$1,504 of loss on extinguishment of debt.

Gain on Forgiveness of Accrued Expenses

During the year ended December 31, 2019, we recognized a gain on forgiveness of accrued expenses of \$38,427, which represents the forgiveness of accrued payroll expenses and director fees due by a former member of the Board of Directors.

Liquidity and Going Concern

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

	December 31,	
	2019	2018
Cash	\$ 27,908	\$ 18,934
Working capital Deficiency	\$(5,596,941)	\$(4,920,171)

We have not generated any revenues since our inception, we have recurring net losses, we have a working capital deficiency as of December 31, 2019 and 2018 of approximately \$5,597,000 and \$4,920,000, respectively. We have used cash in operations of approximately \$2,587,000 and \$2,002,000 during the years ended December 31, 2019 and 2018, respectively. Subsequent to December 31, 2019 and as more fully described in Note 13, *Subsequent Events*, the Company received aggregate proceeds of \$578,000 from convertible notes payable and \$100,000 through the sale of 13,333 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. 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.

[Table of Contents](#)

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, 2019 and 2018, 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, 2019 and 2018 in the amounts of \$2,587,212 and \$2,002,114, respectively. The net cash used in operating activities for the year ended December 31, 2019 was primarily due to cash used to fund a net loss of \$4,475,495, reduced by net non-cash expenses in the aggregate amount of \$1,315,196 and by \$573,087 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, 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.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the years ended December 31, 2019 and 2018 was \$2,596,186 and \$1,650,000, respectively. The net cash provided by financing activities during the year ended December 31, 2019 was attributable to \$1,795,677 of proceeds from the issuance of Series A preferred stock, \$665,000 of proceeds from the issuance of convertible notes payable, \$275,500 of proceeds from an advance payable, \$120,000 of proceeds from the issuance of notes payable, offset by \$140,000 of repayments of advances payable, \$70,000 of repayments of notes payable and \$49,991 of payments of equity issuance costs. 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.

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, 2019, 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 and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, 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 and financial officer concluded that our internal control over financial reporting was effective as of December 31, 2019.

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, 2019 that have materially affected, or are reasonably likely to materially affect, our 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:

<u>Name</u>	<u>Age</u>	<u>Title(s)</u>
Dennis Brown	70	Director (Chairman)
Itamar Shimrat	60	Chief Executive Officer, Chief Financial Officer and Director
David Zolty	70	Director
Ben Friedman	61	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 of Del Mar Pharmaceuticals (BC) Ltd., a subsidiary of DelMar Pharmaceuticals, Inc. (OTCQB: DMPI). 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 - Olim Madrega 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 - Olim Madrega 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.

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 Rane 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.

Table of Contents

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 serves 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.

Table of Contents

Board Meetings and Attendance

During the year ended December 31, 2019, the Company's Board of Directors held four meetings and acted by written consent on thirteen 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

The Audit Committee of the Board of Directors 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. Until April 2019, the members of the Audit Committee were Messrs. Brown (Chair) and Yoram Drucker. Mr. Drucker resigned his position as a member of the Company's Board of Directors in April 2019 and has since been replaced by Ben Friedman.

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

Delinquent Section 16(a) Reports

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, 2019, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with, except that (i) Dennis Brown has not yet filed a Form 4 to report his purchase of 6,667 shares of Series A Preferred Stock in January 2019 and (ii) Dennis Brown, Ben Friedman and David Zolty have not yet filed a report on Form 4 to report the issuance of shares of common stock as payment of in-kind dividends on the shares of Series A Preferred Stock that they own.

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 2019 and 2018:

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Itamar Shimrat Chief Executive Officer	2019	\$ 171,980	\$ -	\$ -	\$ -	\$ -	\$ 171,980
	2018	\$ 165,625	\$ -	\$ -	\$ -	\$ -	\$ 165,625

Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the

fiscal year ended December 31, 2019:

		Change in Present Value and Nonqualified Deferred Compensation					All Other Compensation		
	Year	Fees Earned or Paid In Salary	Stock Awards	Option Awards	Compensation Earnings	Compensation	Compensation	Total	
Dennis Brown	2019	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Yoram Drucker ⁽¹⁾	2019	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
David Zolty	2019	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Ben Friedman	2019	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	

(1) Mr. Drucker resigned his position as a member of the Board of Directors in April 2019.

[Table of Contents](#)

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2019, no awards had been made to any officer or director under our 2019 Equity Incentive Plan.

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 2019, 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 and Series A Preferred Stock by (i) any holder of more than five (5%) percent of the applicable class; (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.

	As of March 30, 2020			
	Common Stock		Series A Preferred Stock	
Name and Address of Beneficial Owner (16)	Amount and Nature of Beneficial Ownership (1)	Percentage of Class (2)	Amount and Nature of Beneficial Ownership	Percentage of Class (3)
Directors and Officers:				
Itamar Shimrat, Chief Executive Officer, Chief Financial Officer and Director	575,004	2.12 %	---	---
David Zolty, Director	1,376,836 (4)	5.03 %	10,888	*
Ben Friedman, Director (5)	4,862,065 (6)	17.62 %	43,553	3.46 %
Dennis Brown, Director (Executive Chairman)	272,604 (7)	*	6,667	*
All directors and executive officers as a group (5 persons)	7,086,509	25.36 %	61,108	4.86 %
Yari Reisner 1515 Holcombe Boulevard Houston, Texas 77030	4,941,976 (8)	16.02 %	---	---
YEDA Research & Development Co., Ltd.P.O. Box 905 Rehovot, 76100, Israel	1,361,170 (9)	4.99 %	---	---
Hua Tuo Online (Hon Kong) Limited Suite 5207, 52/F Central Plaza18 Harbour Road Wanchai, Hong Kong	1,581,231 (10)	5.54 %	133,334	10.60 %

Darlene Soave 341 Lakewood Drive Bloomfield Hills, Michigan 48304	1,471,408 (11)	5.15 %	133,334	10.60 %
Acuity Investments LLC 124 South Gay Street Knoxville, Tennessee 37902	1,485,321 (12)	5.2 %	130,402 (13)	10.36 %
IGEA Brain & Spine 1057 Commerce Avenue Union, New Jersey 07083	1,462,592 (14)	5.12 %	119,250 (15)	9.48 %
Mario Dell' Aerea 217 Park Drive Eastchester, New York 10709	---	---	76,500	6.07

