# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

# CLEVELAND BIOLABS INC

## Form: 10-K

## Date Filed: 2021-03-22

Corporate Issuer CIK: 1318641

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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 10-K

**(Mark One)**

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
**For the fiscal year ended December 31, 2020**
**or**

☐ **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 001-32954**

# CLEVELAND BIOLABS, INC.

**(Exact name of registrant as specified in its charter)**

| **DELAWARE** | **20-0077155** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **73 High Street, Buffalo, NY 14203** | **(716) 849-6810** |
| **(Address of principal executive offices)** | **Telephone No.** |

**Securities Registered Pursuant to Section 12(b) of the Act:**

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| **Common Stock, par value $0.005 per share** | **CBLI** | **NASDAQ Capital Market** |

**Securities Registered Pursuant to Section 12(g) of the Act:**
**None**

Indicate by check mark if 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 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, smaller reporting company or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
The aggregate market value of the voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2020, was $33,224,929. There were 15,468,945 shares of common stock outstanding as of March 1, 2021.

**Cleveland BioLabs, Inc.**

**Form 10-K**

**For the Fiscal Year Ended December 31, 2020**

**INDEX**

## FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements give our current expectations of forecasts of future events. All statements other than statements of current or historical fact contained in this annual report, including statements regarding our future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals or the impact of any laws or regulations applicable to us, and plans and objectives of management for future operations, are forward-looking statements. The words "anticipate," "believe," "continue," "should," "estimate," "expect," "intend," "may," "plan," "project," "will," and similar expressions, as they relate to us, are intended to identify forward-looking statements.*

*We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual future results may differ materially from those discussed here for various reasons. Factors that could contribute to such differences include, but are not limited to:*

- *the risk that the proposed merger with Cytocom, Inc. (" **Cytocom**") may not be completed in a timely manner or at all, which may adversely affect the Company's business and the price of the Company's common stock;*
- *the failure of either the Company or Cytocom to satisfy any of the conditions to the consummation of the proposed merger, including the approval of the Company's stockholders;*
- *uncertainties as to the timing of the consummation of the proposed merger;*
- *the occurrence of any event, change or circumstance that could give rise to the termination of the merger agreement;*
- *the effect of the announcement or pendency of the proposed merger on the Company's business relationships, operating results and business generally;*
- *risks that the proposed merger disrupts current plans an operations;*
- *risks related to diverting management's attention from the Company's ongoing business operations;*
- *the outcome of any legal proceedings that may be instituted against the Company related to the merger agreement or the proposed merger;*
- *unexpected costs, charges or expenses resulting from the proposed merger;*
- *our need for additional financing to meet our business objectives;*
- *our history of operating losses;*
- *our ability to successfully develop, obtain regulatory approval for, and commercialize our products in a timely manner;*
- *our plans to research, develop and commercialize our product candidates;*
- *our ability to attract collaborators with development, regulatory and commercialization expertise;*
- *our plans and expectations with respect to future clinical trials and commercial scale-up activities;*
- *our reliance on third-party manufacturers of our product candidates;*
- *the size and growth potential of the markets for our product candidates, and our ability to serve those markets;*
- *the rate and degree of market acceptance of our product candidates;*
- *regulatory requirements and developments in the United States, the European Union and foreign countries;*
- *the performance of our third-party suppliers and manufacturers;*
- *the success of competing therapies that are or may become available;*
- *our ability to attract and retain key scientific or management personnel;*
- *our reliance on government funding for a significant portion of our operating costs and expenses;*
- *government contracting processes and requirements;*
- *the exercise of control over our company by our largest stockholder;*
- *our potential inability to remain in compliance with the continued listing requirements of the NASDAQ Capital Market;*
- *the geopolitical relationship between the United States and the Russian Federation, as well as general business, legal, financial and other conditions within the Russian Federation;*
- *our ability to obtain and maintain intellectual property protection for our product candidates;*
- *our potential vulnerability to cybersecurity breaches; and*
- *the other factors discussed below in "Item 1A. "Risk Factors," in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other filings we make with the Securities and Exchange Commission.*

*Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included*

*in this report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.*

## PART I

### Item 1. Business

*When used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, the terms "**Cleveland BioLabs**," the "**Company**," "**CBLI**," "**we**," "**us**," and "**our**" refer to Cleveland BioLabs, Inc. and its consolidated subsidiaries, BioLab 612, LLC and Panacela Labs, Inc.*

### GENERAL OVERVIEW

Cleveland BioLabs is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives.

**Entolimod,** a Toll-like receptor 5 ("**TLR5**") agonist, which we are developing as a medical radiation countermeasure ("**MRC**") for reducing the risk of death following exposure to potentially lethal irradiation Acute Radiation Syndrome ("**ARS**") is our most advanced product candidate. Other indications, including immunotherapy for oncology, have been or are being investigated as well.

Entolimod as a MRC is being developed under the United States Food & Drug Administration's ("**FDA's**" or "**Agency's**") Animal Efficacy Rule (the "**Animal Rule**") for the indication of reducing the risk of death following exposure to potentially lethal irradiation occurring as a result of a radiation disaster (see " - *Government Regulation - Animal Rule*"). We believe that entolimod is the most efficacious MRC currently in development. The following is a summary of the clinical development of entolimod as an MRC to date and its related regulatory status.

We have completed two Good Clinical Practices ("**GCP**") clinical studies designed to evaluate the safety, pharmacokinetics and pharmacodynamics of entolimod in a total of 150 healthy subjects. We have completed a Good Laboratory Practices ("**GLP**"), randomized, blinded, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on survival and biomarker induction in 179 non-human primates exposed to 7.2 Gy total body irradiation when entolimod or a placebo was administered at 25 hours after radiation exposure. We have also completed a GLP, randomized, open-label, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on biomarker induction in 160 non-irradiated non-human primates.

In 2015, following confirmation from the FDA on the sufficiency of our existing efficacy and safety data and animal-to-human dose conversion, we submitted to the FDA an application for pre-Emergency Use Authorization ("**pre-EUA**"), a form of authorization granted by the FDA under certain circumstances (see " - *Government Regulation - Emergency Use Authorization*"). As part of the Company's response to pre-EUA review, comments received from the FDA, we met with the Agency in the first quarter of 2016 to discuss various aspects of entolimod manufacturing. The Agency specified that the Company needed to establish comparability between the drug formulation used in previously conducted preclinical and clinical studies and the entolimod drug formulation proposed for commercialization under the pre-EUA. The FDA also indicated that further review of the pre-EUA dossier would not proceed until these comparability data have been evaluated by the Agency.

To establish the comparability of the older formulation and the new formulation, the FDA requested that we first perform a side-by-side analytical comparability study between the two entolimod drug formulations. Thereafter, the Agency requested that we conduct an in vivo study in non-human primates ("**NHP**") to establish bio-comparability. The side-by-side analytical comparability analysis of the two formulations of entolimod was completed and the study report was submitted to the FDA in the first quarter of 2017. The FDA has reviewed this data and indicated that we could proceed with the bio-comparability study in NHP in the second quarter of 2017. Due to unexpected delays in the analytical tests performed by Company vendors, the study was finally completed and data were unblinded in early 2019. While the NHP study was ongoing, the FDA proceeded with further review of the entolimod chemistry, manufacturing, and controls ("**CMC**") information in our pre-EUA dossier and in first quarter 2019 the Agency provided us with comments and questions on various aspects of entolimod CMC. Per FDA recommendation, the Company has now requested a meeting to brief the FDA on the results of the NHP bio-comparability data and is preparing responses to the FDA comments on entolimod CMC. We expect that after review and discussion of the bio-comparability data and the CMC information, the FDA will proceed with review of additional components of the pre-EUA dossier.

In March 2019, at the FDA's suggestion, with positive NHP bio-comparability data in hand, CBLI requested a meeting with the FDA to discuss the re-initiation of pre-EUA review including specifically review of the animal-to-human dose conversion included in the pre-EUA application. Following review of the background information provided for the meeting, the FDA responded that while the NHP biocomparability data were acceptable, the analytical comparability data that they had accepted in 2017 were no longer acceptable and therefore, the review of the pre-EUA application remained on hold. In August 2019, CBLI requested a Special Protocol Assessment to confirm the End-of-Phase 2 agreements on design of the remaining pivotal NHP efficacy study to support submission of an eventual Biologics License Application ("**BLA**"). Following review of the NHP efficacy study protocol, the FDA responded that the previously agreed study design was no longer acceptable. Based on these two documented points of disagreement (one related to the pre-EUA application and one related to a future BLA), CBLI requested a Formal Dispute Resolution ("**FDR**") with the FDA. The outcomes of the FDR included, among other things, an agreement that CBLI had documented both analytical comparability and biocomparability in the NHP. As a result, the review of the animal-to-human dose conversion has recommenced. CBLI has redesigned the remaining pivotal NHP efficacy study to support a future BLA and submitted the protocol synopsis for review with the FDA, agreeing to an accelerated review time-frame. In November 2019, CBLI also submitted a clinical protocol to support the acquisition of the final human safety data and to further support eventual approval of an entolimod BLA. The FDA has placed the protocol on clinical hold with recommendations for design revisions that will allow lifting of the hold following review of the revised protocol.

If the FDA authorizes the pre-EUA application, then Federal agencies will be free to procure entolimod for stockpiling so that the drug is available to distribute in the event of an emergency, i.e., prior to the drug being formally approved by FDA under a BLA. Such authorization is not equivalent to full licensure through approval of a BLA, but precedes full licensure, and, importantly, would position entolimod for potential sales in advance of full licensure in the U.S. We further believe pre-EUA status will position us to explore sales opportunities with foreign governments.

In addition, the Company submitted a Marketing Authorization Application (" **MAA"**) with the European Medicines Agency ("**EMA"**) for entolimod as a MRC in Europe. The MAA was validated by the EMA in the fourth quarter of 2017 but was withdrawn in August 2018 because a complete response to certain questions posed by the EMA could not be prepared in the time frame required by the EMA's review process as a result of the delay in our receipt of the results of the bio-comparability study. The MAA application remains in a withdrawn state and we continue to evaluate our next steps with the EMA in parallel with progress on review of the pre-EUA application.

In September 2015, we announced two awards totaling approximately $15.8 million in funding from the United States Department of Defense (" **DoD**"), office of Congressionally Directed Medical Research Programs to support further development of entolimod as a MRC. These awards funded additional preclinical and clinical studies of entolimod, which are needed for a BLA. In October 2016, the DoD modified the original statement of work of one of these contracts (Joint Warfighter Medical Research Program ("**JWMRP"**) contract award number W81XWH-15-C-0101) by eliminating certain tasks no longer deemed critical for the preparation of the BLA and established new tasks to address the formulation questions raised by the FDA during the review of the pre-EUA dossier, including an aim to conduct the NHP bio-comparability study along with other drug manufacturing -related activities. In September 2017, the DoD further modified the contract by extending its term to 2019 on a no-cost basis. In February 2019, the DoD further modified the contract by extending its term to April 2020 on a no-cost basis. In March 2020, the DoD further modified the contract by extending its term to September 2020 on a no-cost basis. Both contracts providing for these awards from the DoD have concluded.

In addition to development work on the MRC for reducing the risk of death from ARS indication, we have completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. The data for the U.S. study were presented at the 2015 annual meeting of the American Society of Clinical Oncology ("**ASCO**"). Seven (7) additional patients have been dosed with the entolimod drug formulation proposed for commercialization under the pre-EUA and MAA in an extension of this study performed in the Russian Federation ("**Russia**").

In the third quarter of 2018, the Company created a joint venture called Genome Protection, Inc. (" **GPI**") with Everon Biosciences, Inc. (" **Everon**"). GPI, which is currently 50% owned by the Company and 50% owned by Everon, is undertaking a research and development program aimed at clinical testing of entolimod and GP532 (a variant of our entolimod drug candidate) and the development of medications with anti-aging and other indications associated with genome damage. GPI is being initially funded by an investment from venture capital fund Norma Investments Limited ("**Norma**"). Under the terms of the arrangement with Norma, GPI granted Norma the right to purchase shares of GPI's capital stock in the future in exchange for the payment of up to $30 million, of which $10.5 million was paid shortly after execution of the transaction documents.

**Mobilan** is a recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, a secretory non-glycosylated version of entolimod we are also developing through our subsidiary, Panacela Labs, Inc. ("**Panacela"**). Two randomized, placebo-controlled, dose-ranging studies of Mobilan in men with prostate cancer are currently ongoing in the Russian Federation.

***Merger with Cytocom, Inc.***

As previously disclosed, on October 16, 2020, the Company, High Street Acquisition Corp., a Delaware corporation and a wholly owned subsidiary of the Company ("**Merger Sub**"), and Cytocom, Inc., a Delaware corporation (" **Cytocom**"), entered into an Agreement and Plan of Merger (the " **Merger Agreement**"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cytocom, with Cytocom continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "**Merger**"). Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each outstanding share of Cytocom common stock, each outstanding share of Cytocom preferred stock that was not, by its terms, converted into shares of Cytocom common stock immediately prior to the effective time of the merger, and each vested restricted stock unit of Cytocom will be converted into the right to receive a number of shares of the Company's common stock determined by the application of an exchange formula set forth in the Merger Agreement. The exchange formula provides that the total number of shares of the Company's common stock to be issued as merger consideration for the Cytocom's capital stock will, upon issuance, be equal to approximately 61% of the outstanding shares of the combined company's common stock. Accordingly, under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former Cytocom stockholders are expected to own approximately 61% of the outstanding shares of the combined company's common stock on a fully diluted basis and stockholders of the Company as of immediately prior to the Merger are expected to own approximately 39% of the outstanding shares of the combined company's common stock on a fully diluted basis. Certain adjustments to this ratio will be made in respect of each party's net cash at the time of the closing of the Merger, as determined in accordance with the Merger Agreement. Each unvested Cytocom restricted stock unit award will be converted into a restricted stock unit award of the Company. Immediately following the effective time of the Merger, the board of directors of the Company will consist of seven members, three of whom will be designated by the Company and four of whom will be designated by Cytocom. In addition, upon the closing of the Merger, Cytocom's Chief Executive Officer, Michael Handley, will serve as Chief Executive Officer of the combined company. The closing of the Merger is subject to the satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the Company's stockholders, (ii) the accuracy of the respective representations and warranties of each party, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) the absence of any law or order preventing the Merger and related transactions, (v) the shares of the Company's common stock to be issued in the Merger being approved for listing (subject to official notice of issuance) on Nasdaq as of the closing and (vi) a registration statement on Form S-4 having become effective in accordance with the provisions of the Securities Act of 1933, as amended, and not being subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to such registration statement that has not been withdrawn.

**CORPORATE INFORMATION**

We were incorporated in Delaware in June 2003 as a corporation spun off from The Cleveland Clinic. We exclusively license our founding intellectual property from The Cleveland Clinic. In 2007, we relocated our operations to Buffalo, New York and became affiliated with Roswell Park Cancer Institute ("**RPCI**"), through technology licensing and research collaboration relationships. Our common stock is listed on the NASDAQ Capital Market under the symbol "CBLI."

Our principal executive offices are located at 73 High Street, Buffalo, New York 14203, and our telephone number at that address is (716) 849-6810.

Since inception we have formed several subsidiaries to best capitalize on our ability to leverage financial and clinical development resources in Russia. In December 2009, we created Incuron LLC ("**Incuron**") with BioProcess Capital Ventures ("**BCV**") to develop Curaxin compounds (defined below). We have since sold our equity interest in Incuron, but maintain a right to royalty payments, as later described, and we conduct drug development activities on behalf of Incuron in the U.S. In September 2011, we created Panacela, a U.S. entity, with Joint Stock Company "Rusnano" ("**Rusnano**") to develop Mobilan and other product candidates (described below.) Simultaneous with the formation of Panacela, was the creation of a wholly-owned Russian subsidiary of Panacela named Panacela Labs, LLC. Finally, we had a wholly-owned Russian subsidiary, BioLab 612, LLC, that was dissolved in November 2020.

CBLI and Panacela each have development and commercialization rights to product candidates in development, subject to certain financial obligations to our current licensors.

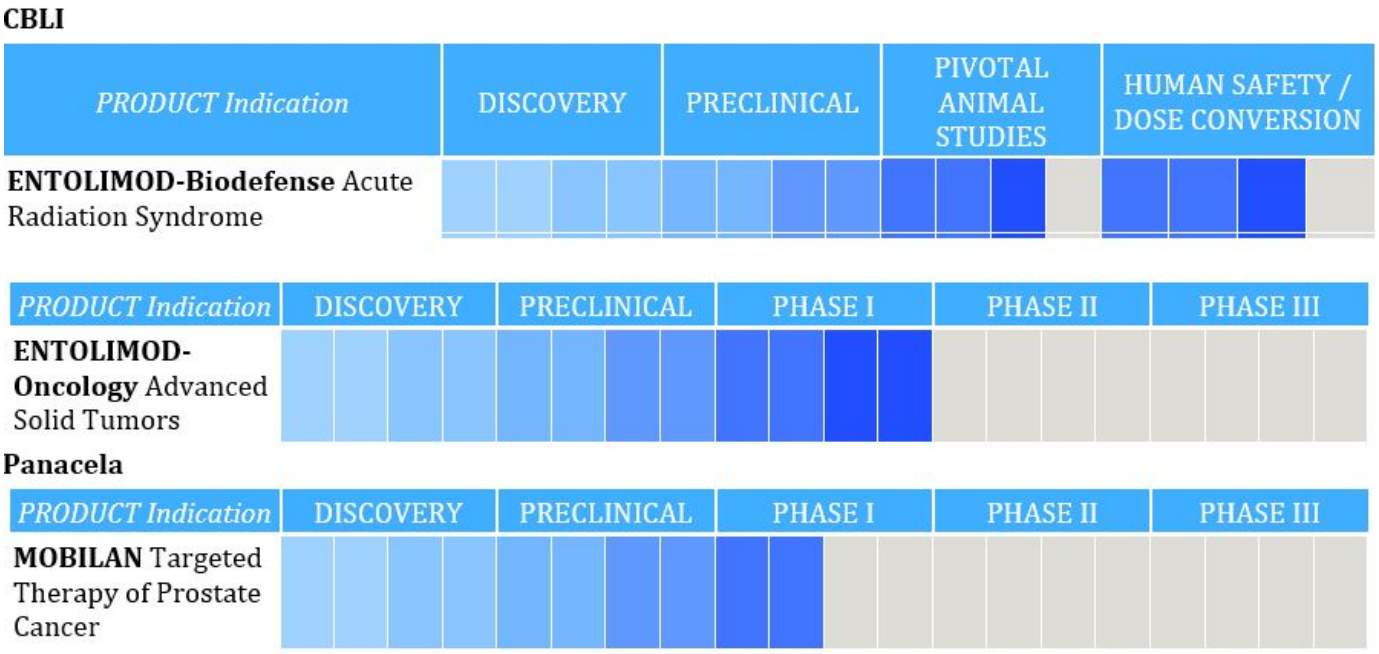
In 2018, as discussed above, we formed GPI with Everon to undertake a research and development program aimed at clinical testing of entolimod and GP532 (a variant of our entolimod drug candidate) and the development of medications with anti-aging and other indications associated with genome damage.

The CBLI logo and CBLI product names are proprietary trade names of CBLI, its subsidiaries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols "®" and "™", respectively. Third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

**PRODUCT DEVELOPMENT PIPELINE**

Our product development programs arise from both internally developed and in-licensed intellectual property from our innovation partners, The Cleveland Clinic and RPCI. In building the Company's product development pipeline, we intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities and ensures that our success is not dependent on any single product or indication. However, most of our efforts during the last four fiscal years have focused on developing entolimod's ARS indication.

Our currently ongoing product development programs and their respective development stages are illustrated below:




Our product development efforts were initiated by discoveries related to apoptosis, a tightly regulated form of cell death that can occur in response to internal stresses or external events such as exposure to radiation or toxic chemicals. Apoptosis is a major determinant of the tissue damage that occurs in a variety of medical conditions involving ischemia, or temporary loss of blood flow, such as cerebral stroke, heart attack and acute renal failure. In addition, apoptotic loss of cells of the hematopoietic system and gastrointestinal tract is largely responsible for the acute lethality of high-dose radiation exposure. On the other hand, apoptosis is also an important protective mechanism that allows the body to eliminate defective cells such as those with cancer-forming potential.

We have developed novel strategies to target the molecular mechanisms controlling apoptotic cell death for therapeutic benefit. These strategies take advantage of the fact that tumor and normal cells respond to apoptosis-inducing stresses differently due to tumor-specific defects in cellular signaling pathways such as inactivation of p53 (a pro-apoptosis regulator) and constitutive activation of Nuclear Factor kappa-B ("**NF-kB**"), (a pro-survival regulator).

Thus, we designed two oppositely-directed general therapeutic concepts:

(a) temporary and reversible suppression of apoptosis in normal cells to protect healthy tissues from stress-induced damage using compounds we categorize as Protectans, which include entolimod and Mobilan; and

(b) reactivation of apoptosis in tumor cells to eliminate cancer using compounds we categorize as Curaxins, which includes CBL0137, currently being developed by our former subsidiary, Incuron.

In recent years, our understanding of the mechanisms of actions underlying the activity of these compounds has grown substantially beyond the initial founding concepts around modulation of apoptosis.

**Entolimod Biodefense Indication**

Our most advanced Protectan product candidate is entolimod, an engineered derivative of the *Salmonella* flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. We are developing entolimod as a medical radiation countermeasure for reducing the risk of death from ARS, which we refer to as a Biodefense Indication.

The market for medical radiation countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack in the U.S. Terrorist activities worldwide have continued in the intervening years and the possibility of chemical, biological, radiation and nuclear attacks continues to represent a perceived threat for governments world wide. In addition to the U.S. government, which maintains a national stockpile of products for emergency use (the "**National Stockpile**"), we believe the potential markets for the sale of radiation countermeasures include U.S. federal, state and local governments, including defense and public health agencies, foreign governments, non-governmental organizations, multinational corporations, transportation and security companies, healthcare providers, and nuclear power facilities.

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the hematopoietic system and gastrointestinal tract, which leads to ARS, a potentially fatal condition. The threat of ARS is primarily limited to emergency/defense scenarios and is significant given the possibility of nuclear/radiological accidents, warfare or terrorist incidents. The scale of possible exposure (number of people affected) has been estimated by the U.S. government to be in the range of 500,000 based on a modeled 10-kiloton device detonation in New York City. We believe the significant limitations of the three currently approved treatments to deal with such an event make entolimod a compelling product candidate. It is not feasible or ethical to test the efficacy of entolimod as a radiation countermeasure in humans. Therefore, we are developing entolimod under the FDA's Animal Rule guidance (see "– *Government Regulation – Animal Rule*"). The Animal Rule authorizes the FDA to rely on data from animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the product. Under these requirements, and with the FDA's prior agreement, medical countermeasures, like entolimod, may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies, evidence of safety derived from studies in humans and any additional supporting data.

Our pivotal efficacy study conducted in 179 non-human primates demonstrated with a high degree of statistical significance that injection of a single dose of entolimod given to rhesus macaques 25 hours after exposure to a 70% lethal dose of total body irradiation improved animal survival by nearly three-fold compared to the control group. Dose-dependence of entolimod's efficacy was demonstrated with doses above the minimal efficacious dose establishing a plateau at approximately 75% survival at 60 days after irradiation, as compared to 27.5% survival in the placebo-treated group.

Our pivotal study conducted in 160 non-irradiated non-human primates established the dose-dependent effect of entolimod on biomarkers for animal-to-human dose conversion.

Our clinical studies of entolimod in 150 healthy human subjects demonstrated the safety profile of entolimod and established the dose-dependent effect of entolimod on efficacy biomarkers in humans. In these studies, and in the oncology studies in which more than 60 cancer patients have been administered to date, transient decrease in blood pressure and elevation of liver enzymes were observed along with transient mild to moderate flu-like syndrome. Such effects are the most common adverse events and they are linked to up-regulation of cytokines that are also biomarkers for efficacy.

As discussed above, we are seeking pre-EUA authorization from the FDA for entolimod, for which we submitted an application and have ongoing discussions with the FDA.

The FDA has granted Fast Track status to entolimod (see " – *Government Regulation – Fast Track Designation* ") and Orphan Drug status for prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster (see "– *Government Regulation – Orphan Drug Designation* ").

**Entolimod Oncology Indication**

In addition to developing entolimod as a MRC for reducing the risk of death from ARS, we have initiated an evaluation of entolimod's potential to treat cancer by activating the innate and adaptive immune response in patients. In preclinical studies, entolimod produced tissue-specific activation of innate immune responses via interaction with its receptor, TLR5, and the liver was identified as a primary mediator of entolimod activity. Entolimod has also been shown to have a direct cytotoxic effect on tumors expressing TLR5 in animal models. Evaluations of local administration of entolimod in organs expressing TLR5, such as the bladder, have also been performed in animal models.

We completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. in 2015 and an extension study in additional patients in Russia receiving the entolimod drug product formulation proposed for commercialization is ongoing. The data for the U.S. study were presented at the 2015 annual meeting of ASCO. 26 patients with previously treated metastatic cancers, including colorectal, non-small cell lung, anal and urothelial bladder tumors were enrolled in the study. Stable disease for more than 6 weeks was observed in 8 patients with various cancer types; among these, 3 patients (with anal, colorectal and urothelial cancers) had maintenance of stable disease for more than 12 weeks. Patients exhibited $CD8^+$ T-cell activation with stable or decreased levels of myeloid-derived suppressive cells, accompanied by increased immunostimulatory cytokines (G-CSF, IL-6, and IL-8). The tolerability profile in patients with advanced cancer was similar to that observed in two previously conducted studies in 150 healthy subjects receiving entolimod. As expected with activation of innate immune pathways, common adverse events were flu-like symptoms and fever, with some patients having transient, spontaneously resolving tachycardia, hypotension and hyperglycemia. Overall, treatment with entolimod was well tolerated.

In addition, we have conducted a clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy before cancer surgery in treatment-naïve patients with primary colorectal cancer. Because the study included older patients (up to 84 years) and those with other health conditions, the trial further extended an understanding of entolimod effects in a broader population of study patients. The safety profile of the drug appeared generally similar to the profiles previously identified in healthy subjects and patients with cancer who participated in prior studies. Increases in plasma cytokines and alterations of blood cells were observed that appeared consistent with TLR5-mediated mobilization and trafficking of immunocytes to peripheral tissues, although changes in tumor immune cell infiltration appeared to be independent of treatment group in this exploratory study.

In February 2016, we announced the publication of studies elucidating immunotherapeutic mechanisms through which entolimod suppresses metastasis in *Proceedings of the National Academy of Sciences* of the United States of America ("**PNAS**"). The studies presented in the PNAS publication decipher the cascade of cell-signaling events that are triggered by entolimod activation of the TLR5 pathway in the liver. The data also define the functional roles of natural killer ("**NK**"), dendritic, and CD8+ T-cells in the drug's activity as a suppressor of metastasis. The studies demonstrate that entolimod administration induces chemokines that attract NK cells to the liver via a CXCR3-dependent mechanism. CXCR3 is a chemokine receptor that is highly expressed on both NK and effector T cells and plays an important role in cell trafficking to tissues. Once in the liver, NK cells, which are components of the innate immune system, engage an adaptive antitumor immune response through dendritic cell activation. This NK-to-dendritic cell interaction generates CD8+ T-cell-dependent antitumor memory that results in tumor rejection upon animal re-challenge with tumor. Importantly, localized antitumor effects in the liver combine with systemic responses that enable suppression of metastasis to the lung.

On August 6, 2018, we entered into a license agreement with GPI pursuant to which the Company licensed to GPI, on an exclusive basis, the right to develop, manufacture, commercialize, and sell entolimod in the field of use related to the prevention or treatment of any disease, disorder, or frailty in humans caused by aging, including treatment of "cancer survivors" (i.e., persons who are proclaimed to be "cancer free" at the time of treatment, but have been damaged by conventional cancer therapy). We retained the exclusive worldwide development and commercialization rights to entolimod for use as an ARS indication and concurrent radiation treatment of humans diagnosed with oncological conditions at the time of treatment.

**Mobilan**

Mobilan is the lead product candidate of Panacela. Mobilan is a recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, a secretory non-glycosylated version of entolimod. In preclinical studies, delivery of Mobilan to tumor cells results in constitutive autocrine TLR5 signaling and strong activation of the innate immune system with subsequent development of adaptive anti-tumor immune responses.

In 2016, Panacela completed enrollment of patients in a Phase 1 multicenter, randomized, placebo-controlled, single-blinded study in Russia evaluating single injections of ascending doses of Mobilan administered directly into the prostate of patients with prostate cancer.

Panacela holds exclusive worldwide development and commercialization rights to Mobilan.

As of December 31, 2020, we owned 67.57% of Panacela.

**CBL0137**

CBL0137 is a small molecule with a multi-targeted mechanism of action that may be broadly useful for the treatment of many different types of cancer and is being developed by Incuron. During 2015 we sold our remaining equity interest in Incuron but retain a 2% royalty on (a) product sales of CBL0137, (b) consideration received by Incuron from a licensee or sublicensee, and (c) consideration received in connection with the first change of control of Incuron. Incuron's royalty obligations continue until April 29, 2025.

CBL0137 may offer greater efficacy and substantially lower risk for the development of drug resistance than conventional chemotherapeutic agents. CBL0137 inhibits MYC protein, NF-kB, Heat Shock Factor Protein-1 ("**HSF-1**"), and Hypoxia-inducible factor 1-alpha; these are transcription factors that are important for the viability of many types of tumors. The drug also activates tumor suppressor protein p53 by modulating intracellular localization and activity of chromatin remodeling complex Facilitates Chromatin Transcription ("**FACT**"). CBL0137 has been shown to be efficacious in animal models of colon, lung, breast, renal, pancreatic, head and neck and prostate cancers; melanoma; glioblastoma; and neuroblastoma. It has also been shown to be efficacious in animal models of hematological cancers, including lymphoma, leukemia and multiple myeloma.

Incuron holds worldwide development and commercialization rights to CBL0137.

**STRATEGIC PARTNERSHIPS**

Since our inception, strategic alliances and collaborations have been integral to our business. We have exclusively licensed rights in each of our technologies from The Cleveland Clinic and RPCI and maintain innovative partnerships with each. We have also leveraged the experience, contacts and knowledge of our founders to engage financial partners in Russia. Through these partnerships we have collaborated with scientists from other countries to develop our novel technologies and accessed non-traditional funding sources, including U.S. federal and foreign government contracts and project-oriented funding. We have received project-oriented funding from Rusnano through the formation of Panacela.

Panacela maintains operations in Russia and benefits from programs supporting domestic pharmaceutical industry development in Russia.

**The Cleveland Clinic**

In July 2004, CBLI entered into an exclusive license agreement with The Cleveland Clinic ("**The Cleveland Clinic License**") pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic's research base underlying our therapeutic platform. We amended The Cleveland Clinic License, effective as of September 22, 2011, pursuant to which we were granted an exclusive license to The Cleveland Clinic's research base underlying certain product candidates in development by Panacela ("**Panacela Products**"), including Mobilan and several earlier-stage compounds that are not currently material to our business.

In consideration for The Cleveland Clinic License, we agreed to issue The Cleveland Clinic common stock and make certain milestone, royalty, and sublicense royalty payments as described below.

The Cleveland Clinic License requires milestone payments, which may be credited against future royalties owed to The Cleveland Clinic, as described in the table below.

| Milestone Description | For Products Limited to Biodefense Uses | For All Other Products (Maximum amount)* |
|---|---|---|
| **For any IND filing for a product** | $ 50,000 | $ 50,000 |
| **For any product entering Phase II clinical trials or similar registration** | 100,000 | 250,000 |
| **For any product entering Phase III clinical trials** | — | 700,000 |
| **For any product license application, BLA or NDA Filing for a product**** | 350,000 | 1,500,000 |
| **Upon regulatory approval permitting any product to be sold to the commercial market** | 1,000,000 | 4,000,000 |

* Maximum amounts listed for achievement of milestone in U.S. If milestones are reached in another country first, milestone payments will be prorated for certain products under the license based on the market size for the product in such country as that market relates to the then current U.S. market.