* 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 30, 2020 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 27,076,762 shares issued and outstanding as of March 30, 2020.
- (3) Based on 1,258,416 shares of Series A Preferred Stock issued and outstanding as of March 30, 2020.
- (4) Includes warrants to purchase a total of 160,000 shares of common stock with an exercise price of \$0.75 per share and 108,880 shares of common stock issuable upon conversion of 10,888 shares of Series A Preferred Stock.
- (5) Mr. Friedman's beneficial ownership includes shares beneficially owned by his wife, Phyllis Friedman.
- (6) Includes 435,530 shares of common stock issuable upon conversion of 43,553 shares of Series A Preferred Stock. 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.
- (7) Includes a five-year warrant to purchase 100,000 shares of common stock with an exercise price of \$0.75 per share and 66,670 shares of common stock issuable upon conversion of 6,667 shares of Series A Preferred Stock.
- (8) Includes 3,782,004 shares of common stock issuable upon the exercise of options to purchase common stock at an exercise price of \$.075 per share. Excludes a warrant to purchase 48,459 shares of common stock with an exercise price of \$0.75 per share, which warrant is subject to a 4.99% conversion limitation.
- (9) Includes 201,198 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) Includes 1,333,340 shares of common stock issuable upon conversion of 133,334 shares of Series A Preferred Stock.
- (11) Includes 1,333,340 shares of common stock issuable upon conversion of 133,334 shares of Series A Preferred Stock.
- (12) Includes 1,304,420 shares of common stock issuable upon conversion of 130,402 shares of Series A Preferred Stock and 40,209 shares of common stock owned by Acuity Capital LLC, an affiliate of the shareholder.
- (13) Includes 30,934 shares owned by Acuity Capital LLC, an affiliate of the shareholder
- (14) Includes 1,192,500 shares of common stock issuable upon conversion of 119,250 shares of Series A Preferred Stock and 106,049 shares of common stock owned by IGEA Ventures, an affiliate of the shareholder.
- (15) Includes 42,667 shares owned by IGEA Ventures, an affiliate of the shareholder.
- (16) 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.

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.

In connection with Amendments No. 5 and 6 to the License Agreement, the latest of which was dated December 31, 2019, the research conducted (“Further Research”) under the Agreement was extended to cover the period from July 1, 2019 to March 31, 2020 and the associated research budget for this period shall be a total of \$185,000 which is payable on January 1, 2020. As of the date of filing, the payment had not been made by the Company.

For the years ended December 31, 2019 and 2018, the Company recorded expenses in operations of approximately \$173,000 and \$450,000, respectively, related to its research and license agreement with Yeda. At December 31, 2019, approximately \$123,000 was accrued and is payable to Yeda.

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, which are non-interest bearing and became due on May 18, 2018, remained outstanding as of December 31, 2019. As of December 31, 2019, the Company had accrued an obligation to issue warrants to purchase 49,500 and 198,000 shares, respectively, at an exercise price of \$0.75 per share to the entity owned by Mr. Friedman and Mr. Zolty as a result of the Company’s failure to repay these notes on the maturity date.

In December 2018, the Company received a non-interest-bearing short-term advance in the amount of \$100,000 from David Zolty. Because the short-term advance was not repaid by the Company on or before January 15, 2019, the Company is required under the terms of the advance to (i) issue to Mr. Zolty warrants to purchase 100,000 shares of common stock on such date and (ii) to further issue warrants to purchase 25,000 shares of common stock for each month that the advance remains outstanding after such date. As of December 31, 2019, the entire amount of the advance was outstanding. As of December 31, 2019, the Company was required to issue warrants to purchase an aggregate of 375,000 shares at an exercise price of \$0.75 per share to Mr. Zolty in connection with this advance.

The Company has agreed to issue warrants to purchase 134,000 shares of common stock at an exercise price of \$0.75 per share to Mr. Zolty in consideration of Mr. Zolty making a \$134,000 payment to Yeda on the Company’s behalf in 2016. As of December 31, 2019, the Company had not issued the warrants to Mr. Zolty.

In January 2019, the Company received proceeds of \$50,000 from the sale of 6,667 shares of Preferred Stock to Dennis Brown, the Chairman of the Company's Board of Directors.

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, 2019 and 2018:

	<u>2019</u>	<u>2018</u>
Audit Fees	\$ 103,520	\$ 185,900
Tax fees	--	--
All other fees	--	--
	<u>\$ 103,520</u>	<u>\$ 185,900</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
4.1*	Description of Common Stock
10.1 (1)	Form of Subscription Agreement
10.2 (1)	Form of Registration Rights Agreement
10.4 (1)	Form of Consultant Warrant(8)
10.5 (1)	Form of Researcher Company Warrant
10.6 (1)	Form of Company Warrant
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

Table of Contents

<u>10.12(1)</u>	<u>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</u>
<u>10.13(1)</u>	<u>Consulting Agreement by and between Cell Source Limited and Professor Yair Reisner</u>
<u>10.14(6)</u>	<u>Form of Amendment No. 1 to Registration Rights Agreement</u>
<u>10.15(7)</u>	<u>Bridge Funding Agreement</u>
<u>10.16(5)</u>	<u>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</u>
<u>10.17(8)</u>	<u>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</u>
<u>10.18(9)</u>	<u>Form of Promissory Note issued to the Company's Chief Executive Officer</u>
<u>10.19(10)</u>	<u>Form of March 2015 Promissory Note</u>
<u>10.20(10)</u>	<u>Form of March 2015 Warrant</u>
<u>10.21(11)</u>	<u>Form of Note Amendment Letter Agreement</u>
<u>10.22(11)</u>	<u>Form of May 2015 Note</u>
<u>10.23(11)</u>	<u>Form of May 2015 Warrant</u>
<u>10.24(12)</u>	<u>Form of Advisory/Consulting Agreement</u>
<u>10.25(13)</u>	<u>Zolty Promissory Note</u>
<u>10.26(13)</u>	<u>Zolty Warrant</u>
<u>10.27(13)</u>	<u>Form of July 2015 Convertible Promissory Note</u>
<u>10.28(13)</u>	<u>Form of July 2015 Warrant</u>
<u>10.29(15)</u>	<u>Form of Bridge Note Subscription Agreement</u>
<u>10.30(15)</u>	<u>Form of Convertible Note</u>
<u>10.31(15)</u>	<u>Form of March 2016 Note</u>
<u>10.32(15)</u>	<u>Form of March 2016 Warrant</u>
<u>10.33(18)</u>	<u>Form of July 2016 Warrants</u>
<u>10.34(18)</u>	<u>Second Amendment to Research and License Agreement dated as of November 28, 2016 between the Company and Yeda Research and Development Company Limited</u>
<u>10.35(18)</u>	<u>Third Amendment to Research and License Agreement dated as of March 29, 2018 between the Company and Yeda Research and Development Company Limited</u>
<u>10.36(18)</u>	<u>Fourth Amendment to Research and License Agreement dated as of March 30, 2018 between the Company and Yeda Research and Development Company Limited</u>
<u>10.37(16)</u>	<u>Convertible Note due July 27, 2016</u>
<u>10.38(17)</u>	<u>Promissory Note dated May 10, 2016</u>
<u>10.39(19)</u>	<u>Sponsored Research Agreement dated November 28, 2018 between The University of Texas M.D. Anderson Cancer Center and Cell Source Limited**</u>
<u>10.39(a)</u> <u>(20)</u>	<u>Amendment No. 1 to Veto Cell Production and Clinical Trial Program Agreement dated as of April 4, 2019 between Cell Source Limited and the University of Texas M.D. Cancer Center**</u>
<u>10.40(19)</u>	<u>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**</u>
<u>10.41(21)</u>	<u>2019 Equity Incentive Plan</u>
<u>10.42(21)</u>	<u>Stock Option Agreement dated as of August 11, 2019 before Cell Source, Inc. and Yair Reisner</u>
<u>10.43(21)</u>	<u>Stock Option Agreement dated as of August 11, 2019 between Cell Source, Inc. and Yair Reisner</u>
<u>10.44(21)</u>	<u>Convertible Promissory Note dated July 2, 2019</u>