** New Drug Application ("**NDA**")

We have also agreed to make milestone payments of up to approximately $6.5 million for each Panacela Product that achieves certain developmental and regulatory milestones, provided that if CBLI or an affiliate of CBLI and The Cleveland Clinic jointly own the Panacela Product, the milestone amounts will be reduced by 50%.

The Cleveland Clinic License requires royalty payments of (a) 2% of net sales of any product candidate under a licensed patent solely owned by The Cleveland Clinic; and (b) 1% of net sales of any product candidate under a licensed patent that is jointly owned by The Cleveland Clinic and CBLI or an affiliate of CBLI. Further, if CBLI receives upfront sublicense fees or sublicense royalty payments for sublicenses granted by CBLI to third parties for any licensed patents solely owned by The Cleveland Clinic, CBLI will pay The Cleveland Clinic (i) 35% of such fees if the sublicense is granted prior to filing an IND application, (ii) 20% of such fees if the sublicense is granted after an IND filing but prior to final approval of the Product License Application or NDA, or (iii) 10% of such fees if the sublicense is granted after final approval of the relevant Product License Application or NDA, provided that such sublicense fees shall not be less than 1% of net sales. The above sublicense fees and sublicense royalty payments are reduced by 50% if The Cleveland Clinic and CBLI or an affiliate of CBLI jointly own the licensed patent.

Through December 31, 2020, CBLI had paid The Cleveland Clinic $150,000 for milestone payments on products limited to biodefense uses, and $400,000 for all other products.

**Roswell Park Cancer Institute**

We have entered into a number of agreements with RPCI relating to the licensure and development of our product candidates including:

- Two exclusive license and option agreements effective December 2007 and September 2011;
- Various sponsored research agreements entered into between January 2007 to present; and
- Clinical trial agreements for the conduct of our Phase 1 entolimod oncology study and Incuron's Phase 1 CBL0137 intravenous administration study.

In December 2007, CBLI entered into an agreement with RPCI pursuant to which CBLI has an option to exclusively license any technological improvements to our foundational technology developed by RPCI for the term of the agreement. We believe our option to license additional technology under the agreement potentially provides us with access to technology that may supplement our product pipeline in the future. In consideration for this option and exclusive license, we agreed to make certain milestone, royalty and sublicense royalty payments.

In September 2011, Panacela entered into an agreement with RPCI (the " **Panacela-RPCI License**") to exclusively license from RPCI certain rights to the Panacela Products, including Mobilan and several earlier-stage compounds that are not currently material to our business, and to non-exclusively license from RPCI certain know-how relating to the aforementioned product candidates for the limited purposes of research and development and regulatory, export and other government filings. Additionally, under the Panacela-RPCI License, Panacela has a right to exclusively license from RPCI (i) any technological improvements to the Panacela

Products developed by RPCI before September 2016, and (ii) any technology jointly developed by Panacela and RPCI. In consideration for the Panacela-RPCI License, Panacela agreed to issue RPCI common stock and to make certain milestone, royalty and sublicense royalty payments as described below.

The Panacela-RPCI License requires milestone payments for developmental and regulatory milestones reached in the U.S. of up to approximately $2.5 million for each Panacela Product that achieves certain developmental and regulatory milestones. Additionally, Panacela will owe additional payments of up to approximately $275,000 for each other country where a licensed Panacela Product achieves similar milestones.

The Panacela-RPCI License requires royalty payments on net sales based on percentages in the low single digits. In addition, if Panacela sublicenses any of the licensed Panacela Products, Panacela will owe sublicensing fees ranging from 5% to 15% of any fees received from the sublicensee by Panacela or an affiliate depending upon whether or not an IND has been filed or final approval of the relevant NDA has been obtained for such licensed product.

We have also entered into a number of sponsored research agreements with RPCI pursuant to which both parties have sponsored research to be conducted by the other party. Under our sponsored research agreement with RPCI, title to any inventions under the agreement is determined in a manner substantially similar to U.S. patent law, and we have the option to license from RPCI, on an exclusive basis, the right to develop any inventions of RPCI (whether solely or jointly developed) under the agreement for commercial purposes.

Under the sponsored research agreements with RPCI, we own any invention that is described in our research plan, co-own any inventions not described in our research plan that are made by Dr. Andrei Gudkov, our Chief Scientific Officer, and RPCI owns any other inventions not described in our research plan. We further have a right to exclusively license from RPCI any invention developed under such sponsored research agreements that are owned by RPCI. Such sponsored research agreements with RPCI expired in 2019.

We entered into an asset transfer and clinical trial agreement with RPCI for the conduct, by RPCI, of our Phase 1 clinical trial to evaluate the safety and pharmacokinetic profile of entolimod in patients with advanced cancers, which has now been largely completed.

**Rusnano**

In 2011, we formed Panacela with Rusnano to carry out a complete cycle of development and commercialization of medications in Russia for the treatment of oncological, infectious or other diseases. We invested $3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or exclusively licensed, as applicable, to Panacela worldwide development and commercialization rights to five preclinical product candidates in exchange for Panacela common shares. Rusnano invested $9.0 million in Panacela preferred shares and warrants. In 2013, Rusnano loaned Panacela $1.5 million through a convertible term loan (the "**Panacela Loan**"). In December of 2015, together with Rusnano, we recapitalized Panacela to fully retire the Panacela Loan and certain other trade payables. Rusnano maintained its ownership percentage in Panacela, while CBLI's ownership stake grew to 66.77%. As of December 31, 2020, we had an ownership stake of approximately 67.57%.

**Everon Biosciences**

On August 6, 2018, we entered into a series of transactions with our joint venture, GPI, and Everon. GPI was formed by the Company to undertake a research and development program aimed at clinical testing of entolimod and GP532 (a variant of our entolimod drug candidate) and to develop medications with anti-aging and other indications associated with genome damage. Under the terms of a license agreement entered into with GPI, we agreed to license to GPI, on an exclusive basis, the right to develop, manufacture, commercialize, and sell products utilizing the Company's intellectual property underlying the Company's entolimod drug candidate, solely in the field of use related to the prevention or treatment of any disease, disorder, or frailty in humans caused by aging. Entolimod's use as an acute radiation treatment medication is retained by the Company under the license agreement. The intellectual property is licensed pursuant is separate licenses; the license of our intellectual property underlying entolimod's oncology indication is being licensed on a paid-up, royalty-free basis while the license of our intellectual property underlying entolimod's composition is being granted on a fee-bearing and royalty-bearing basis, with such fees and royalties comprising those included in the original license agreement pursuant to which we originally licensed such intellectual property from The Cleveland Clinic Foundation, with such fees and royalties payable to The Cleveland Clinic Foundation.

Under the license agreement, GPI retains responsibility for its own development and commercialization activities but is required to provide us with access to all clinical, safety, and other data arising from its development activities. We must disclose and transfer all of our know-how pertaining to the licensed intellectual property and provide entolimod product samples to GPI for use in GPI's clinical trials. The license agreement requires the parties to work together to coordinate efforts between them with respect to regulatory filings, proper reporting of adverse events, the development of standard clinical and quality assurance operating procedures, and the amount of product to be supplied by us to GPI for the conduct of GPI's development activities.

We also entered into an assignment agreement with GPI, under which we assigned certain intellectual property underlying our GP532 product candidate and our entolimod vaccine product candidate and GPI licensed back to us, on an exclusive, irrevocable basis, the right to develop manufacture, commercialize, and sell products relating to the assigned intellectual property for use as a medical countermeasure to treat acute radiation exposure or as a cancer treatment. Under the terms of the assignment, we retain responsibility for our own development and commercialization activities, but GPI is required to use commercially reasonable efforts to supply to us at no surcharge the number of product samples that it has available for clinical trials that we sponsor and necessary in connection with our efforts to obtain regulatory approval for any drug candidates. The assignment requires us to pay a royalty to GPI of 2% of our net sales of any products covered by or using the assigned intellectual property subject to the license-back in each calendar year beginning on the date of the first commercial sale of any such product until patent protection is no longer available for the assigned intellectual property in the U.S., France, Germany, Italy, Japan, Spain, or the United Kingdom. We are further required to make payments to GPI upon the achievement of certain milestones in the development of product candidates utilizing the licensed intellectual property.

As consideration for the licenses granted to GPI and the assignment of the intellectual property to GPI, GPI issued to the Company 1,000 shares of GPI's common stock. Contemporaneously with the Company's entry into the license and assignment, Everon contributed certain of its intellectual property related to the potential development of treatments that address serious medical needs associated with human aging to GPI, also in exchange for 1,000 shares of GPI's common stock. As a result of each of the Company's and Everon's receipt of 1,000 shares of GPI's common stock, each of the Company and Everon became the owner of 50% of all of the outstanding capital stock of GPI. Additionally, in exchange for providing funding, Norma, a venture capital fund, has the right to acquire shares of GPI's capital stock in the future. We currently own 50% of the outstanding capital stock of GPI.

**INTELLECTUAL PROPERTY**

Our intellectual property consists of patents, trademarks, trade secrets, and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents for our technologies and products, maintain trade secrets, operate without infringing the rights of others, and prevent others from infringing our proprietary rights. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations, and methods of use. Some of our issued patents, and the patents that may be issued based on our patent applications, may be eligible for patent life extension under the Drug Price Competition and Patent Term Restoration Act of 1984 in the U.S., supplementary protection certificates in the European Union ("**E.U.**") or similar mechanisms in other countries or territories. The following are the patent positions relating to our product candidates as of December 31, 2020.

In the U.S., we have 25 issued patents or allowed patent applications relating to our clinical-stage programs expiring on various dates between 2024 and 2032 as well as numerous pending patent applications and foreign counterpart patent filings which relate to our proprietary technologies. These patents and patent applications include claims directed to compositions of matter and methods of use.

We have 22 issued or allowed U.S. patents covering entolimod, which expire between 2024 and 2032. These patents include composition of matter claims, as well as method of use claims relating to our biodefense and oncology indications, reducing effects of chemotherapy, and treatment of reperfusion injuries. In addition, we have pending U.S. patent applications related to compositions of matter, oncology methods of use, and others biodefense methods, which, if issued, will expire between 2025 and 2035.

We have 2 issued or allowed U.S. patents covering CBLB612 and related agents, which expire between 2026 and 2027. These patents include composition of matter and methods of use claims.

We have one issued U.S. patent covering compositions of matter for various vectors, including Mobilan, which expires in 2032. We also have issued or allowed patents covering Mobilan and related agents, which expire in 2030 that cover a broad list of international territories including the E.U., Australia, Japan, and Russia. These patents include composition of matter and methods of use claims.

In addition, as of December 31, 2020, we have approximately 35 additional patents and patent applications filed worldwide. Any patents that may issue from our pending patent applications would expire between 2024 and 2035, excluding patent term extensions. These patents and patent applications disclose compositions of matter and methods of use.

Our policy is to seek patent protection for the inventions that we consider important to the development of our business. We intend to continue to file patent applications to protect technology and compounds that are commercially important to our business, and to do so in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators, and contractors.

**RESEARCH AND DEVELOPMENT**

As of December 31, 2020, our research and development group, including Russian-based personnel, consisted of 2 individuals. Our research and development focuses on management of outsourced preclinical research, clinical trials, and manufacturing technologies. We invested $0.7 million and $1.7 million in research and development during the years ended December 31, 2020 and 2019, respectively.

**SALES AND MARKETING**

We currently do not have marketing, sales, or distribution capabilities. We do, however, currently have worldwide development and commercialization rights for products arising out of substantially all of our programs, as discussed above. In order to commercialize any of these drugs, if and when they are approved for sale, we will need to enter into partnerships for the commercialization of the approved product(s) or develop the necessary marketing, sales, and distribution capabilities.

**COMPETITION**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes from both biotechnology and major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do, including, in some cases, considerably more experience in clinical testing, manufacturing, and marketing of pharmaceutical products. There are also academic institutions, governmental agencies, and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts. We expect to encounter significant competition for any products we develop. Our product candidates' competitive position among other biotechnology and biopharmaceutical companies will be based on, among other things, time to market, patent position, efficacy, safety, reliability, availability, patient convenience, ease of delivery, manufacturing cost, and price. In these cases, we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our business.

Specifically, the competition for entolimod and our other clinical-stage product candidates includes the following:

**Entolimod Biodefense Indication**

Product candidates for treatment of ARS face significant competition for U.S. government funding for both development and procurement of medical countermeasures and must satisfy government procurement requirements for biodefense products. Currently the only FDA-approved drugs for the treatment of ARS are filgrastim (Neupogen™) peg-filgrastim (Neulasta™) and sargramostim (Leukine®). Filgrastim (granulocyte colony-stimulating factor ("**GCS-F**") and peg-filgrastim (PEGylated form of GCS-F) stimulate neutrophils and may reduce infection related to ARS. Unlike entolimod, these drugs do not improve platelet counts or lessen bleeding, and do not ameliorate gastrointestinal dysfunction due to ARS. Sargramostim is a leukocyte growth factor which induces partially committed hematopoietic progenitor cells to divide and differentiate in the granulocyte-macrophage pathways which include neutrophils and other hematopoietic cell types. In label-supporting survival studies, all three products required repeated administration and treatment was accompanied by laboratory monitoring. In addition, filgrastim and peg-filgrastim required intensive supportive care (including platelet transfusions). By contrast, entolimod survival studies included only a single injection, without laboratory monitoring and without any intensive medical support, which we believe makes it significantly more suitable for use in a mass-casualty situation.

The U.S. government has purchased several colony-stimulating factors to treat injuries to bone marrow in victims of radiological or nuclear accidents or acts of terrorism for the National Stockpile. In 2013, it paid $157 million to Amgen USA, Inc. for 541,000 doses of Neupogen® and $37 million to Sanofi-Aventis U.S., LLC for 66,000 doses of Leukine® (granulocyte-macrophage colony-stimulating factor). In October 2016, the U.S. government purchased an additional $37.6 million worth of Leukine® and peg-filgrastim, Neulasta®, from Amgen USA, Inc., for another $37.7 million. The U.S government also announced that it continues to work with Sanofi-Aventis to support the studies needed to request FDA approval of Leukine®. These purchases were made using funding and authority provided through the Project BioShield Act of 2004. Under the Project BioShield Act, the U.S. government supports the advanced development and procurement of new medical countermeasures - drugs, vaccines, diagnostics, and medical supplies - to protect health against chemical, biological, radiological, and nuclear threats.

In addition to the colony-stimulating factors, we are aware of a number of companies also developing radiation countermeasures to treat the effects of ARS including: Aeolus Pharmaceuticals, Araim Pharmaceuticals, Inc., Cellerant Therapeutics, Inc., Humanetics Corporation, Neumedicines, Inc., Pluristem Therapeutics, Inc, RxBio, Inc., and Soligenix, Inc. Although their approaches to treatment of ARS are different, we compete with these companies for U.S. government development funding and may ultimately compete with them for U.S. and foreign government purchase and stockpiling of radiation countermeasures.

Additionally, our ability to sell to the government also can be influenced by competition from the products, such as Neupogen®, Neulasta®, and Leukine®, which were previously purchased by the U.S. government for the National Stockpile.

**Entolimod Immuno-Oncology Program and Mobilan**

Immunotherapies are major drivers of commercial growth in cancer therapy and constitute the primary competition for a potential immunotherapeutic agent like entolimod or Mobilan. Examples of marketed drugs in these categories include: pembrolizumab (Keytruda®) (Merck) indicated for advanced melanoma, metastatic non-small cell lung cancer ("NSCLC"), recurrent or metastatic head and neck squamous cell carcinoma, refractory classical Hodgkin lymphoma, and urothelial carcinoma; nivolumab (Opdivo®) (Bristol-Myers Squibb Company) for advanced melanoma and metastatic squamous NSCLC, hepatocellular carcinoma, head and neck squamous cell carcinoma, renal cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, and high or mismatch repair deficient metastatic colorectal cancer; ipilimumab (Yervoy®) (Bristol-Myers Squibb) of unresectable or metastatic melanoma, and for non-muscle-invasive bladder cancer. These drugs may be appropriate combination partners for entolimod or Mobilan in the appropriate treatment settings. However, these drugs may also be competitors for the market share in the treatment of various tumor types.

**MANUFACTURING**

Our product candidates are biologics and small molecules that can be readily synthesized by processes that we have developed. We do not own or operate manufacturing facilities for the production of our product candidates for preclinical, clinical, or commercial quantities. We rely on third-party manufacturers, and in most cases only one third-party, Wacker Biotech B.V., to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development, and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop.

**GOVERNMENT REGULATION**

Government authorities in the U.S. and in other countries regulate the research, development, testing, manufacture, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, quality control, labeling, and export and import of pharmaceutical products such as those that we are developing. We cannot provide assurance that any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

**U.S. Drug Development Process**

In the U.S., the FDA regulates drugs and drug testing under the Federal Food, Drug, and Cosmetic Act and in the case of biologics, also under the Public Health Service Act. Our product candidates must follow processes consistent with these laws before they may be marketed in the U.S.:

- preclinical laboratory and animal tests performed in compliance with current GLPs;
- development of manufacturing processes which conform to current Good Manufacturing Practices ( **"GMPs"**);
- submission and acceptance of an Investigational New Drug ( **"IND"**) application which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in compliance with current Good Clinical Practices ( **"GCPs"**) to establish the safety and efficacy of the proposed drug for its intended use; or in the case of entolimod, for reducing the risk of death following exposure to potentially lethal radiation, we are required to perform pivotal animal studies in compliance with GLP and some aspects of GCP to establish efficacy; and
- submission to and review and approval by the FDA of a NDA or BLA prior to any commercial sale or shipment of a product; or in the case of entolimod, a pre-EUA prior to sales to the National Stockpile.

***Nonclinical testing.*** Nonclinical testing includes laboratory evaluation of a product candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including cGMP and GLP. Prior to the initiation of GLP animal studies, including our pivotal studies for development of entolimod under the Animal Rule, an Institutional Animal Care and Use Committee ("**IACUC**") at each testing site must review and approve each study protocol and any amendments thereto.

We must submit to the FDA the results of nonclinical studies, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first clinical trial of the drug as part of an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to the interstate shipment and administration of any new drug that is not the subject of an approved pre-EUA, NDA, or BLA. Nonclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

***The IND process.*** The FDA requires a 30-day waiting period after the submission of an IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a "clinical hold" that may affect one or more specific studies, or all studies conducted under the IND. In the case of a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials placed on hold can begin or continue. The IND application process may be extremely costly and could substantially delay development of our products. Moreover, positive results of preclinical animal tests do not necessarily indicate positive results in clinical trials.

Prior to the initiation of each clinical study, the corresponding clinical protocol must be submitted as part of the IND and to an independent Institutional Review Board ("**IRB**") at each medical site proposing to conduct the clinical trial. The IRB must review and approve each study protocol, and any amendments thereto, and study subjects must sign an informed consent. Protocols include, among other things, the objectives of the study, dosing procedures, subject selection, and exclusion criteria and the parameters to be used to monitor patient safety. Progress reports of work performed in support of IND studies must be submitted at least annually to the FDA. Reports of serious, unexpected, and related adverse events must be submitted to the FDA and the investigators in a timely manner.

***Clinical trials.*** Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The drug is introduced into healthy human subjects or patients with advanced disease (in the case of certain inherently toxic products for severe or life-threatening diseases such as cancer) and tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion;

- Phase 2: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage; and

- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy, and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

We cannot be certain that we will successfully complete any phase of clinical testing of our product candidates within any specific time period, if at all. Clinical testing must meet the requirements of IRB oversight, informed consent and GCP. The FDA, the sponsor, or the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the participants are being exposed to an unacceptable health risk.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These meetings typically occur prior to submission of an IND, at the end of Phases 1 and 2 and before NDA or BLA submission. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

***The NDA or BLA process.*** If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA or BLA, as applicable. The NDA or BLA, as applicable, is a vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the U.S. The NDA or BLA, as applicable, must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the application, unless an exemption applies. Every newly marketed pharmaceutical must be the subject of an approved NDA or BLA.

Upon submission of an NDA or BLA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the prescription drug user fee law in effect at that time. Current timing commitments under the user fee law vary depending on whether an NDA or BLA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a product candidate subject to the completion of post-marketing studies, commonly referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling or may impose other restrictions on marketing or distribution such as the adoption of a Risk Evaluation and Mitigation Strategies ("**REMS**").

***Manufacturing and post-marketing requirements.*** If approved, a pharmaceutical may only be marketed in the dosage forms and for the indications approved in the NDA or BLA, as applicable. Special requirements also apply to any samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA's GMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA, and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third-party manufacturers to comply with GMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals. With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

**Animal Rule**

In 2002, the FDA amended its requirements applicable to BLAs/NDAs to permit the approval of certain drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from clinical trial(s) in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, which are known as the "Animal Rule", authorize the FDA to rely on animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the agent. Under these requirements, and with the FDA's prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated under this rule must demonstrate effectiveness through pivotal animal studies, which are generally equivalent in design and robustness to Phase 3 clinical studies. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies must allow for selection of an effective dose in humans. Safety under this rule is established under preexisting requirements, including safety studies in both animals (toxicology) and humans. Products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution and requirements to provide information to patients.

We intend to utilize the Animal Rule in seeking marketing approval for entolimod as a medical radiation countermeasure because we cannot ethically expose humans to lethal doses of radiation. Other countries may not at this time have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no "Animal Rule" equivalent in countries other than the U.S., but some may have similar policy objectives in place for these product candidates. Given the nature of nuclear and radiological threats, we do not believe that the lack of established criteria for review and approval of these types of products in other countries will significantly inhibit us from pursuing sales of entolimod to foreign countries.

All data obtained from the preclinical studies and clinical trials of entolimod, in addition to detailed information on the manufacture and composition of the product, would be submitted in a BLA to the FDA for review and approval for the manufacture, marketing, and commercial shipment of entolimod.

**Emergency Use Authorization**

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services (" **DHHS**") may, under certain circumstances, issue an Emergency Use Authorization ("**EUA**") that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of the Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;
- a determination by the Secretary of the DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- a determination by the Secretary of the DHHS that a public health emergency that effects, or has the significant potential to effect, national security and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing a disease attributable to the agents described above, that the product's potential benefits outweigh its potential risks and that there is no adequate approved alternative to the product.

Although an EUA cannot be issued until after an emergency has been declared by the Secretary of DHHS, the FDA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited.

We submitted a pre-EUA in 2015 in order to inform and expedite the FDA's issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions. Additionally, there is no guarantee that the FDA will agree that entolimod meets the criteria for EUA, or, if they do agree, that such agreement by the FDA will lead to procurement by the U.S. or other governments or further development funding.

**Public Readiness and Emergency Preparedness Act**

The Public Readiness and Emergency Preparedness Act (the " **PREP Act"**), provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products", including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of DHHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. Since 2007, the Secretary of DHHS has issued nine declarations under the PREP Act to protect countermeasures that are necessary to prepare the nation for potential pandemics or epidemics from liability. We believe, in the event of an emergency, were the FDA to issue an EUA for entolimod, it would receive protection under the terms of the PREP Act.

**Fast Track Designation**

Entolimod has been granted Fast Track designation by the FDA for reducing the risk of death following total body irradiation. The FDA's Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials and may submit portions of an NDA or BLA on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval, under which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued. Receipt of Fast Track designation does not guarantee that we will experience a faster development process, review or approval as compared to conventional FDA procedures or that we will qualify or be able to take advantage of the FDA's expedited review procedures.

**Orphan Drug Designation**

Entolimod has been granted Orphan Drug designation by the FDA for prevention of death following a potentially lethal dose of total body irradiation. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting fewer than 200,000 individuals in the U.S. or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the U.S. Orphan Drug designation must be requested before submitting an NDA or BLA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If an Orphan Drug-designated product subsequently receives the first FDA approval for the disease for which it has such designation, the product will be entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances for seven years as compared to five years for a standard new drug approval. As referenced above, we have received Orphan Drug designation for entolimod. We intend to seek Orphan Drug designation for our other products as appropriate, but an Orphan Drug designation may not provide us with a material commercial advantage.

**Foreign Drug Development and Approval Regulation**

In addition to regulations in the U.S., we are and will be subject to a variety of foreign regulations governing clinical trials and will be subject to a variety of foreign regulation governing commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country. To our knowledge, other countries, at this time, do not have an equivalent to the Animal Rule and, as a result, do not have established criteria for review and approval of these types of products outside their normal review process, but some countries may have similar policy objectives in place for these product candidates.

***Russian Drug Development and Approval Regulations.*** Our Russian activities are regulated by the Ministry of Health of the Russian Federation (" **Minzdrav**"). This federal executive authority is responsible for developing state policies as well as normative and legal regulations in the healthcare and pharmaceutical industries, including policies and regulations regarding the quality, efficacy and safety of pharmaceutical products.

In addition, the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation, known as Roszdravnadzor, is the executive authority subordinated to Minzdrav, which, among other things, (i) performs control and surveillance of certain activities, including preclinical and clinical trials, and monitors compliance with the state standards for medical products and pharmaceutical activities; (ii) issues licenses for the manufacture of drug products and pharmaceutical activities; (iii) grants allowance for clinical trials, use of new medical technologies and import and export of medical products, including import of products for use in clinical trials; and (iv) reviews and grants or denies registrations of medical products for sale in Russia.

The principal statute that governs our activities in Russia is the Federal Law No. 61-FZ "On Medicine Circulation" of April 12, 2010 (as amended). This law regulates the research, development, testing, preclinical and clinical studies, state registration, quality control, manufacture, storage, transporting, export and import, licensing, advertisement, sale, transfer, utilization and destruction of medical products within Russia, among other things. All medical products must be registered in Russia and comply with stringent safety and quality controls and testing.

In addition, our activities are subject to a number of other Russian laws, regulations and orders relating to the drug development activities, taxation, corporate governance, employment and other areas. In particular, the incorporation, corporate governance, shareholders' rights, and contractual matters related to our Russian subsidiaries and joint ventures are governed by the Civil Code of the Russian Federation and the Federal Law No. 14-FZ "On Limited Liability Companies" of February 8, 1998 (as amended). In accordance with this legislation we must comply with certain shareholders' and board of directors' approval requirements, including those applicable to major and interested party transactions.

Also, pursuant to the Russian Labor Code, our Russian subsidiaries and joint ventures must enter into employment contracts with each employee, afford them at least 28 days paid vacation period, limit the working week to 40 hours per week and follow the code's specific procedures in case of employment termination.

**EMPLOYEES**

As of February 14, 2021, CBLI and its consolidated subsidiaries had 6 employees, 3 of whom are located in the U.S. and 3 of whom are located outside of the U.S. Of these employees, 2 were employed on a full-time basis and 4 were employed on a part-time basis.

**ENVIRONMENT**

We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws and regulations have not had, and are not expected to have, a material effect on our capital expenditures, results of operations, or competitive position.

**AVAILABLE INFORMATION**

We maintain a website at cbiolabs.com. Information on our website is not incorporated by reference into this Annual Report on Form 10-K and does not constitute a part of this Annual Report on Form 10-K. We make available, free of charge, on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are available, electronically filed with, or furnished to the SEC. These reports are also available at the SEC's website at www.sec.gov.

**Item 1A. Risk Factors**

**Risk Factors Summary**

The following is a summary of the principal risks that could adversely affect our business, operations and financial results:

- We will require substantial additional financing in order to meet our business objectives;
- We expect to continue to incur losses;
- The exchange ratio in the Merger will not be adjusted based on the market price of our common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed;
- Failure to complete the Merger may result in either the Company paying a termination fee and/or expense reimbursement amounts to Cytocom, which could harm the price of our common stock and/or our future business and operations;
- If the conditions to the Merger are not satisfied or waived, the Merger may not occur;
- If the Merger is not completed, the price of our common stock may decline significantly;
- We may not be able to successfully and timely develop our products;
- We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or pivotal animal studies do not demonstrate efficacy;
- Risks arising from our reliance on third-party manufacturers for our product candidates;
- We may not be able to obtain regulatory approval in a timely manner;
- Even if our drug candidates obtain regulatory approval, we will be subject to ongoing government regulation;

- If we are unable to procure additional government funding, we may not be able to fund future research and development and implement technological improvements;
- The market for U.S. and other government funding is highly competitive;
- We rely on licensed patents to protect our technology and may be unable to obtain or protect such rights;
- If we fail to comply with our obligations under our license agreements with third parties, we could lose our ability to develop our product candidates;
- The biopharmaceutical market in which we compete is highly competitive;
- The COVID-19 pandemic could adversely impact our business, operations and clinical development timelines and plans;
- We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate;
- Political or social factors may delay or impair our ability to market our products;
- Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results;
- The current geopolitical instability arising from U.S. relations with Russia, and related sanctions by the U.S. government against certain Russian companies and individuals, may have an adverse effect on us;
- Our principal stockholder has the ability to control our business, which may be disadvantageous to other stockholders;
- The price of our common stock has been and could remain volatile;
- Issuance of additional equity may adversely affect the market price of our stock; and
- We have in the past failed to satisfy certain continued listing requirements of the Nasdaq Capital Market and could fail to satisfy these requirements again in the future.

**Risks Relating to our Financial Position and Need for Additional Financing**

**We will require substantial additional financing in order to meet our business objectives.**

Since our inception, most of our resources have been dedicated to preclinical and clinical research and development (" **R&D**") of our product candidates. In particular, we are currently developing several product candidates, each of which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in the development of these product candidates. These expenditures will include costs associated with preclinical and clinical R&D, obtaining regulatory approvals, product manufacturing, corporate administration, business development, and marketing and selling for approved products. In addition, other unanticipated costs may arise. As of December 31, 2020, our cash, cash equivalents, and short-term investments amounted to $2.3 million.

Because the outcome and timing of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results, and costs of researching and developing our product candidates, and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for any of our product candidates that are approved for sale, including marketing, sales, and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the success of the pre-EUA submission we made with the FDA, and any future submissions in the U.S., E.U., and other countries that we may make; and
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any.

When our available cash and cash equivalents become insufficient to satisfy our liquidity requirements, or if and when we identify additional opportunities to do so, we will likely seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stockholders and could contain covenants that would restrict our operations. Furthermore, any funds raised through collaboration and licensing arrangements with third parties may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In any such event, our business prospects, financial condition and results of operations could be materially, adversely affected.

We may require additional capital beyond our currently forecasted amounts and additional funds may not be available when we need them, on terms that are acceptable to us, or at all. In addition, the recent outbreak of the novel coronavirus known as COVID-19 has significantly disrupted world financial markets, negatively impacted US market conditions and may reduce opportunities for us to seek out additional funding. In particular, a decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, our patent licenses may be terminated, and we may be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations.

**We expect to continue to incur losses.**

We have incurred significant losses to date. We reported net losses of approximately $2.4 million and $2.7 million for the years ended December 31, 2020 and 2019, respectively. We expect significant losses to continue for the next few years as we spend substantial sums on the continued R&D of our proprietary product candidates, and there is no certainty that we will ever become profitable as a result of these expenditures. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our product candidates.

Our ability to become profitable depends primarily on the following factors:

- our ability to obtain adequate sources of continued financing;
- our ability to obtain approval for, and if approved, to successfully commercialize our product candidates;
- our ability to successfully enter into license, development or other partnership agreements with third-parties for the development and/or commercialization of one or more of our product candidates;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing, and distribution.

Even if we successfully develop and market our product candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

**Our ability to use our net operating loss carryforwards may be limited.**

As of December 31, 2020, we had federal net operating loss carryforwards (" **NOLs**") of $148.0 million to offset future taxable income, of which $139.7 million begins to expire if not utilized by 2023, and $8.3 million, which has no expiration. We also had approximately $4.3 million of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $93.8 million, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $0.3 million, which begin to expire if not utilized by 2022.

The July 2015 purchase of 6,459,948 shares of common stock by David Davidovich, currently our largest stockholder, yielded a post-transaction ownership percentage of 60.2% for him. We believe it highly likely that this transaction will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code ("**Section 382**"). Consequently, the utilization of the NOL and tax credit carryforwards in existence at July 9, 2015, will be limited according to the provisions of Section 382, which could significantly limit the Company's ability to use these carryforwards to offset taxable income on an annual basis in future periods. As such, a significant portion of these carryforwards could expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carry forwards.