Table of Contents

[10.45\(21\)](#) [Convertible Promissory Note dated May 20, 2019](#)
[10.46\(21\)](#) [Promissory Note dated July 29, 2019](#)
[10.47*](#) [Convertible Note effective October 28, 2019](#)
[10.48*](#) [Sixth Amendment to Research and License Agreement effective December 31, 2019 between Yeda Research and Development Company Limited and Cell Source Limited**](#)

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 * Inline XBRL Instance Document

101.SCH * Inline XBRL Taxonomy Extension Schema Document

101.CAL * Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF * Inline XBRL Taxonomy Extension Definition Linkbase Document

101.LAB * Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE * Inline 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) Incorporated by reference to the Company's Form 10-K/A filed with the Securities and Exchange Commission on June 19, 2019.
- (20) Incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019.
- (21) Incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2019.

* Filed Herewith

** Certain information has been excluded from this exhibit because (i) it is not material and (ii) would be competitively harmful if publicly disclosed.

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 30, 2020

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	Dated: March 30, 2020
By: <u>/s/ Itamar Shimrat</u> Itamar Shimrat	Chief Executive Officer, Chief Financial Officer and Director (Principal Executive, Financial and Accounting Officer)	Dated: March 30, 2020
By: <u>/s/ Ben Friedman</u> Ben Friedman	Director	Dated: March 30, 2020
By: <u>/s/ David Zolty</u> David Zolty	Director	Dated: March 30, 2020

CELL SOURCE, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets as of December 31, 2019 and 2018</u>	F-2
<u>Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018</u>	F-3
<u>Consolidated Statements of Stockholders' Deficiency for the Years Ended December 31, 2019 and 2018</u>	F-4
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cell Source, Inc. (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders’ deficiency and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 audits 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 LLP

Marcum LLP

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

New York, New York

March 30, 2020

CELL SOURCE, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
Assets		
Current Assets:		
Cash	\$ 27,908	\$ 18,934
Prepaid expenses	57,196	38,926
Other current assets	29,679	7,932
Total Assets	<u>\$ 114,783</u>	<u>\$ 65,792</u>
Liabilities and Stockholders' Deficiency		
Current Liabilities:		
Accounts payable	\$ 135,415	\$ 277,786
Accrued expenses	1,051,961	532,790
Accrued expenses - related parties	195,334	72,000
Accrued interest	426,516	367,389
Accrued interest - related parties	146,491	82,642
Accrued compensation	603,520	566,293
Advances payable	235,500	100,000
Advances payable - related party	100,000	100,000
Notes payable, net of debt discount of \$1,292 and \$0, as of December 31, 2019 and 2018, respectively	1,111,708	1,463,000
Notes payable - related parties	150,000	150,000
Convertible notes payable - current portion, net of debt discount of \$1,467 and \$0, as of December 31, 2019 and 2018, respectively	966,533	835,000
Convertible notes payable - related parties	225,000	225,000
Derivative liabilities	351,900	200,500
Accrued dividend payable	11,846	13,563
Total Current Liabilities	<u>5,711,724</u>	<u>4,985,963</u>
Convertible notes payable - non-current portion	<u>145,000</u>	<u>-</u>
Total Liabilities	<u>5,856,724</u>	<u>4,985,963</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, 1,245,083 and 860,291 shares issued and outstanding as of December 31, 2019 and 2018, respectively; liquidation preference of \$9,349,969 and \$6,465,745 as of December 31, 2019 and 2018, respectively	1,245	860
Common Stock, \$0.001 par value, 200,000,000 shares authorized, 27,076,762 and 26,077,611 shares issued and		

outstanding as of December 31, 2019 and 2018, respectively	27,077	26,078
Additional paid-in capital	15,375,565	11,723,224
Accumulated deficit	<u>(21,145,828)</u>	<u>(16,670,333)</u>
Total Stockholders' Deficiency	<u>(5,741,941)</u>	<u>(4,920,171)</u>
Total Liabilities and Stockholders' Deficiency	<u>\$ 114,783</u>	<u>\$ 65,792</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,	
	2019	2018
Operating Expenses:		
Research and development	\$ 2,457,051	\$ 274,937
Research and development - related party	173,334	450,151
General and administrative	1,174,816	1,281,055
Total Operating Expenses	<u>3,805,201</u>	<u>2,006,143</u>
Loss From Operations	<u>(3,805,201)</u>	<u>(2,006,143)</u>
Other (Expense) Income:		
Interest expense	(228,842)	(219,122)
Interest expense - related parties	(64,135)	(49,875)
Amortization of debt discount	(14,970)	(181,299)
Amortization of debt discount - related parties	-	(28,356)
Change in fair value of derivative liabilities	146,700	485,500
Gain on exchange of accrued liabilities for warrants	-	73,100
Warrant modification expense	(283,500)	-
Loss on exchange of notes payable for Series A Convertible Preferred Stock	(262,470)	(191,251)
Loss on extinguishment of debt	(1,504)	-
Gain on forgiveness of accrued expenses	38,427	-
Total Other Expense	<u>(670,294)</u>	<u>(111,303)</u>
Net Loss	(4,475,495)	(2,117,446)
Dividend attributable to Series A preferred stockholders	(741,981)	(451,283)
Net Loss Applicable to Common Stockholders	<u>\$ (5,217,476)</u>	<u>\$ (2,568,729)</u>
Net Loss Per Common Share - Basic and Diluted	<u>\$ (0.18)</u>	<u>\$ (0.09)</u>
Weighted Average Common Shares Outstanding - Basic and Diluted	<u>28,328,575</u>	<u>27,549,867</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, 2019 AND 2018

	Convertible Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficiency
	Stock - Series A						
	Shares	Amount	Shares	Amount			
Balance, January 1, 2018	643,790	\$ 644	25,349,236	\$ 25,349	\$ 9,969,520	\$ (14,552,887)	\$ (4,557,374)
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	860,291	860	26,077,611	26,078	11,723,224	(16,670,333)	(4,920,171)