**Risks Related to the Merger with Cytocom**

**The exchange ratio will not be adjusted based on the market price of our common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.**

At the effective time of the Merger, outstanding shares of Cytocom capital stock will be converted into shares of the Company's common stock. Applying the exchange ratio, the former Cytocom securityholders immediately before the Merger are expected to own approximately 61% of the aggregate number of shares of the combined company's common stock following the Merger on a fully diluted basis and our securityholders immediately before the Merger are expected to own approximately 39% of the aggregate number of shares of the combined company's common stock following the Merger on a fully diluted basis. Certain adjustments to the exchange ratio will be made in respect of net cash, as determined in the Merger Agreement. Any changes in the market price of our stock before the completion of the Merger will not affect the number of shares Cytocom stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger, the market price of our common stock increases from the market price on the date of the Merger Agreement, then Cytocom stockholders could receive merger consideration with substantially more value for their shares of Cytocom capital stock than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Cytocom stockholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

**Failure to complete the Merger may result in either the Company paying a termination fee and/or expense reimbursement amounts to Cytocom, which could harm the price of our common stock and/or our future business and operations.**

If the Merger is not completed, the Company is subject to the following risks:

- if the Merger Agreement is terminated under specified circumstances, we may be required to pay Cytocom a termination fee of $300,000 and/or Cytocom's expenses up to $200,000;
- the price of our common stock may decline and could fluctuate significantly; and
- costs related to the Merger, such as financial advisor, legal and accounting fees, which must be paid even if the Merger is not completed.

If the Merger Agreement is terminated and the board of directors of the Company determines to seek another business combination, there can be no assurance that the Company will be able to find a partner with whom a business combination would yield greater benefits than the benefits to be provided under the Merger Agreement.

**If the conditions to the Merger are not satisfied or waived, the Merger may not occur.**

Even if the Merger is approved by the stockholders of Cytocom, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement. The Company cannot assure you that all of the conditions to the consummation of the Merger will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or the closing may be delayed, and the Company may lose some or all of the intended benefits of the Merger.

**The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry-wide changes or other causes.**

In general, neither we nor Cytocom is obligated to complete the Merger if there is a material adverse effect affecting the other party between October 16, 2020, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or political conditions, industry wide changes, changes resulting from the announcement of the Merger, natural disasters, pandemics (including the COVID-19 pandemic), other public health events and changes in GAAP. Therefore, if any of these events were to occur impacting the Company or Cytocom, the other party would still be obliged to consummate the closing of the Merger. If any such adverse changes occur and the Company and Cytocom consummate the closing of the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger to the stockholders of the Company.

**Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.**

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

**If the Merger is not completed, the price of our common stock may decline significantly.**

The market price of our common stock is subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our common stock will likely be volatile based on whether stockholders and other investors believe that the Company can complete the Merger or otherwise raise additional capital to support our operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our common stock is exacerbated by low trading volume. Additional factors that may cause the market price of our common stock to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend its intellectual property rights or defend against claims involving the intellectual property rights of others;
- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the combined company's product candidates, including with respect to other products and potential products in that market;
- the introduction of technological innovations or new therapies that compete with its future products;
- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

**Company and Cytocom securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.**

After the completion of the Merger, the current stockholders of the Company and Cytocom will own a smaller percentage of the combined company than their ownership of their respective companies prior to the Merger. Immediately after the Merger, Company securityholders as of immediately prior to the Merger are expected to own approximately 39% of the outstanding shares of the combined company on a fully diluted basis and former Cytocom securityholders are expected to own approximately 61% of the outstanding shares of the combined company on a fully diluted basis. The Chief Executive Officer of Cytocom will serve as the Chief Executive Officer of the combined company following the completion of the Merger.

**During the pendency of the Merger, the Company and Cytocom may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.**

Covenants in the Merger Agreement impede the ability of the Company and Cytocom to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, proposing, seeking or knowingly encouraging, facilitating or supporting any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them.

**Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.**

The terms of the Merger Agreement prohibit each of the Company and Cytocom from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances. In addition, if the Company terminates the Merger Agreement under specified circumstances, the Company may be required to pay Cytocom a termination fee of $300,000 and in some circumstances one party may be required to pay the other party such party's expenses up to $200,000. This termination fee may discourage third parties from submitting competing proposals to the Company or its stockholders, and may cause our board of directors to be less inclined to recommend a competing proposal.

**Because the lack of a public market for Cytocom's capital stock makes it difficult to evaluate the fair market value of Cytocom's capital stock, we may pay more than the fair market value of Cytocom's capital stock and/or the stockholders of Cytocom may receive consideration in the Merger that is less than the fair market value of Cytocom's capital stock.**

The outstanding capital stock of Cytocom is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Cytocom's capital stock. Because the percentage of our equity to be issued to Cytocom stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be received by Cytocom stockholders will be less than the fair market value of Cytocom's capital stock, or the Company may pay more than the aggregate fair market value for Cytocom's capital stock.

**Risks Related to Product Development**

**We may not be able to successfully and timely develop our products.**

Our product candidates range from ones currently in the research stage to ones currently in the clinical stage of development and all require further testing to determine their technical and commercial viability. Our success will depend on our ability to achieve scientific, clinical, and technological advances and to translate such advances into reliable, commercially competitive products in a timely manner. In addition, the success of our subsidiaries and joint ventures will depend on their ability to meet developmental milestones in a timely manner or to fulfill certain other development requirements under contractual agreements, which are prerequisites to their receipt of additional funding from their non-controlling interest holders or the government agency funding their R&D efforts. Products that we may develop are not likely to be commercially available for some time. The proposed development schedules for our products may be affected by a variety of factors, including, among others, technological difficulties, proprietary technology of others, the government approval process, the availability of funds, disagreements with the financial partners in our subsidiaries or joint ventures, the effects of the ongoing coronavirus pandemic, including access to clinical trial sites both by patents and our clinical research organizations, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and the unproven technology involved, we may not be able to successfully complete the development or marketing of any products.

We may fail to develop and commercialize some or all of our products successfully or in a timely manner because:

- preclinical or clinical study results may show the product to be less effective than desired (e.g., a study may fail to meet its primary objectives) or to have harmful or problematic side effects;
- we fail to receive the necessary regulatory approvals or there may be a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or pre-EUA, MAA, NDA, or BLA preparation, discussions with the FDA, EMA, and other regulatory agencies, and their request for additional preclinical or clinical data or unexpected safety or manufacturing issues;
- our contract laboratories fail to follow good laboratory practices or sufficient quantities of the drug are not available for clinical studies or commercialization;
- we fail to receive funding necessary for the development of one or more of our products;
- they fail to conform to a changing standard of care for the diseases they seek to treat;
- they are less effective or more expensive than current or alternative treatment methods;
- patients withdraw or die during a clinical trial for a variety of reasons, including adverse events associated with the advanced stage of their disease and medical problems that may or may not be related to our products or product candidates;
- the clinical or animal trial design, although approved, is inadequate to demonstrate safety and/or efficacy;
- the third-party clinical investigators or contract organizations do not perform our clinical or animal studies on our anticipated schedule or consistent with the study protocol or do not perform data collection and analysis in a timely or accurate manner;
- the economic feasibility of the product is not attainable due to high manufacturing costs, pricing or reimbursement issues, or other factors;
- one or more of our financial partners in our subsidiaries or joint ventures and us do not agree on the development strategy of our products; or
- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized.

**Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.**

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering entolimod for its biodefense indication to government agencies may require us to develop new sales, marketing or distribution capabilities beyond those already existing in the Company and we may not be successful in selling entolimod for its biodefense indication in the U.S. or in foreign countries despite our efforts. Selling oncology drugs will require a more significant infrastructure. We plan to sell oncology drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with a third-party capable of providing these services and we can make no guarantee that we will be able to enter into a strategic collaboration in the future. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third-party collaborations with our manufacturers. Manufacturers producing our product candidates must follow GMP regulations enforced by the FDA and foreign equivalents.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory, or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. In addition, to the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

**We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or pivotal animal studies do not demonstrate efficacy.**

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must conduct extensive preclinical and clinical studies to demonstrate that our product candidates are safe and clinical or pivotal animal trials to demonstrate that our product candidates are efficacious. And for entolimod's biodefense indication we must demonstrate a logical dosing correlation between animals and humans. These R&D activities are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. In addition, we will likely have to continue to outsource all or part of individual R&D activities and may not successfully or promptly finalize agreements for the conduct of these activities. Consequently, delays in completion of contracted activities may result.

Engagement of contract research organizations ("**CROs**"), study investigators, and other third parties for clinical or animal testing or data management services, for example, transfers substantial responsibilities to these parties. As such we are dependent on these parties to timely execute their contracted work in a quality manner that complies with relevant standards and regulations such as GLPs. Failure of these parties to deliver timely and quality services could result in delays in, or termination of, contracted R&D activities. For example, if any of our clinical trial sites fail to comply with GCPs or our pivotal animal studies fail to comply with GLP regulations we may be unable to use the data generated. Consequently, if contracted CROs or other third parties do not properly execute their duties or fail to meet expected deadlines, our research activities may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our pivotal nonclinical and clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our trial sites are not in compliance with applicable regulatory requirements for conducting such trials, we or they may receive warning letters or other correspondence detailing deficiencies and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be the subject of an enforcement action, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or we may be criminally prosecuted.

In addition, a failure of one or more of our clinical trials or animal studies can occur at any stage of testing and such failure could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us to commence a clinical trial, conduct a clinical trial at a prospective trial site or continue a clinical trial following amendment of a clinical trial protocol or an IACUC may not authorize us to commence an animal study at a prospective study site;
- we may decide, or regulators may require us, to conduct additional preclinical or clinical studies, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we may have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;
- regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;
- the cost of our clinical trials or animal studies could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study;
- the effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics; and
- our collaborators that conduct our clinical or pivotal animal studies could go out of business and not be available for FDA inspection when we submit our product for approval.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

**Panacela and GPI have significant non-controlling interest holders and, as such, each may not be operated solely for our benefit.**

As of December 31, 2020, we owned 67.57% of the equity interests in Panacela and 50% of the equity interests in GPI. Rusnano, a fund regulated by the Russian government, is a significant shareholder, along with other minority shareholders, in Panacela. Everon, a Buffalo, New York-based biopharmaceutical company, holds the other 50% of the equity interest in GPI. Additionally, as a result of its investment in GPI, Norma was granted a number of governance and other rights with respect to GPI. As such, we share ownership and management of Panacela and GPI with other parties who may not have the same goals, strategies, priorities or resources as we do.

With respect to Panacela, both we and Rusnano have certain rights, including the right to designate board members and the need for either supermajority votes or consent of all members of Panacela's board of directors in order to take certain actions. Additionally, the right to transfer ownership is restricted by rights of first refusal, tag-along and drag-along rights. Consequently, if a co-owner sells its equity interest to a new party, the new party may adversely affect the operation of Panacela. These restrictions lead to organizational formalities that may be time-consuming. In addition, the benefits from a successful product development effort are shared among the co-owners.

With respect to GPI, under the terms of Norma's investment, upon the occurrence of a number of different events, Norma has the right to require GPI to issue to Norma a number of shares in GPI, thereby further diluting our interest. Additionally, the Company, Everon, GPI and Norma each made certain commitments as to voting and transfer of their shares of GPI and GPI's governance, including an agreement that the board of directors of GPI will consist of four members, two of whom will be selected by Norma, one of whom will be selected by the Company and one of whom will be selected by Everon. GPI is also prohibited from taking a number of actions without the unanimous consent of all of the members of GPI's board of directors, including, among other things, effecting a change of control transaction, terminating its operations, dissolving or liquidating, amending its organizational documents, transferring or licensing its intellectual property, or issuing any shares of capital stock.

**If parties on whom we rely to manufacture our product candidates do not manufacture them in satisfactory quality, in a timely manner, in sufficient quantities, or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.**

We do not own or operate manufacturing facilities. Consequently, we rely on third parties as sole suppliers of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce supplies for preclinical, clinical, and pivotal animal studies and for commercial quantities of any products or product candidates that we market or may supply to our collaborators. We also rely on third parties as sole providers of certain testing of our products. Our dependence on third parties for the manufacture and testing of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for preclinical studies and initial clinical trials. We rely on a single contract organization, Wacker Biotech B.V., for production of each of our product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates in a timely and competitive manner. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities of the product candidate from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies and commensurate financial investments by the contract manufacturers. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage of supply, which could limit our sales and could initiate regulatory intervention to minimize public health risk.

Other risks associated with our reliance on contract manufacturers include the following:

- contract manufacturers may encounter difficulties in achieving volume production, quality control, and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates, including delays or shortages due to limited supply or capacity of production facilities as a result of the COVID-19 pandemic;

- if, for any circumstance, we are required to change manufacturers, we could be faced with significant monetary and lost opportunity costs with switching manufacturers. Furthermore, such change may take a significant amount of time. The FDA and foreign regulatory agencies must approve these manufacturers in advance. This requires prior approval of regulatory submissions as well as successful completion of pre-approval inspections to ensure compliance with FDA and foreign regulations and standards;

- contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with GMPs and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with GMPs and other FDA requirements or other regulatory requirements outside the U.S. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business;

- contract manufacturers might not be able or refuse to fulfill our commercial or clinical trial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market or clinical trial demands;

- our product costs may increase if our manufacturers pass their increasing costs of manufacture on to us;

- if our contract manufacturers do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to obtain or maintain regulatory approvals for our products and product candidates and will not be able to successfully commercialize our products and product candidates. In such event, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all; and

- contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during the conduct of clinical trials or after marketing approval also require regulatory submissions and the demonstration to the FDA or other regulatory authorities that the product manufactured under the new conditions complies with GMPs requirements. These requirements especially apply to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about changes in the manufacturing process must be submitted to the regulatory authorities and may require prior approval before implementation with the potential of substantial delay or the inability to implement the requested changes.

**Risks Relating to Regulatory Approval**

**We may not be able to obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable.**

The testing, marketing, and manufacturing of any product for use in the U.S. and the E.U. will require approval from the FDA and the EMA, respectively. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Obtaining approval for products requires manufacturing the product and testing in animals and human subjects of substances whose effects on humans are not fully understood or documented. The manufacturing processes for our product candidates are not yet fully developed and identifying a reproducible process may prove difficult. Additionally, preclinical studies, animal efficacy studies, or clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive.

In addition, we expect to rely on the FDA Animal Rule to obtain approval for entolimod's biodefense indication in the U.S. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. Additionally, we submitted an application with the FDA for pre-EUA in 2015 so that entolimod may be used in an emergency situation. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for pre-EUA or BLA approval and require additional preclinical, clinical, or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. The FDA has previously requested additional data and studies with respect to our pre-EUA application for entolimod (as a result of which the FDA has placed our clinical protocol on clinical hold), and the FDA may do so again in the future. If we are not successful in completing the development, licensure, and commercialization of entolimod for its biodefense indication, or if we are significantly delayed in doing so, our business will be materially harmed.

Delays in obtaining FDA, EMA, or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product's potential commercial success and/or on our business, prospects, financial condition and results of operations.

**Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.**

We intend to market our product candidates, including specifically the product candidates being developed by our Russian subsidiaries, in the U.S., Europe, Russia, and other countries and regulatory jurisdictions. In order to market our product candidates in the U.S., Europe, Russia, and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements to file for and obtain marketing approval for drugs in countries outside of the U.S., Europe, and Japan and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the U.S., Europe, and Japan. Also, the time required to obtain approval in markets outside of the U.S. may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the U.S. or the EMA in the E.U., does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, to our knowledge, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not likely have established criteria for review and approval for this type of product outside their normal review process. Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for entolimod's biodefense indication outside the U.S. based on our animal efficacy and human safety data.

**The Fast Track designation for entolimod may not actually lead to a faster development or regulatory review or approval process.**

We have obtained a "Fast Track" designation from the FDA for entolimod's biodefense indication. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

**The pre-EUA submission we made to the FDA in 2015 may not be successful and, even if such submission is successful, it may not accelerate BLA approval of entolimod or result in any purchase by the U.S. government for this product.**

In July 2014, we met with the FDA regarding human dose-conversion of entolimod and based on the results of that meeting, we submitted a pre-EUA dossier in the second quarter of 2015 in order to inform and expedite the FDA's issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions and, therefore, the timing of any approval of a pre-EUA submission is uncertain.