Issuance of Series A Convertible Preferred Stock for cash, net of offering expenses [1]	239,425	240	-	-	1,734,539	-	1,734,779
Issuance of Series A Convertible Preferred Stock in exchange for notes payable	145,367	145	-	-	1,090,109	-	1,090,254
Series A Convertible Preferred Stock dividends:							
Accrual of earned dividends	-	-	-	-	(741,981)	-	(741,981)
Payment of dividends in kind	-	-	991,651	991	742,706	-	743,697
Stock-based compensation:							
Options	-	-	-	-	825,100	-	825,100
Common stock	-	-	7,500	8	1,868	-	1,876
Net loss	-	-	-	-	-	(4,475,495)	(4,475,495)
Balance, December 31, 2019	<u>1,245,083</u>	<u>\$ 1,245</u>	<u>27,076,762</u>	<u>\$ 27,077</u>	<u>\$ 15,375,565</u>	<u>\$ (21,145,828)</u>	<u>\$ (5,741,941)</u>

[1] Includes gross proceeds of \$1,795,677, less issuance costs of \$60,898 (which includes cash costs of \$49,991 and accrued placement agent warrants with a fair value of \$10,907).

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,	
	2019	2018
Cash Flows From Operating Activities:		
Net loss	\$ (4,475,495)	\$ (2,117,446)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	(146,700)	(485,500)
Warrant modification expense	283,500	-
Amortization of debt discount	14,970	209,655
Loss on exchange of notes payable for Series A Convertible Preferred Stock	262,470	191,251
Gain on exchange of accrued liabilities for warrants	-	(73,100)
Loss on extinguishment of debt	1,504	-
Gain on forgiveness of accrued expenses	(38,427)	-
Non-cash interest expense - warrants	96,751	57,262
Stock-based compensation:		
Common Stock	4,397	(22,500)
Options	825,100	-
Warrants	14,631	3,300
Changes in operating assets and liabilities:		
Prepaid expenses	(18,270)	85,767
Other current assets	(21,747)	28,004
Accounts payable	(142,371)	75,962
Accrued expenses	385,682	(24,955)
Accrued expenses - related parties	123,334	-
Accrued interest	192,864	97,201
Accrued interest - related parties	3,000	14,250
Accrued compensation	47,595	(41,265)
Net Cash Used In Operating Activities	<u>(2,587,212)</u>	<u>(2,002,114)</u>
Cash Flows From Financing Activities:		
Proceeds from issuance of notes payable	120,000	500,000
Proceeds from issuance of convertible notes payable	665,000	-
Proceeds from advances payable	275,500	-
Proceeds from advances payable - related party	-	100,000
Repayment of advances payable	(140,000)	-
Repayment of notes payable	(70,000)	-
Proceeds from issuance of Series A Preferred Stock	1,795,677	1,050,000
	(49,991)	-
Net Cash Provided By Financing Activities	<u>2,596,186</u>	<u>1,650,000</u>
Net Increase (Decrease) In Cash	8,974	(352,114)

Cash - Beginning of Year	<u>18,934</u>	<u>371,048</u>
Cash - End of Year	<u>\$ 27,908</u>	<u>\$ 18,934</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid for:		
Interest	<u>\$ -</u>	<u>\$ 18,030</u>
Income taxes	<u>\$ -</u>	<u>\$ -</u>
Non-cash investing and financing activities:		
Preferred stock issued in exchange for notes and advances payable	<u>\$ 10,907</u>	<u>\$ -</u>
Repayment of convertible note payable and accrued interest by third party	<u>\$ 133,488</u>	<u>\$ -</u>
Accrual of earned preferred stock dividends	<u>\$ 741,981</u>	<u>\$ 451,283</u>
Common stock issued in connection with payment of Series A Convertible Preferred Stock dividends in-kind	<u>\$ 743,697</u>	<u>\$ 546,281</u>
Warrants and conversion options issued in connection with issuance and extension of notes payable	<u>\$ 15,600</u>	<u>\$ 57,800</u>
Warrants issued in satisfaction of accrued liabilities	<u>\$ -</u>	<u>\$ 35,900</u>
Original issue discount in connection with convertible note payable	<u>\$ 6,000</u>	<u>\$ -</u>
Extinguishment of conversion option in connection with repayment of notes payable	<u>\$ 1,000</u>	<u>\$ -</u>

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, 2019 and 2018, the Company had not generated any revenues, had recurring net losses of approximately \$4,475,000 and \$2,117,000, respectively, and used cash in operations of approximately \$2,587,000 and \$2,002,000, respectively. As of December 31, 2019, the Company had a working capital deficiency of \$5,597,000 and an accumulated deficit of approximately \$21,146,000. Subsequent to December 31, 2019 and as more fully described in Note 13, *Subsequent Events*, the Company received aggregate proceeds of \$578,000 from convertible notes payable and \$100,000 through the sale of 13,333 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.

[Table of Contents](#)

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 judgements 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 and contingencies. 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, 2019 and 2018, 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, 2019, 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.

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. Any warrants granted after this date were determined to be and were recorded as derivative liabilities.

[Table of Contents](#)

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, a wholly owned Israeli subsidiary. The Company is subject to federal and New York state and city income taxes in the United States and federal income taxes in the State of Israel.

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 such 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.

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. No tax related interest or penalties were incurred during the years ended December 31, 2019 and 2018.

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.

[Table of Contents](#)

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. The fair value of the award is measured on the grant date and 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 considered in management's estimation of fair value during the years ended December 31, 2019 and 2018. The Company, in estimating the fair value of its common stock as of December 31, 2019, 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, 2019 and (b) the Company continued to raise capital during the year ended December 31, 2019 at the same valuation as the capital raised during the year ended December 31, 2018. 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 \$18,000 and \$3,000 of transaction losses for the years ended December 31, 2019 and 2018, 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, 2019 and 2018 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:

	December 31,	
	2019	2018
Options	3,782,004	-
Warrants	4,059,157	11,414,818

Convertible notes	1,855,778	1,564,110
Convertible preferred stock	<u>12,450,830</u>	<u>8,602,910</u>
Total	<u>22,147,769</u>	<u>21,581,838</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, 2019. 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.

[Table of Contents](#)

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, 2019, the exchange rate between the U.S. Dollar and the New Israeli Shekel was 1 to 3.46 and the weighted average exchange rate for the year then ended was 1 to 3.57. 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.

Reclassifications

Certain prior period accrued liabilities have been reclassified from accrued compensation to accrued interest to conform to the fiscal 2019 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 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 December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021. The Company is currently evaluating ASU 2019-12 and its impact financial position, results of operations, and cash flows.

Recently Adopted Accounting Standards

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 adopted ASU 2018-07 effective July 1, 2019 and its adoption did not have a material impact on the Company's 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 was effective in annual periods beginning after December 15, 2018. The Company adopted this standard on January 1, 2019 and its adoption did not have a material impact on the Company’s financial position, results of operations or cash flows.

Note 4 – Fair Value

The following table summarizes the Company’s instruments recorded at fair value as of December 31, 2019 and 2018:

	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	\$ 40,021	\$ -	\$ -	\$ 40,021
Accrued compensation - warrants	17,931	-	-	17,931
Accrued interest - warrants	57,343	-	-	57,343
Accrued interest - warrants - related party	115,932	-	-	115,932
Derivative liabilities	<u>351,900</u>	<u>-</u>	<u>-</u>	<u>351,900</u>
Balance - December 31, 2019	<u><u>\$ 583,127</u></u>	<u><u>\$ -</u></u>	<u><u>\$ -</u></u>	<u><u>\$ 583,127</u></u>
Accrued compensation - common stock	\$ 37,500	\$ -	\$ -	\$ 37,500
Accrued compensation - warrants	3,300	-	-	3,300
Accrued interest - warrants	21,441	-	-	21,441
Accrued interest - warrants - related party	55,083	-	-	55,083
Derivative liabilities	<u>200,500</u>	<u>-</u>	<u>-</u>	<u>200,500</u>
Balance - December 31, 2018	<u><u>\$ 317,824</u></u>	<u><u>\$ -</u></u>	<u><u>\$ -</u></u>	<u><u>\$ 317,824</u></u>

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.

In applying the Black-Scholes option pricing model utilized in the valuation of Level 3 liabilities, the Company used the following approximate assumptions:

	For the Years Ended December 31,	
	<u>2019</u>	<u>2018</u>
Risk-free interest rate	1.17% - 2.44%	1.73% - 2.91%
Expected term (years)	0.02 - 5.00	0.08 - 5.00

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.

[Table of Contents](#)

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, 2019 and 2018:

	<u>Accrued Interest</u>	<u>Accrued Compensation</u>	<u>Derivative Liability</u>	<u>Total</u>
Balance - December 31, 2017	\$ 19,262	\$ 60,000	\$ 628,200	\$ 707,462
Issuance of warrants and conversion options	-	-	57,800	57,800
Accrued compensation - warrants	-	3,300	-	3,300
Accrued interest - warrants	21,000	-	-	21,000
Accrued interest - warrants - related party	36,000	-	-	36,000
Change in fair value	<u>262</u>	<u>(22,500)</u>	<u>(485,500)</u>	<u>(507,738)</u>
Balance - December 31, 2018	76,524	40,800	200,500	317,824
Issuance of warrants and conversion options	-	-	15,600	15,600
Extinguishment of conversion option	-	-	(1,000)	(1,000)
Warrant modification	-	-	283,500	283,500
Accrued compensation - common stock	-	2,521	-	2,521
Accrued compensation - warrants	-	14,662	-	14,662
Accrued interest - warrants	36,098	-	-	36,098
Accrued interest - warrants - related party	61,361	-	-	61,361
Change in fair value	<u>(708)</u>	<u>(31)</u>	<u>(146,700)</u>	<u>(147,439)</u>
Balance - December 31, 2019	<u>\$ 173,275</u>	<u>\$ 57,952</u>	<u>\$ 351,900</u>	<u>\$ 583,127</u>

As of December 31, 2019, the Company had an obligation to issue 160,083 shares of common stock to service providers. The shares had a fair value of \$40,021, which was a component of accrued compensation on the consolidated balance sheet.

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>2019</u>	<u>2018</u>
Accrued research and development	\$ 644,445	\$ 302,433
Accrued third-party payments	133,488	-
Accrued legal fees	123,417	122,351

Accrued other professional fees	115,245	70,399
Accrued director compensation	9,750	12,000
Other accrued expenses	25,616	25,607
Total accrued expenses	<u>\$ 1,051,961</u>	<u>\$ 532,790</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:

	December 31,	
	2019	2018
Withholding tax	\$ 118,017	\$ 116,401
Social security	36,945	34,825
Stock-based compensation - common stock	40,021	37,500
Stock-based compensation - warrants	17,931	3,300
Pension insurance	157,562	117,897
Accrued payroll	65,979	98,505
Vacation	51,565	46,808
Severance	115,500	111,057
Total accrued compensation	<u>\$ 603,520</u>	<u>\$ 566,293</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, 2019 and through the date of this filing, notes payable with principal amounts totaling \$1,983,000 and \$1,888,000, respectively, were past due and are classified as current liabilities on the consolidated balance sheet as of December 31, 2019. Such notes continue to accrue interest and all relevant penalties have been accrued as of December 31, 2019. 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, 2019 and 2018, the Company recorded interest expense of \$292,977 and \$268,997, respectively, and amortization of debt discount of \$14,970 and \$209,655, respectively. As of December 31, 2019 and 2018, the Company had \$573,007 and \$450,031, respectively, of accrued interest (including interest in the form of warrants (see Note 4)) and penalties related to notes payable, which is included with accrued interest and accrued interest – related parties on the consolidated balance sheets.

a) Notes payable consist of the following:

	December 31,	
	2019	2018
i) Notes issued on March 26, 2015	\$ 500,000	\$ 500,000
ii) Note issued on May 15, 2015	250,000	250,000
iii) Notes issued on March 8, 2016	-	-
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	160,000	160,000
vi) Notes issued on February 21, 2018	-	400,000
vii) Note issued on February 26, 2018	100,000	100,000
viii) Note issued on May 15, 2019	-	-
ix) Note issued on July 29, 2019, net of debt discount of \$1,292 as of December 31, 2019	50,000	-
	<u>\$ 1,113,000</u>	<u>\$ 1,463,000</u>

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

- i) 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.
- iii) On December 12, 2018, the holder of a 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.
- vi) 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.

On March 31, 2019, holders of notes with aggregate principal amounts of \$400,000 and aggregate late payment penalties of \$40,000 exchanged those notes for 70,400 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 \$88,000 was recorded in the consolidated statement of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

- vii) 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.

viii) On May 15, 2019, the Company issued a note payable in the principal amount of \$70,000. The note did not accrue interest and matured on May 25, 2019. In connection with the note issuance, the Company issued a five-year immediately vested warrant for the purchase of 35,000 shares of common stock at \$0.75 per share. The warrant had an issuance date fair value of \$5,800, which was recorded as a debt discount and was amortized over the term of the note.

The note was repaid in full on May 22, 2019.

ix) On July 29, 2019, the Company issued a note payable in the principal amount of \$50,000. The note does not accrue interest and matured on January 29, 2020. In connection with the note issuance, the Company issued to the noteholder a five-year immediately vested warrant for the purchase of 50,000 shares of common stock at \$0.75 per share. The warrant had an issuance date fair value of \$8,200, which was recorded as a debt discount and was amortized over the term of the note.