The FDA may decide not to accept the data or may decide that our data are insufficient for pre-EUA. The FDA may require additional Chemistry, Manufacturing, and Controls ("**CMC**"), preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. For example, in 2016, the FDA asked the Company to establish the comparability of an older formulation of entolimod that had been used for preclinical and clinical studies and a newer to-be-marked formulation. The FDA requested that we perform a side-by-side analytical comparability study and then an *in vivo* study in NHP to establish bio-comparability between the two entolimod drug formulations. The FDA agreed last year that the Company had documented analytical comparability and bio-comparability in NHP and agreed to continue the review of the pre-EUA dossier by the Agency. There can be no guarantee that the FDA will not request any additional information related to our preclinical, clinical or manufacturing programs. Additionally, an authorization of our pre-EUA submission will not guarantee, and may not accelerate, BLA approval of entolimod as a radiation countermeasure.

Further, even if our pre-EUA submission is authorized, there is no guarantee that such authorization will lead to procurement by the U.S. or other governments or any additional development funding as it is possible that the U.S. or other government may not be interested in our product or our proposed terms of sale for any number of reasons including, but not limited to, lack of available funding, potential lack of government co-sponsorship of our pre-EUA, perceptions about the safety and effectiveness of entolimod, the storage requirements for entolimod or one of our competitors receiving pre-EUA authorization for their product. If we are not successful in partnering entolimod or completing the development, licensure and commercialization of entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

**Even if our drug candidates obtain regulatory approval, we will be subject to ongoing government regulation.**

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by international health authorities, including record-keeping requirements, submitting periodic reports, reporting of any adverse experiences with the product and complying with Risk Evaluation and Mitigation Strategies and drug sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the authorities. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting non-approved or "off-label" indications or products. Failure to comply with these requirements could result in significant enforcement action by the international health authorities, including warning letters, orders to pull the promotional materials and substantial fines.

After the approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or regulatory agency-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA and other international health authorities are likely to require post-market clinical testing of products approved under the Animal Rule or similar regulations at the time of a declared emergency and may require post-market clinical testing of other products. They may also require surveillance to monitor the product's safety or efficacy to evaluate long-term effects. It is also possible that rare but serious adverse events not seen in our drug candidates may be identified after marketing approval. This could result in withdrawal of our product from the market.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

**If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.**

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

- perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;
- published studies demonstrating the safety and effectiveness of our drugs;
- adequate reimbursement for our products from payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

**Risks Related to our Dependence on U.S. and Foreign Government Contracts and Grants**

**If we are unable to procure additional government funding, we may not be able to fund future R&D and implement technological improvements, which would materially harm our financial condition and operating results.**

In September 2015, we announced the grant of two awards from DoD, totaling approximately $15.8 million for advanced development of entolimod as a medical radiation countermeasure. These awards, the contracts for which have been amended since the initial grants to approximately $3.8 million earlier this year, were earned as the contracted development work was performed over a multi-year period. For the years ended December 31, 2020 and 2019, we received 81.2%, and 64.5% of our revenues from the U.S. government. The contracts with the DoD providing for these awards have expired.

These revenues have funded some of our operating costs and expenses. However, we will continue to incur substantial additional costs to fund our operations for which we may apply for other sources of government funding. If we do submit proposals for new grants or contracts, the review of such proposals and ultimate funding of an award may take significant time. Contract and grant awards are subject to a significant amount of uncertainty, including, but not limited to, successful negotiation and availability of funds. In addition, in our experience, contracts from Russian government entities require matching funds and posting of performance guarantees. Therefore, we expect that our acceptance of new contracts or grants from Russian government entities will also be subject to our ability to provide matching funds and to post performance guarantees.

If we are unable to obtain sufficient grants and contracts on a timely basis, our ability to fund future operations would be diminished, which would negatively impact our ability to compete in our industry and could materially and adversely affect our business, financial condition and operating results.

**Our future business may be harmed as a result of the foreign and U.S. government contracting process as it involves risks not present in the commercial marketplace.**

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts, both U.S. and foreign, which may be awarded through competitive bidding. For example, as described above, since 2015, we have received funding from DoD to support further development of entolimod. Additionally, in Russia we may seek additional funding from the Skolkovo Foundation or the Russian Federation Ministry of Industry and Trade (the "**MPT**"). Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and
- the risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

The U.S. government may choose to award future contracts for the supply of medical radiation countermeasures to our competitors instead of to us. If we are unable to win particular contracts, or if the government chooses not to fully exercise all options under contracts awarded to us, we may not be able to operate in the market for products that are provided under those contracts for a number of years. If we are unable to consistently win new contract awards, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

Additionally, government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts.

**The market for U.S. and other government funding is highly competitive.**

We periodically submit applications for funding of various research studies of our product candidates to the U.S. and other governments. There is no guarantee that any proposals that we plan to submit will be funded even if we receive positive reviews of such proposals as funding by the government is highly competitive and limited to the availability of funds. Failure to receive funding from U.S. and other government sources for the development of our product candidates could impair our ability to fund the development programs for our product candidates and thus could result in delays in development, or even stopping of development, of certain indications for our product candidates.

Notably, our biodefense product candidate, entolimod, faces significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if entolimod does not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in the biodefense industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

**U.S. government agencies have special contracting requirements, which create additional risks.**

We have historically entered into contracts with various U.S. government agencies. Due to these contracts with government agencies, we are subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit by the government at its sole discretion even after the end of the period of performance under the contract, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing contracts;
- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

Pursuant to our government contracts, we are generally permitted to retain title to any patentable invention or discovery made while performing the contract. However, the U.S. government is generally entitled to receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, our government contracts generally provide that the U.S. government retains unlimited rights in the technical data produced under such government contract.

**Our business could be adversely affected by a negative audit by the U.S. government.**

As a U.S. government contractor, we may become subject to periodic audits and reviews by U.S. government agencies such as the Defense Contract Audit Agency ("**DCAA**"). These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed and, such costs already reimbursed must be refunded.

Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, which have already been paid to us, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs, and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits, and other legal actions and liabilities to which purely private sector companies are not.

**Risks Relating to our Intellectual Property**

**We rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights and we may be liable for infringing upon the intellectual property rights of others.**

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have entered into five separate exclusive license agreements to license from third parties our product candidates that are not owned by us and some product candidates are covered by up to three separate license agreements. Pursuant to these license agreements we maintain patents and patent applications covering our product candidates. We do not know whether any of these patent applications that are still in the approval process will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial and the litigation would divert our management's efforts and our resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

**If we fail to comply with our obligations under our license agreement with third parties, we could lose our ability to develop our product candidates.**

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained exclusive licenses for our product candidates from The Cleveland Clinic and RPCI with regard to the use of patent applications as described above and certain processes, products and information of others, these licenses could be terminated or expire during critical periods and we may not be able to obtain licenses for other rights that may be important to us, or, if obtained, such licenses may not be obtained on commercially reasonable terms. Furthermore, some of our product candidates require the use of technology licensed from multiple third parties, each of which is necessary for the development of such product candidates. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Additionally, the patents underlying any licenses may not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

Our current exclusive licenses impose various development, royalty, diligence, record keeping, insurance, solvency and other obligations on us. If we breach any of these obligations and do not cure such breaches within the relevant cure period, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

In addition, while we cannot currently determine the dollar amount of the royalty and other payments we will be required to make in the future under the license agreements, if any, the amounts may be significant. The dollar amount of our future payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

**If we are not able to protect and control our unpatented trade secrets, know-how and other technology, we may suffer competitive harm.**

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

**Risks Relating to our Industry and Other External Factors**

**The biopharmaceutical market in which we compete is highly competitive.**

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. In addition, there are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these companies have substantially greater financial, technical, research and development resources, and human resources than us. Competitors may develop products or other technologies that are more effective than those that are being developed by us or may obtain FDA or other governmental approvals for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience.

**The COVID-19 pandemic could adversely impact our business, operations and clinical development timelines and plans.**

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States, where a national emergency was declared, and several European countries. If COVID-19 continues to spread in the United States and worldwide, we may experience disruptions that could severely impact our business, operations, preclinical studies and clinical trials, including:

- delays, difficulties or postponement in enrolling and retaining patients in our clinical trials;
- delays, difficulties or postponement in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials unrelated to infectious diseases;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our research and development efforts, preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with other individuals; or
- inability or difficulty in obtaining additional financing or access the financial markets.

Additionally, on March 20, 2020, the Governor of New York announced that 100% of the workforce of all businesses, excluding essential services, must stay home. During the effectiveness of this order , we implemented a work-from-home policy for all employees based in our Buffalo, New York headquarters. Under new applicable state orders, our offices may be occupied at 50% of their normal capacity if other safety precautions are taken, however, generally very few of our employees have returned to the office.

The global outbreak of COVID-19 continues to rapidly evolve and has begun to have indeterminable adverse effects on general commercial activity and the world economy. The extent to which COVID-19 may impact our business, research and development efforts, preclinical studies, clinical trials, prospects for regulatory approval of our drug candidates, and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the pace and effectiveness of vaccination efforts, the extent and duration of travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business prospects and the value of our common stock. Furthermore, if we or any of the third parties with whom we engage were to experience or re-experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

**Our growth could be limited if we are unable to attract and retain key personnel and consultants.**

Our success depends, in large part, on our ability to identify, hire, integrate, retain, and motivate qualified executive officers and other key employees throughout all areas of our business. We greatly depend on the efforts of our executive officers to manage our operations. However, we currently do not employ a permanent chief executive officer or chief financial officer. Our board of directors is currently undertaking a search for permanent replacement officers. While we have designated our Vice President of Finance as our interim principal executive officer and principal financial officer, our lack of a permanent chief executive officer and chief financial officer may materially and adversely affect our business prospects and investor confidence in our Company, which could cause the trading price of our common stock to decline. In addition, we utilize highly skilled personnel in operating and supporting our business, as we have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more members of our management, key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. Furthermore, we may be unable to attract and retain additional qualified executive officers and key employees as needed in the future. We currently do not maintain directors and officers liability insurance, which may make it more difficult for us to retain and attract talented and skilled directors and officers to serve our Company.

Additionally, we depend on our scientific, manufacturing, regulatory clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. Furthermore, to the extent that we are unable to engage certain collaborators or advisors for certain periods of time due to lack of relevant work or lack of available funds, there is a risk that such collaborators or advisors will not be available to provide services in the future at such time when there is available work and/or funds. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific, manufacturing, business development, regulatory, clinical collaborators, advisors, and opinion leaders in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. We face significant competition for this type of personnel and for employees from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

**We may be subject to damages resulting from claims that we, our employees or our consultants have wrongfully used or disclosed alleged trade secrets of their former employers.**

We engage as employees and consultants individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may become subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

**We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate.**

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if the product candidates are sold commercially. An individual may bring a product liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;

- diversion of our management's time and attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize product candidates; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance and intend to expand such coverage from coverage for clinical trials to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage that will be adequate to satisfy any liability that may arise.

From time to time, we may also become subject to litigation, such as stockholder derivative claims or securities fraud claims, including as a result of our pending merger with Cytocom, which could involve our directors and officers as defendants. We currently do not have director and officer insurance to cover such risk exposure for our directors and officers. Our certificate of incorporation and bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. We would be obligated to cover all such expenses for all directors and officers, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity.

**Our former laboratories used, and our subtenants use, certain chemical and biological agents and compounds that may be deemed hazardous and we are subject to various safety and environmental laws and regulations. Our compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.**

Until late 2013, we operated laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment and we currently sublease these laboratories for operation by other companies, which currently use hazardous materials. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal and we currently require that our laboratory sub-lessors do the same. We contracted with a third party to properly dispose of these materials and wastes and our laboratory sub-lessors now manage such contracts. We were and continue to be subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs if we unknowingly failed to comply with environmental laws and regulations.

**We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.**

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

**Political or social factors may delay or impair our ability to market our products.**

Entolimod is being developed to treat ARS, which is a disease that may be caused by terrorist acts. The political and social responses to terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

We announced in September 2015 that we received two awards from the DoD for the further development of entolimod. We hope to receive additional funding in the future from U.S. or foreign government agencies for the development of entolimod and our other products. Changes in government budgets and agendas, however, have previously resulted in termination of our contract negotiations and may, in the future, result in future funding being decreased and de-prioritized. In addition, government contracts contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue development of entolimod or continue our other operation. Similarly, if our pre-EUA submission for entolimod is authorized by the FDA, but the U.S. government does not place sufficient orders for this product, our future business may be harmed.

**Failure to comply with the U.S. Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.**

We are required to comply with the U.S. Foreign Corrupt Practices Act ("**FCPA**"), which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some that may compete with us, are not subject to these prohibitions. Furthermore, foreign jurisdictions in which we operate may have laws that are similar to the FCPA to which we are or may become subject. This may place us at a significant competitive disadvantage. Corruption, extortion, bribery, pay-offs, theft, and other fraudulent practices may occur from time to time in the foreign markets where we conduct business. Although we inform our personnel that such practices are illegal, we can make no assurance that our employees or other agents will not engage in illegal conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and similar foreign anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, such anti-bribery laws present particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees may be considered foreign officials.

**Risks Related to Conducting Business in Russia**

**Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results.**

Panacela Labs, LLC, which is the wholly-owned subsidiary of Panacela, conducts business, including clinical trials, in Russia through Russian legal entities. Also, Rusnano is a Russian joint-stock company created as a private equity and venture capital vehicle by the government of Russia. Panacela Labs, LLC owns the worldwide rights to Mobilan. Rusnano has certain shareholder rights which could block our ability to execute strategic transactions such as an asset sale or licensing arrangement. All clinical development activity conducted by these Russian entities was funded by grants from MPT. As such, any political, economic, or governmental instability in Russia could impact future funding, if any, by MPT, our access to trial data and our access to intellectual property for out-licensing purposes.

In addition to geopolitical events, other factors, including the steady fall in oil prices, the global strengthening of the U.S. dollar and the Russian Central Bank's reduction of currency rate support, have negatively affected the value of the Russian ruble relative to the U.S. dollar. Fluctuations in the rates at which the U.S. dollar is exchanged into Russian rubles may result in both foreign currency transaction and translation losses. We are subject to exchange rate fluctuations if we or one of our subsidiaries exchanges one currency into another, in order to conduct cross-border operations, and as we translate ruble denominated assets and liabilities that fluctuate from period-to-period. The former results in a transaction gain/loss that is reflected in our operating results. The latter results in a translation gain/loss reflected in other comprehensive income/loss in equity. Additionally, translation of historical operating results at average exchange rates for respective periods of time will also generate foreign currency translation adjustments that are reflected in our operating results. Presently, Panacela conducts most of its activities in Russia. As such we expect most of the foreign currency fluctuations to be related to accounting translations, versus transaction gains and losses.

Even before the current events mentioned above, and since the early 1990s, Russia has sought to transform from a one-party state with a centrally planned economy to a democracy with a market economy. As a result of the sweeping nature of various reforms and the failure of some of them, the political system of Russia remains vulnerable to popular dissatisfaction, including demands for autonomy from particular regional and ethnic groups. Current and future changes in the Russian government, major policy shifts or lack of consensus between various branches of the government and powerful economic groups could disrupt or reverse economic and regulatory reforms. Furthermore, the Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, and has experienced periods of considerable instability. Although the Russian economy showed positive trends until 2008, including annual increases in the gross domestic product, a relatively stable currency, strong domestic demand, rising real wages and a reduced rate of inflation, these trends were interrupted by the global financial crisis in late 2008, in which Russia experienced adverse economic and financial effects including a substantial decrease in the growth rate of gross domestic product, depreciation of local currency and a decline in domestic and international demand for its products and services. Economic instability in Russia could materially adversely affect our business, financial condition and results of operations.

**The current geopolitical instability arising from U.S relations with Russia, and related sanctions by the U.S. government against certain Russian companies and individuals, may have an adverse effect on us.**

Political and economic relations between Russia and the U.S., two of the jurisdictions in which we operate, are complex. Recent situations involving Ukraine, Crimea, Iran, Syria, and alleged cyberespionage by the Russian government against the U.S. Democratic National Committee and in connection with the 2016 U.S. presidential election, the cyberespionage effort effected through SolarWinds Inc. that has been alleged to have been perpetrated by Russian state actors, along with the response of the governments of Russia, the U.S., member states of the E.U., the E.U. itself and other nations, have the potential to materially adversely affect our operations in Russia through a variety of situations. In particular, due to Russia's recent military intervention in Ukraine, the United States, Canada and the E.U. have imposed sanctions against Russian officials, certain Russian companies and individuals. These sanctions were designed to affect various elements of Russia's economy, with a particular focus on defense companies, individuals identified by the U.S. Department of State as being in the "inner circle" of the current Russian president, banks and energy companies. Russia has responded with certain countermeasures, including limiting the import of certain goods from the U.S. and other countries.

There can be no assurance that such sanctions will not be expanded more broadly to impact a greater variety of actors in the Russian economy. If the U.S. government significantly broadens the scope of sanctions against Russia to impose further political and economic costs, and/or the Russian government responds with further countersanctions, the operation of our direct and indirect Russian subsidiary Panacela Labs, LLC, which performs clinical development work under grants received from the MPT and have development or other intellectual property rights to certain of our drug candidates, may be materially and adversely affected. Furthermore, because the largest holder of our company's outstanding common stock is an investor with ties to Russia, and several Russian citizens and residents serve on our board of directors, our ability to secure and maintain contracts with the U.S. Department of Defense and other U.S. government agencies or departments, from which we received 81.2% and 64.5% of our revenues for the years ended December 31, 2020 and 2019, respectively, may become more difficult, which could cause a material adverse impact on our business, prospects, results of operation, and financial condition.

**Emerging markets, such as Russia, are subject to greater risks than more developed markets and financial turmoil in Russia could disrupt our business.**

Investors in emerging markets, such as Russia, should be aware that these markets are subject to greater risks than more developed markets, including significant economic risks. For example, the Russian economy has periodically experienced high rates of inflation. According to The World Bank, the annual inflation rate in Russia, as measured by the consumer price index, was 7.1% in 2016, 3.7% in 2017, 2.9% in 2018, 4.47 in 2019, and 3.22% in 2020. Periods of higher inflation may slow economic growth. Inflation also is likely to increase some of our costs and expenses including the costs for our Russian subsidiary to conduct business operations, including any outsourced product testing costs.

Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set forth in our filings with the SEC about our operations in Russia may become outdated relatively quickly.

**The legal system in Russia can create an uncertain environment for business activity, which could materially adversely affect our business and operations in Russia.**

The legal framework in Russia is still under development and large portions of this framework have only recently become operational. The relatively recent enactment of many laws and the lack of consensus about the aims, scope, content, and pace of economic and political reforms have resulted in ambiguities, inconsistencies, and anomalies in the Russian legal system. The enforceability and underlying constitutionality of more recently enacted laws are in doubt, and many new laws remain untested.

As a result, its legal system can be characterized by: inconsistencies between and among laws and governmental, ministerial, and local regulations, orders, decisions, resolutions, and other acts; gaps in the regulatory structure resulting from the delay in adoption or absence of implementing regulations; selective enforcement of laws or regulations, sometimes in ways that have been perceived as being motivated by political or financial considerations; limited judicial and administrative guidance on interpreting legislation; relatively limited experience of judges and courts in interpreting recent commercial legislation; a perceived lack of judicial and prosecutorial independence from political, social and commercial forces; inadequate court system resources; a high degree of discretion on the part of the judiciary and governmental authorities; and underdeveloped bankruptcy procedures that are subject to abuse.

In addition, as is true of civil law systems generally, judicial precedents generally have no binding effect on subsequent decisions. Not all legislation and court decisions in Russia are readily available to the public or organized in a manner that facilitates understanding. Enforcement of court orders can in practice be very difficult. All of these factors make judicial decisions difficult to predict and effective redress uncertain. Additionally, court claims and governmental prosecutions may be used in furtherance of what some perceive to be political or commercial aims.

The untested nature of much of recent legislation in Russia and the rapid evolution of its legal system may result in ambiguities, inconsistencies, and anomalies in the application and interpretation of laws and regulations. Any of these factors may affect our ability to enforce our rights under our contracts or to defend ourselves against claims by others, or result in our being subject to unpredictable requirements. These uncertainties also extend to property rights and the expropriation or nationalization of any of our entities, their assets or portions thereof, potentially without adequate compensation, could materially adversely affect our business, financial condition and results of operations.

Judgments rendered by a court in any jurisdiction outside Russia are likely to be recognized by courts in Russia only if: (i) an international treaty providing for the recognition and enforcement of judgments in civil cases exists between Russia and the country where the judgment is rendered; and/or (ii) a federal law of Russia providing for the recognition and enforcement of foreign court judgments is adopted. No such federal law has been passed and no such treaty exists between the United States and Russia for the reciprocal enforcement of foreign courts' judgments. In the absence of an applicable treaty or convention providing for the recognition and enforcement of judgments in civil and commercial matters between the United States and Russia, a judgment of a U.S. court may be recognized and enforced in Russia only on the grounds of reciprocity. In each case, reciprocity must be established and, in the absence of a developed court practice, it is difficult to predict whether a Russian court will be inclined to recognize and enforce a U.S. court judgment on the grounds of reciprocity in any particular instance.

**Actions by the tax authorities in Russia may result in the sudden imposition of arbitrary or onerous taxes on our operations in Russia.**

BioLab 612 and Panacela Labs, LLC's tax liabilities are subject to periodic tax inspections that may result in tax assessments, penalties and interest being claimed from such subsidiaries for prior tax periods. Generally, tax declarations of Russian subsidiaries remain open and subject to audit by tax and/or customs authorities for three calendar years immediately preceding the year in which the decision to conduct an audit is taken. However, the fact that a particular year has been reviewed by tax authorities does not preclude that year from further review or audit during the eligible three-year limitation period by a superior tax authority. Moreover, the Russian tax authorities are allowed to carry out repeat field tax audits in connection with the restructuring or liquidation of a taxpayer or if the taxpayer resubmits an adjusted tax return based on which the amount of tax is reduced. The limitation of the tax audit period corresponds to the statute of limitations on the commission of a tax offense, which is also limited to three years from the date on which a tax offense was committed or from the date following the end of the tax period during which the tax offense was committed depending on the nature of the tax offense. The Russian Tax Code provides for the extension of the three-year statute of limitations if the actions of the taxpayer created insurmountable obstacles for the tax audit.

As none of the relevant terms are defined, tax authorities may have broad discretion to argue that a taxpayer has "obstructed", "hindered," or "created insurmountable obstacles" with respect to an inspection and may ultimately seek to review and possibly to apply penalties beyond the three-year term. Further, there is no guarantee that the tax authorities will not review compliance with applicable tax law beyond the three-year limitation period. Tax audits may result in additional costs if the relevant authorities conclude that the BioLab 612, Panacela Labs, LLC, or both did not satisfy their tax obligations in any given year. The outcome of these audits may result in significant fines, penalties and enforcement measures which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

The tax system in Russia imposes additional burdens and costs on our operations there and complicates our tax planning and related business decisions. For example, the tax environment in Russia has historically been complicated by contradictions in Russian tax law and ambiguity in areas such as the deductibility of certain expenses. This uncertainty could result in a greater than expected tax burden and potentially exposes us to significant fines and penalties and enforcement measures, despite our best efforts at compliance. These factors raise the risk of a sudden imposition of arbitrary or onerous taxes on our operations in Russia. This could materially adversely affect our financial condition and results of operations.

**Selective or arbitrary government action may have an adverse effect on our business.**

Government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify, or terminate contracts. Selective or arbitrary actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

**Shareholder liability under Russian legislation could cause us to become liable for the obligations of our subsidiaries.**

Under Russian law, we may become liable for the obligations of our Russian subsidiaries if it was determined that: (i) we had the ability to make, or exert influence on, decisions for such subsidiaries as a result of our equity interest, the terms of a binding contract with such Russian subsidiary or in any other way; and (ii) the relevant Russian subsidiary concluded the transaction giving rise to the obligations pursuant to the Company's instructions or consent. In addition, we may have secondary liability for the obligations of our Russian subsidiaries in a situation where the respective Russian subsidiary becomes insolvent or bankrupt and this was a result of, or was otherwise attributable to, actions of the Company. This type of liability could result in significant losses, and could have a material adverse effect on the Company's business, results of operations or financial position.

Accordingly, in the Company's position as a parent of Russian subsidiaries, there is a risk that it could be held liable in certain limited circumstances for the debts of its effective subsidiaries. If this liability is significant, it could materially adversely affect our business, financial condition or our results of operations.

**Our Russian operating entities can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.**

Panacela Labs, LLC was organized under the laws of Russia. Certain provisions of Russian law may allow a court to order the liquidation of a locally organized legal entity on the basis of its formal noncompliance with certain requirements during formation, reorganization, or during its operations. Additionally, Russian corporate law allows the government to liquidate a company if its net assets fall below a certain threshold. Similarly, there have also been cases in Russia in which formal deficiencies in the establishment process of a legal entity or noncompliance with provisions of law have been used by courts as a basis for liquidation of a legal entity. Weaknesses in the legal systems of Russia create an uncertain legal environment, which makes the decisions of a court or a governmental authority difficult, if not impossible, to predict. If involuntary liquidation of Panacela Labs, LLC were to occur, such liquidation could materially adversely affect our financial condition and results of operations.

**Crime and corruption could disrupt our ability to conduct our business.**

Political and economic changes in Russia in recent years have resulted in significant dislocations of authority. The local and international press has reported the existence of significant organized criminal activity, particularly in large metropolitan centers. In addition, the local and international press has reported high levels of corruption, including the bribing of officials for the purpose of initiating investigations by government agencies. Press reports have also described instances in which state officials have engaged in selective investigations and prosecutions to further the interests of the state and individual officials, as well as private businesses, including competitors and corporate raiders. Corruption in Russia is perceived to be pervasive and, in some cases, worsening. The government in Russia has recently pursued a campaign against corruption. However, there is no assurance that such laws or other laws enacted elsewhere will be applied with any effectiveness by the local authorities and the continuing effects of corruption, money laundering and other criminal activity could have a negative effect on the Russian economy and could materially adversely affect our business in Russia.

**Risks Relating to our Securities**

**Our largest stockholder has the ability to control our business, which may be disadvantageous to other stockholders .**

As of the date of this filing, Mr. David Davidovich, a venture capital investor, beneficially owns or controls approximately 48.3% of the voting power of our outstanding common stock. As a result of his being the single largest holder of the voting power of our outstanding common stock, Mr. Davidovich has the ability to substantially control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. Mr. Davidovich may have interests that are different from those of other stockholders and may vote in a way with which other stockholders disagree and that may be adverse to other stockholders' interests. Moreover, this concentration of share ownership makes it extremely difficult for other stockholders to replace directors and management without the consent of Mr. Davidovich. In addition, this significant concentration of share ownership may adversely affect the price prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders and may have the effect of delaying, preventing, or deterring a change of control of the Company and could deprive our stockholders of an opportunity to receive a premium for their company stock as part of a sale of the Company. Additionally, our corporate structure, including the ownership of Mobilan in Panacela, and the licensing of certain of entolimod's indications to GPI, may deter third parties from entering into collaboration and licensing arrangements with us.

**The price of our common stock has been and could remain volatile, which may in turn expose us to securities litigation.**

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 1, 2019 through December 31, 2020, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $4.26 per share in the second quarter of 2020 to a low of $0.51 in the fourth quarter of 2019. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent, and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility in addition to volatility caused by the occurrence of industry and company specific events. Factors that could cause fluctuations include, but are not limited to, the following:

- our progress in developing and commercializing our products;
- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- major catastrophic events;
- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our product candidates, including results of our preclinical studies and clinical trials;
- status of contract and funding negotiations relating to our product candidates;
- events affecting our collaborators;
- events affecting our competitors;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;

- the recent COVID-19 pandemic;
- regulatory developments in the U.S. and other countries;
- failure of our common stock to be listed or quoted on the NASDAQ Capital Market, another national market system, or any national stock exchange;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock market in general, and the stock price of companies listed on the NASDAQ, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance.

As a result of the volatility of our stock price, we could be subject to securities litigation, which could result in substantial costs and divert management's attention and company resources from our business.

**Issuance of additional equity may adversely affect the market price of our stock.**

We are currently authorized to issue 25,000,000 shares of common stock and 1,000,000 shares of preferred stock. As of this filing, 15,469,055 shares of our common stock were issued and outstanding, we had outstanding warrants to purchase 299,519 shares of our common stock at an average exercise price of $5.62 per share, and options to purchase 76,064 shares of our common stock at an average exercise price of $27.35 per share. To the extent we issue shares of common stock or our outstanding options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any other future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, certain of our outstanding warrants contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such securities to increase and/or the exercise price of such warrants to decrease.

Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve, or wind up our business and other terms. If we issue shares of preferred stock in the future that have preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Additionally, the conversion of any preferred stock issued in the future into our common stock could result in significant dilution to the holders of our common stock.

**The eventual public resale by certain of our significant stockholders could have a negative effect on the trading price of our common stock** .

In July 2015, we issued an aggregate of 6,716,163 shares of our Company's common stock to Mr. Davidovich and Rusnano. The issuances of these shares were not registered under the Securities Act of 1933, and the shares are only able to be resold pursuant to a separate registration statement or an applicable exemption from registration (under both federal and state securities laws). Contractual restrictions prohibiting Mr. Davidovich from selling his shares have expired and pursuant to the terms of registration rights agreements entered into between the Company and each of Mr. Davidovich and Rusnano, we have filed a registration statement on Form S-3 with the SEC to register the public offer and resale of the shares held by these stockholders. The registration statement has been declared effective by the SEC and Mr. Davidovich and Rusnano are each able to freely sell some or all of their shares of our Company's common stock. If all or a substantial portion of these shares are resold into the public markets under such registration statement or otherwise, such transactions may cause a decline in the trading price of our common stock.

**We do not intend to pay dividends for the foreseeable future** .

We do not intend to declare or pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We also consider from time to time various strategic alternatives that could involve issuances of additional shares of common stock or shares of preferred stock, including but not limited to acquisitions and business combinations.

**If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.**

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these reports and we currently do not have any industry analysts covering us. In the event we do regain analyst coverage, there can be no assurance that analysts will provide favorable coverage. Our stock price may be adversely impacted by our current lack of analyst coverage as we may have less visibility in the financial markets than other companies in our industry, which may cause declined trading volume and stock price.

**We have, in the past, failed to satisfy certain continued listing requirements of the Nasdaq Capital Market and could fail to satisfy those requirements again in the future, which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.**

Currently, our common stock trades on the Nasdaq Capital Market. During 2019 and 2020, we received notification from Nasdaq informing us of certain listing deficiencies related to the minimum required stockholders' equity and minimum bid price listing requirements, which led to the issuance of delisting notices. Although we have since cured these deficiencies and our common stock continues to trade on the Nasdaq Capital Market, it is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any Nasdaq listing requirements, our common stock could be delisted from the Nasdaq Capital Market. This could severely limit the liquidity of our common stock and your ability to sell our securities on the secondary market.

**Our operations could be disrupted by natural or human causes beyond our control.**

Our operations are subject to the risk of disruption by hurricanes, severe storms, floods and other forms of severe weather, earthquakes and other natural disasters, accidents, fire, power shortages, geopolitical unrest, war and other military action, terrorist attacks and other hostile acts, public health issues, epidemics or pandemics (including, for example, the recent novel coronavirus outbreak), and other events, such as raw material or supply scarcity, that are beyond our control and the control of the third parties on which we depend. Any of these catastrophic events, whether in the United States or abroad, may have a strong negative impact on the global economy, our employees, facilities, suppliers, or potential customers and could materially adversely affect our business, financial condition or results of operations.

## Item 1B. Unresolved Staff Comments

None.

## Item 2. Description of Properties

Our corporate headquarters is located at 73 High Street, Buffalo, New York 14203. This space serves as our corporate headquarters and U.S. corporate headquarters for Panacela. In addition, we have approximately 187 square feet under lease outside of the U.S. expiring at varying times through 2021. We do not own any real property.

## Item 3. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows, or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

While the outcome of these proceedings and claims cannot be predicted with certainty, other than as set forth below, there are no matters, that in the opinion of management might have a material adverse effect on our financial position, results of operations, or cash flows, or that are required to be disclosed under the rules of the SEC.