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

	December 31,	
	2019	2018
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,	
	2019	2018
i) Convertible notes issued on July 24, 2015	\$ 145,000	\$ 145,000
ii) Convertible notes issued on October 7, 2015	265,000	265,000
iii) Convertible notes issued on various dates from January 6, 2016 to March 15, 2016	-	290,000
iv) Convertible notes issued on May 18, 2017	135,000	135,000
v) Convertible note issued on May 20, 2019	-	-
vi) Convertible note issued on July 2, 2019, net of debt discount of \$1,467 as of December 31, 2019	68,000	-
vii) Convertible note issued on October 28, 2019	500,000	-
	<u>\$ 1,113,000</u>	<u>\$ 835,000</u>

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

- i) See Note 13, *Subsequent Events – Convertible Notes Payable*, for details associated with the extension of these convertible notes.
- iii) On March 31, 2019, holders of notes with aggregate principal amounts of \$290,000 and aggregate accrued interest of \$97,784 exchanged those notes for 74,967 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 6, *Stockholders' Deficiency - Series A Convertible Preferred Stock*, this difference of \$174,470 was recorded in the consolidated statements of operations as a loss on exchange of notes payable for Series A Convertible Preferred Stock.
- iv) As of December 31, 2019, the Company had accrued an obligation to issue warrants to purchase 148,500 shares of common stock at an exercise price of \$0.75 per share as a result of the Company's failure to repay these notes on the May 18, 2018 maturity date. As a result, the Company had accrued an aggregate of \$21,242 associated with the fair value of these obligations as of December 31, 2019, which amount is included in accrued interest on the consolidated balance sheet.
- v) On May 20, 2019, the Company issued a convertible note payable in the principal amount of \$103,000 for cash proceeds of \$100,000 which matured on November 20, 2019. The note accrues interest at 8% per annum, of which, twelve months of interest was guaranteed. The note also includes certain prepayment penalties that provide for payments ranging from 115% to 140% of the then outstanding principal and interest. The note is convertible at the option of the holder into common stock at either (i) \$0.75 per share or (ii) in the event of a default, at 75% of the volume-weighted average price in the ten consecutive trading

days prior to the conversion date. The conversion option had an issuance date fair value of \$1,600 and, together with the original issuance discount of \$3,000, was recorded as a debt discount and was amortized to expense over the term of the note. In accordance with the Company's sequencing policy, this conversion option was determined to be a derivative liability.

On June 27, 2019, a third-party repaid the note in full on behalf of the Company, which payment included a 20% prepayment penalty for an aggregate total payment of \$133,488, which has been recorded as accrued expenses on the Company's consolidated balance sheet as of December 31, 2019. The Company determined the transaction was a note extinguishment and recorded a loss on extinguishment of debt of \$1,504 in the consolidated statements of operations.

Table of Contents

- vi) On July 2, 2019, the Company issued a convertible note payable in the principal amount of \$68,000. The note accrues interest at 12% per annum and matures on July 2, 2020 and any amount of principal or interest which is not paid at maturity shall accrue interest at 22% per annum. The note also includes certain prepayment penalties that provide for payments ranging from 115% to 140% of the then outstanding principal and interest. The note is convertible at the option of the holder into common stock at 61% of the lowest trading price during the ten consecutive trading days prior to the conversion date at any time during the period which is 180 days following the issuance date of the convertible note and ending on the later of (i) July 2, 2020 or (ii) in the event of default, the date of the payment of the default amount. The convertible note contained an original issuance discount of \$3,000 which was recorded as a debt discount and will be amortized to expense over the term of the note. See Note 13, *Subsequent Events – Convertible Notes Payable*, for details associated with the prepayment of this convertible note.
- vii) On October 28, 2019, the Company issued a convertible note payable in the aggregate principal amount of \$1,500,000 and received initial proceeds of \$500,000 on the same date. The Company expects to receive the remaining \$1,000,000 during the four-month period following the issuance date. The note accrues interest at 8% per annum and matures on October 31, 2020. After the Company sells shares of its Series B Convertible Preferred Stock, the note becomes convertible at the option of the holder at any time at a conversion price equal to the price paid by the investors in the Company’s offering of Series B Convertible Preferred Stock. In the event that the Company is awarded a grant by the Cancer Prevention and Research Institute of Texas (“CPRIT Grant”) and the lender has converted all or a portion of the note into Series B Convertible Preferred Stock, then the lender will have the option to purchase, at an exercise price of \$1.25 per share, a number of shares of the Company’s common stock that shall be determined by multiplying 7,400,000 by a fraction, the numerator of which shall be the number of shares of Series B Convertible Preferred Stock owned by the lender and the denominator of which shall be 666,666. The Company shall provide written notice to the lender of each funding of the CPRIT Grant and the option must be exercised by the holder within thirty (30) days after the receipt of such notice. As of the date of issuance of the note and through December 31, 2019 as well as through the date of filing, the Series B Convertible Preferred Stock had not been designated by the Board nor had the Company sold shares of its Series B Convertible Preferred Stock. As a result, the Company did not analyze the note’s embedded conversion option as the definition of a firm commitment had not been met since the notes was not convertible as of its date of issuance or as of December 31, 2019.

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

	December 31,	
	2019	2018
Convertible notes issued on May 18, 2017	<u>\$ 225,000</u>	<u>\$ 225,000</u>

- i) As of December 31, 2019, the Company had accrued an obligation to issue warrants to purchase 49,500 and 198,000 shares of common stock at an exercise price of \$0.75 per share as a result of the Company’s failure to repay these notes on the May 18, 2018 maturity date. As a result, the Company had accrued an aggregate of \$35,403 associated with the fair value of these obligations as of December 31, 2019, which amount is included in accrued interest – related parties on the consolidated balance sheet.

Note 9 – Income Taxes

The loss before income taxes consists of the following US and Israeli components:

	For the Years Ended	
	December 31,	
	2019	2018
United States	\$(4,014,647)	\$(1,133,751)

Israel	<u>(460,848)</u>	<u>(983,695)</u>
Loss before income taxes	<u>\$ (4,475,495)</u>	<u>\$ (2,117,446)</u>

[Table of Contents](#)

The provision for income taxes consists of the following expenses (benefits):

	For the Years Ended December 31,	
	2019	2018
Deferred tax benefit:		
Federal	\$ (836,320)	\$ (403,587)
Foreign	(105,994)	(226,000)
US State and local	(474,635)	(87,413)
	(1,416,949)	(717,000)
Change in valuation allowance	1,416,949	717,000
Provision for income taxes	<u>\$ -</u>	<u>\$ -</u>

The provision for income taxes differs from the United States federal statutory rate as follows:

	For the Years Ended December 31,	
	2019	2018
Tax expense at the federal statutory rate	(21.0%)	(21.0%)
State taxes, net of federal benefit	(11.7%)	(11.3%)
Statutory rate differential - domestic versus foreign	(0.2%)	4.3%
Permanent differences:		
Change in fair value of derivatives	(1.1%)	(7.4%)
Warrant modification expense	2.2%	0.0%
Loss on exchange of notes payable for preferred stock	2.0%	2.9%
Gain on forgiveness of debt	(0.3%)	0.0%
Other	0.0%	(0.2%)
Research and development tax credits	(1.6%)	0.0%
Other	0.0%	(1.2%)
Change in valuation allowance	31.7%	33.9%
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

Deferred tax assets consist of the following:

	As of December 31,	
	2019	2018
Net operating loss carryforwards	\$ 5,676,425	\$ 4,536,000
Stock-based compensation	343,342	26,000
Deferred foreign research and development expenses	113,845	224,000
Research and development tax credits	69,337	-
Deferred tax assets	6,202,949	4,786,000
Valuation allowance	(6,202,949)	(4,786,000)
Deferred tax assets, net	<u>\$ -</u>	<u>\$ -</u>

As of December 31, 2019, the Company had approximately \$8,071,000 of domestic federal, state and local net operating loss carryforwards ("NOLs") that may be available to offset future taxable income in that jurisdiction. Approximately \$3,832,000 of those NOLs will expire during the years ranging from 2034 to 2037. The balance of approximately \$4,239,000 has no expiration dates for federal and local purposes, but expires in 2038 to 2039 for state purposes. The utilization of NOLs to offset future taxable income may be subject to annual limitations under Internal Revenue Code Section 382 and similar state and local statutes as a result of ownership changes that could occur in the future. As of December 31, 2019, the Company had approximately \$13,148,000 of Israeli NOLs that may be available to offset future taxable income in that jurisdiction. Those NOLs have no expiration dates.

Table of Contents

The Company has assessed the likelihood that deferred tax assets will be realized in accordance with the provisions of ASC 740 *Income Taxes* ("ASC 740"). ASC 740 requires that such a review considers all available positive and negative evidence, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. ASC 740 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. After the performance of such reviews as of December 31, 2019 and 2018, 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 those dates. Thus, the Company increased the valuation allowance by \$1,416,949 and \$717,000 during the years ended December 31, 2019 and 2018, respectively.

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, 2019 and 2018. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

The Company has not filed its US federal, state, and local tax returns for the years ended December 31, 2016 through 2019 and its Israeli tax returns for the years ended December 31, 2014 through 2019. No tax audits were commenced or were in process during the years ended December 31, 2019 and 2018.

Note 10 – Stockholders' Deficiency

Authorized Capital

As of December 31, 2019, 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 December 24, 2019, the Company issued 7,500 shares of immediately-vested common stock to a service provider in connection with consulting services provided. The shares had a fair value of \$1,876, which was recognized immediately.

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

The Board of Directors extended the expiration date of the Private Placement Memorandum ("PPM"), under which the Company continues to raise up to \$10,000,000 via the sale of up to 1,333,333 shares of Series A Convertible Preferred Stock at \$7.50 per share, on various dates in 2019, the latest of which occurred on November 27, 2019 when the Board of Directors further extended the expiration date of the PPM to January 28, 2020. See Note 13, *Subsequent Events* for additional details.

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.

Table of Contents

On March 31, 2019, in connection with the exchange of various notes payable, accrued interest and late payment penalties totaling \$827,784, the Company issued 145,367 shares of Series A Convertible Preferred Stock under the terms of the PPM with a total value of \$1,090,254, as more fully described in Note 8, *Notes Payable*. As the value of those shares exceeded the carrying value of the note payable, accrued interest and late payment penalties, the difference of \$262,470 was recorded in the consolidated statement of operations during the year ended December 31, 2019 as a loss on exchange of notes payable for Series A Convertible Preferred Stock.

During the year ended December 31, 2019, the Company sold an aggregate of 239,425 shares of Series A Convertible Preferred Stock at \$7.50 per share for aggregate gross proceeds of \$1,795,677, less issuance costs of \$68,898 (which includes cash costs of \$49,991 and accrued placement agent warrants with a fair value of \$10,907 which are included in accrued compensation as of December 31, 2019), such that the net proceeds were an aggregate of \$1,734,779.

As of January 1, 2018, there was an accrued dividend payable of \$108,562. During the year ended December 31, 2018, the Company accrued additional preferred dividends of \$451,283 and issued 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 with a value of \$546,281, such that there was an accrued dividend payable as of December 31, 2018 of \$13,563. During the year ended December 31, 2019, the Company accrued additional preferred dividends of \$741,981 and issued 991,651 shares of common stock at \$0.75 per share pursuant to the terms of the Series A Convertible Preferred Stock Certificate of Designation with a value of \$743,697, such that there was an accrued dividend payable as of December 31, 2019 of \$11,846.

Equity Incentive Plan

On August 13, 2019, the Company's Board of Directors approved the adoption of the Company's 2019 Equity Incentive Plan (the "Plan"). A total of 7,900,000 shares of common stock are reserved for issuance under the Plan, which permits the Board of Directors to issue stock options, stock appreciation rights, restricted stock, restricted stock units, performance and other awards to employees, consultants and directors of the Company.

Stock-Based Compensation

During the years ended December 31, 2019 and 2018, the Company recognized stock-based compensation expense of \$844,128 (consisting of expense related to common stock, options and warrants of \$4,397, \$825,100 and \$14,631, respectively) and a benefit of \$19,200 (consisting of expense related to warrants of \$3,300 and a benefit related to common stock of \$22,500), respectively. During the year ended December 31, 2019, \$825,100 of stock-based compensation expense was included within research and development expenses and \$19,028 was included within general and administrative expenses on the consolidated statement of operations. During the year ended December 31, 2018, the stock-based compensation benefit of \$19,200 was included within general and administrative expenses on the consolidated statement of operations. As of December 31, 2019, there was no unrecognized stock-based compensation expense.

Stock Warrants

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

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)(vi), *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)(vii), *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.

On June 25, 2019, the Company extended the expiration date of a warrant to purchase 1,600,000 shares of common stock at an exercise price of \$0.75 per share originally from June 27, 2019 to June 27, 2023.

On July 20, 2019, the Company extended the expiration dates of certain warrants to purchase an aggregate of 377,500 shares of common stock at an exercise price of \$0.75 per share from July 2019 to July 2023.

As a result of the above modifications during the year ended December 31, 2019, the Company recognized warrant modification expense of \$283,500 during the year ended December 31, 2019.

[Table of Contents](#)

A summary of the warrant activity during the year ended December 31, 2019 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, January 1, 2019	13,458,653	\$ 0.64		
Granted	85,000	0.75		
Exercised	-	-		
Expired	(7,440,661)	0.75		
Outstanding, December 31, 2019	<u>6,102,992</u>	<u>\$ 0.50</u>	<u>1.9</u>	<u>\$ 508,915</u>
Exercisable, December 31, 2019	<u>6,102,992</u>	<u>\$ 0.50</u>	<u>1.9</u>	<u>\$ 508,915</u>

Information regarding outstanding and exercisable warrants at December 31, 2019 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	0.9	2,043,835
\$ 0.750	4,059,157	2.4	4,059,157
	<u>6,102,992</u>	1.9	<u>6,102,992</u>

Stock Options

On August 13, 2019, the Board of Directors approved the grant under the Plan of ten-year stock options to purchase an aggregate of 3,782,004 shares of common stock at an exercise price of \$0.75 per share to a consultant of the Company. The shares vested immediately on the date of grant. The stock options had a grant date fair value of \$825,100, which the Company recognized immediately on the date of grant.

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following approximate assumptions:

	For the Years Ended December 31,	
	2019	2018
Risk-free interest rate	1.68%	n/a
Expected term (years)	10.00	n/a
Expected volatility	110%	n/a
Expected dividends	0.00%	n/a

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.

[Table of Contents](#)

The weighted average estimated grant date fair value of the stock options granted for the year ended December 31, 2019 was approximately \$0.22 per share.

A summary of the option activity during the year ended December 31, 2019 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, January 1, 2019	-	\$ -		
Granted	3,782,004	0.75		
Exercised	-	-		
Expired/forfeited	-	-		
Outstanding, December 31, 2019	<u>3,782,004</u>	<u>\$ 0.75</u>	<u>9.6</u>	<u>\$ -</u>
Exercisable, December 31, 2019	<u>3,782,004</u>	<u>\$ 0.75</u>	<u>9.6</u>	<u>\$ -</u>

Note 11 – Commitments and Contingencies

Yeda 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, for research conducted at the Weizmann Institute 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, 2019, the Company has made all required payments under the terms of the amended agreement.

In connection with Amendments No. 5 and 6 to the Agreement, the latest of which was dated December 31, 2019, the research conducted (“Further Research”) under the Agreement was extended to cover the period from July 1, 2019 to March 31, 2020 and the associated research budget for this period shall be a total of \$185,000 which is payable on January 1, 2020. As of the date of filing, the payment had not been made by the Company.

During the years ended December 31, 2019 and 2018, the Company recorded research and development expenses of approximately \$173,000 and \$450,000, respectively, related to this Agreement. As of December 31, 2019 and 2018, the Company had \$123,334 and \$0, respectively, of accrued research and development expenses pursuant to the agreements with Yeda, which are included within accrued expenses on the consolidated balance sheet.

[Table of Contents](#)

MD Anderson Sponsored Research Agreements

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.

On February 19, 2019, the Company entered into an agreement, which was amended on April 4, 2019 and August 13, 2019, with The University of Texas M.D. Anderson Cancer Center (“MD Anderson”) for the latter to perform cell production and conduct Phase 1/2 human clinical trials. In connection with that agreement, the Company committed to fund such work in the amount of approximately \$2,038,000 over a two-year period beginning that same date, with payments becoming due as certain specified milestones are met by MD Anderson.

The Company recognized \$1,355,358 and \$0 of research and development expenses during the years ended December 31, 2019 and 2018, respectively, associated with services provided by MD Anderson, under the two agreements dated November 2018 and February 2019. As of December 31, 2019, the Company had \$382,398 of accrued research and development expenses pursuant to the agreements with MD Anderson, which are included within accounts payable and accrued expenses on the consolidated balance sheet.

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.

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 July 12, 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, 2019 and 2018, the Company has not accrued any amounts for contingencies.

[Table of Contents](#)

Note 12 – Related Party Transactions

See Note 8, *Notes Payable* and Note 11, *Commitments and Contingencies* for additional details associated with the Company's related party transactions.

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, 2019. Because the short-term advance was not repaid by the Company on or before January 15, 2019, the Company is required under the terms of the advance to (i) issue the director warrants to purchase 100,000 shares of common stock on such date (ii) to further issue warrants to purchase 25,000 shares of common stock for each month that the advance remains outstanding after such date. As of December 31, 2019, the Company was required to issue warrants to purchase an aggregate of 375,000 shares at an exercise price of \$0.75 per share to the director in connection with this advance. As a result, the Company had accrued \$61,361 associated with the fair value of the obligation as of December 31, 2019, which amount is included in accrued interest – related parties on the consolidated balance sheet.

On January 7, 2019, the Company received proceeds of \$50,000 from the Chairman of the Board through the sale of 6,667 shares of Series A Convertible Preferred Stock at \$7.50 per share, which amount is included in the issuances disclosed in Note 10, *Stockholders' Deficiency*.

The Company had agreed to issue warrants to purchase 134,000 shares of common stock at an exercise price of \$0.75 per share to a director of the Company in consideration of the director making a \$134,000 payment to Yeda on the Company's behalf in 2016. As of December 31, 2019, the Company had not issued the warrants to the director and, accordingly, the Company had accrued \$19,168 associated with the fair value of the obligation as of December 31, 2019, which amount is included in accrued interest – related parties on the consolidated balance sheet.

Note 13 – Subsequent Events

Series A Convertible Preferred Stock

On various dates from January 14, 2020 through January 24, 2020, the Company received proceeds of \$100,000 through the sale of 13,333 shares of Series A Convertible Preferred Stock at \$7.50 per share.

On January 29, 2020, the Board of Directors extended the expiration date of the PPM to March 31, 2020 and has authorized two sixty-day extensions beyond that date at management's discretion, under which the Company continues to raise up to \$10,000,000 via the sale of up to 1,333,333 shares of Series A Convertible Preferred Stock at \$7.50 per share.

On March 25, 2020, the Board of Directors extended the expiration date of the PPM to May 30, 2020.

Convertible Notes Payable

On January 3, 2020, the Company fully prepaid principal and interest of \$68,000 and \$32,896, respectively, of a convertible note as more fully described in Note 8(c)(vi), *Notes Payable*.

On January 10, 2020, the Company issued a convertible note payable in the principal amount of \$78,000. The note accrues interest at 12% per annum and matures on January 10, 2021.

On various dates from February 20, 2020 through February 24, 2020, the maturity date of three convertible notes in the aggregate principal amount of \$145,000, was extended to February 15, 2021. In connection to these extensions, the Company agreed to issue an aggregate of 227,500 shares of common stock and amended the conversion price of these three convertible notes to a minimum of \$0.75 per share.

On March 2, 2020, the Company received further proceeds of \$500,000 through a previously issued convertible note as more fully described in Note 8(c)(vii), *Notes Payable*.