On March 12, 2021, a complaint, captioned *Teo v. Cleveland BioLabs, Inc. et al.*, Case 1:21-cv-02187, was filed in the U.S. District Court for the Southern District of New York in connection with the Merger (the "Teo Action"). The Teo Action names as defendants the Company, each director on the Company's board of directors and Cytocom. The complaint in the Teo Action alleges that (i) the Company's board of directors breached its fiduciary duties to the plaintiff stockholder in entering into the Merger Agreement and (ii) the Company and the Company's board of directors omitted and/or provided misleading information in the registration statement on Form S-4 filed with the SEC in connection with the Merger in violation of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and related SEC regulations. The Teo Action seeks, among other things, an injunction preventing the closing of the merger, rescission of the merger if it is consummated, damages and an award of plaintiffs' attorneys' and experts' fees.

On March 18, 2021, a complaint, captioned *Wang v. Cleveland BioLabs, Inc. et al.*, Case 1:21-cv-02395, was filed in the U.S. District Court for the Southern District of New York in connection with the Merger (the "Wang Action"). The Wang Action names as defendants the Company, each director on the Company's board of directors and Cytocom. The complaint in the Wang Action alleges that the Company and the Company's board of directors omitted and/or provided misleading information in the registration statement on Form S-4 filed with the SEC in connection with the Merger in violation of the Exchange Act and related SEC regulations. The Wang Action seeks, among other things, an injunction preventing the closing of the merger, rescission of the merger if it is consummated, the dissemination by the Company of a revised registration statement on Form S-4 and an award of plaintiffs' attorneys' and experts' fees.

The outcome of this lawsuits is uncertain. The Company believes that the claims asserted are without merit.

## Item 4. Mine Safety Disclosure

None.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

**STOCK EXCHANGE LISTING**

Our common stock trades on The NASDAQ Capital Market under the symbol "CBLI." We have not paid dividends on our common stock. We currently intend to retain all future income for use in the operation of our business and for future stock repurchases and, therefore, we have no plans to pay cash dividends on our common stock at this time.

**STOCKHOLDERS**

As of February 8, 2021, there were approximately 24 stockholders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

**DIVIDENDS**

We have never declared or paid any cash dividends on our capital stock. We currently intend to use the net proceeds from any offerings of our securities and our future earnings, if any, to finance the further development and expansion of our business and do not intend or expect to pay cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness, and plans for expansion and restrictions imposed by lenders, if any. Additionally, our merger agreement with Cytocom contains negative covenants that restrict us from, without Cytocom's consent, declaring or paying any dividends or other distributions on our common stock until the closing of the merger with Cytocom.

**UNREGISTERED SALE OF SECURITIES**

Except as previously disclosed, we did not sell any equity securities during the fiscal year ended December 31, 2020 in transactions that were not registered under the Securities Act.

**ISSUER PURCHASES OF EQUITY SECURITIES**

We made no repurchases of our securities during the year ended December 31, 2020.

See Part III, Item 12 "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*" for information about the securities authorized for issuance under our equity compensation plans.

### Item 6. Selected Financial Data

Not required for smaller reporting company filers.

### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

**OVERVIEW**

We are an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and radiation oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and other indications in radiation oncology. We conduct business in the U.S. and Russia through two subsidiaries, one of which is wholly owned, BioLab 612, which was dissolved in November 2020; and one of which is owned in collaboration with a financial partner, Panacela. In addition, we conducted business with a former subsidiary, Incuron, which will pay us a 2% royalty on future commercialization, licensing, or sale of certain technology we sold to Incuron. We also partner in a joint venture, GPI, with Everon Biosciences, Inc. See Item 1, "*Business*" for more information on our product candidates and our strategic partnerships.

## RECENT DEVELOPMENTS

### *Merger with Cytocom, Inc.*

As previously disclosed, on October 16, 2020, the Company, Merger Sub, and Cytocom entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cytocom, with Cytocom continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each outstanding share of Cytocom common stock, each outstanding share of Cytocom preferred stock that was not, by its terms, converted into shares of Cytocom common stock immediately prior to the effective time of the merger, and each vested restricted stock unit of Cytocom will be converted into the right to receive a number of shares of the Company's common stock determined by the application of an exchange formula set forth in the Merger Agreement. The exchange formula provides that the total number of shares of the Company's common stock to be issued as merger consideration for the Cytocom's capital stock will, upon issuance, be equal to approximately 61% of the outstanding shares of the combined company's common stock. Accordingly, under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former Cytocom stockholders are expected to own approximately 61% of the outstanding shares of the combined company's common stock on a fully diluted basis and stockholders of the Company as of immediately prior to the Merger are expected to own approximately 39% of the outstanding shares of the combined company's common stock on a fully diluted basis. Certain adjustments to this ratio will be made in respect of each party's net cash at the time of the closing of the Merger, as determined in accordance with the Merger Agreement. Each unvested Cytocom restricted stock unit award will be converted into a restricted stock unit award of the Company. Immediately following the effective time of the Merger, the board of directors of the Company will consist of seven members, three of whom will be designated by the Company and four of whom will be designated by Cytocom. In addition, upon the closing of the Merger, Cytocom's Chief Executive Officer, Michael Handley, will serve as Chief Executive Officer of the combined company. The closing of the Merger is subject to the satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the Company's stockholders, (ii) the accuracy of the respective representations and warranties of each party, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) the absence of any law or order preventing the Merger and related transactions, (v) the shares of the Company's common stock to be issued in the Merger being approved for listing (subject to official notice of issuance) on Nasdaq as of the closing and (vi) a registration statement on Form S-4 having become effective in accordance with the provisions of the Securities Act of 1933, as amended, and not being subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to such registration statement that has not been withdrawn.

### *COVID-19 Pandemic*

The COVID-19 pandemic has continued to affect multiple countries, including the United States, where a national emergency was declared, and several European and Asian countries. The continued spread of COVID-19 in the United States and worldwide, as well as the government-ordered shutdown and shelter-in-place orders imposed to counter the pandemic, have led to severe disruptions to the global economy. In this connection, on March 20, 2020, the Governor of New York announced that 100% of the workforce of all businesses, excluding essential services, must stay home. During the effectiveness of this order, we implemented a work-from-home policy for all employees based in our Buffalo, New York headquarters. Under new applicable state orders, our offices may be occupied at 50% of their normal capacity if other safety precautions are taken, however, generally very few of our employees have returned to the office. We are continuing to monitor the situation and will take such further action as may be required by federal, state or local authorities, or that we determine are in the best interests of our employees. COVID-19 and the governmental responses to it may cause us to experience disruptions that could severely impact our business, operations, preclinical studies and clinical trials. The global outbreak of COVID-19 continues to rapidly evolve and has begun to have indeterminable adverse effects on general commercial activity and the world economy. The extent to which COVID-19 may impact our business, research and development efforts, preclinical studies, clinical trials, prospects for regulatory approval of our drug candidates, and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the pace and effectiveness of vaccination efforts, the extent and duration of travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business prospects and the value of our common stock. Furthermore, if we or any of the third parties with whom we engage were to experience or re-experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

### *Registered Direct Offering*

As previously disclosed, on February 19, 2021, the Company entered into a Securities Purchase Agreement (the " **Purchase Agreement**") with several healthcare-focused and institutional investors for the sale by the Company of 2,000,000 shares (the "**Shares**") of the Company's common stock at a purchase price of $7.00 per share, in a registered direct offering. The closing of the sale of the Shares under the Purchase Agreement occurred on February 23, 2021. The gross proceeds to the Company from the transaction were approximately $14 million, before deducting the placement agent's fees and other estimated offering expenses. The Shares were offered and sold by the Company under a prospectus supplement and accompanying prospectus filed with the SEC pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on May 21, 2020 and subsequently declared effective on May 29, 2020 (File No. 333-238578). Under the Company's engagement letter (the "**Engagement Letter**") with H.C. Wainwright & Co., LLC ("**Wainwright**"), pursuant to which Wainwright agreed to serve as exclusive placement agent for the issuance and sale of the Shares and Warrants, the Company agreed to pay Wainwright an aggregate fee equal to 7.25% of the gross proceeds received by the Company from the sale of the securities in the transaction as well as a management fee equal to 1.0% of the gross proceeds received by the Company from the sale of the securities in the transactions. Pursuant to the Engagement Letter, the Company also issued to designees of Wainwright warrants to purchase up to 7.5% of the aggregate number of shares of Common Stock sold in the transactions, or warrants to purchase up to 150,000 shares of Common Stock (the "**Placement Agent Warrants**"). Subject to certain ownership limitations, the Placement Agent Warrants are immediately exercisable at an exercise price of $8.75 per share of Common Stock, subject to customary adjustments as provided under the terms of the Placement Agent Warrants. The Warrants are exercisable for five years from the commencement of sales of the shares being offered.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("**GAAP**"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues, and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, income taxes, stock-based compensation, investments, and in-process R&D. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

**Revenue Recognition**

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectability is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. We generate our revenue from two different types of contractual arrangements: (i) cost-reimbursement grants and contracts and (ii) fixed-price grants and contracts. Costs consist primarily of actual internal labor charges, subcontractor and material costs incurred, plus an allocation of fringe benefits, overhead and general and administrative expenses ("**G&A**"), and applicable fees, if any, based on the terms of the contract.

Revenues on cost-reimbursement grants and contracts are recognized in an amount equal to the costs incurred during the period, plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract; if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned. Otherwise, we compute fee income earned in a given period by using a proportional performance method based on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the grant or contract.

Revenues on fixed-price grants and contracts are recognized using a percentage-of-completion method, which uses assumptions and estimates, as appropriate. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-price grant or contract to determine levels of accomplishments throughout the life of the grant or contract.

**Stock-Based Compensation**

We expense all share-based awards to employees and consultants, including grants of stock options and shares, based on their estimated fair value at the date of grant. Costs of all share-based payments are recognized over the requisite service period that an employee or consultant must provide to earn the award (i.e., the vesting period) and allocated to the functional operating expense associated with that employee or consultant.

**Fair Value of Financial Instruments**

The carrying value of cash and cash equivalents, accounts receivable, short-term investments, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Certain common stock warrants, which are classified as liabilities, are recorded at their fair market value as of each reporting period.

The measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.
- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 – Instruments where significant value drivers are unobservable to third parties.

We use the Black-Scholes model to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 3. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life of the warrants; (iii) the expected volatility using historical volatilities of CBLI; and (iv) the risk-free market rate.

As of December 31, 2020, there was $0.00 million in accrued expenses relating to Level 3 securities for warrants to purchase common stock.

**Income Taxes**

Determining the consolidated provision for income tax expense, deferred tax assets and liabilities and related valuation allowance, if any, involves judgment. On an on-going basis, we evaluate whether a valuation allowance is needed to reduce our deferred income tax assets to an amount that is more likely than not to be realized. The evaluation process includes assessing historical and current results in addition to future expected results. Upon determining that we would be able to realize our deferred tax assets, an adjustment to the deferred tax valuation allowance would increase income in the period we make such determination.

**Research and Development Expenses**

Research and development ("**R&D**") costs are expensed as incurred. Advance payments are deferred and expensed as performance occurs. R&D costs include the cost of our personnel (which consists of salaries and incentive and stock-based compensation), out-of-pocket preclinical and clinical trial costs usually associated with contract research organizations, drug product manufacturing and formulation, and a pro-rata share of facilities expense and other overhead items.

**General and Administrative Expenses**

General and administrative ("**G&A**") functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, and legal and compliance. The specific costs include the cost of our personnel consisting of salaries, incentive and stock-based compensation, out-of-pocket costs usually associated with attorneys (both corporate and intellectual property), bankers, accountants and other advisors, and a pro-rata share of facilities expense and other overhead items.

**Other Income and Expenses**

Other recurring income and expenses primarily consists of interest income on our investments, changes in the market value of our derivative financial instruments, and foreign currency transaction gains or losses.

**YEAR ENDED DECEMBER 31, 2020 COMPARED TO YEAR ENDED DECEMBER 31, 2019**

**Revenue**

Revenue decreased from $1.1 million for the year ended December 31, 2019 to $0.3 million for the year ended December 31, 2020, representing a decrease of $0.8 million, or 76%, primarily due to a decrease in revenue from the JWMRP DoD contract and PRMRP DoD grant for preclinical studies, and the Incuron service contract for continued preclinical development. We do not anticipate any revenues from JWMRP or PRMRP in 2021 due to the completion of the contract and grant in 2020. Service revenue from Incuron is also expected to cease as our service contract was not extended.

Since these revenue sources are cost reimbursable in nature, variances in these activities, period to period, are directly aligned with variances in the underlying costs of service. Differences in our revenue sources, by program, between 2020 and 2019 are set forth in the following table:

| | | Year Ended December 31, | | | | |
|---|---|---|---|---|---|---|
| Funding Source | Program | 2020 | Percent of Total | 2019 | Percent of Total | Variance |
| DoD | JWMRP Contract | $ 156,685 | 59.6% | $ 637,355 | 57.3% | $ (480,670) |
| DoD | PRMRP Grant | 56,900 | 21.6% | 80,522 | 7.2% | (23,622) |
| DoD | DTRA Contract | — | —% | 0 | —% | - |
| Incuron | Service Contracts | 49,357 | 18.8% | 395,544 | 35.5% | (346,187) |
| | | $ 262,942 | 100.0% | $ 1,113,421 | 100.0% | $ (850,479) |

The following table sets forth information regarding our recently completed grant contracts as of December 31, 2020:

| Funding source | Program | Total award value | Funded award value | Cumulative revenue recognized | Funded backlog | Unfunded backlog |
|---|---|---|---|---|---|---|
| DoD | JWMRP Contract | $ 9,226,455 | $ 3,558,603 | $ 3,558,603 | $ - | $ - |
| DoD | PRMRP Grant | 6,573,992 | 214,860 | 214,860 | - | - |
| | | $ 15,800,447 | $ 3,773,463 | $ 3,773,463 | $ - | $ - |

Contract modifications with the DoD were entered into during the third quarter of 2020 that reduced the JWMRP and PRMRP funded awards from an aggregate of $15,800,447 to an aggregate of $3,773,463, as reflected in the table above.

**Research and Development Expenses**

R&D expenses decreased from $1.7 million for the year ended December 31, 2019 to $0.7 million for the year ended December 31, 2020, representing a decrease of $1.0 million, or 58%. Variances in individual development programs are noted in the table below. Significant reductions include the $0.6 million reduction of funds spent on entolimod for biodefense indication due to reduced preclinical development activity resulting from our previously disclosed vendor delays in the analytical analyses required to complete the biocomparability study and the FDA having not agreed with the Company's conclusions regarding the biocomparability study until earlier this year, which has prevented further development progress from occurring, and a decrease of $0.3 million related to Curaxins. We anticipate that R&D expenses associated with the development of our drug candidates will increase in 2021 as we plan to address some FDA questions concerning our pre-EUA submission. However, should the FDA have additional questions regarding the pre-EUA submission, we could conduct additional significant unplanned studies as necessary to respond to the FDA questions, within the confines of current funding limitations.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | Variance |
| Entolimod's biodefense indication | $ 657,443 | $ 1,302,572 | $ (645,129) |
| CBLB612 | - | 5,825 | (5,825) |
| Entolimod's oncology indications | - | 7,598 | (7,598) |
| | 657,443 | 1,315,995 | (658,552) |
| Curaxins | 12,272 | 310,566 | (298,294) |
| Panacela product candidates | 21,355 | 29,866 | (8,511) |
| Total research & development expenses | $ 691,070 | $ 1,656,427 | $ (965,357) |

**General and Administrative Expenses**

G&A expenses increased from $1.8 million for the year ended December 31, 2019 to $2.2 million for the year ended December 31, 2020, representing an increase of $0.4 million, or 19%. This increase consisted primarily of a $0.5 million increase in professional fees associated with activities related to the potential Cytocom merger and the filing of the Company's Form S-3 Registration Statement, a $0.15 million increase in other costs for cash awards to certain members of the Company's board of directors, and a $0.08 million increase in CBLI's property taxes compared 2019 when we received a property tax refund, partially offset by a $0.4 million decrease in personnel and consulting costs.

**Other Income and Expenses**

Other income and expense changed from $0.3 million of other expense for the year ended December 31, 2019 to $0.1 million of other income for the year ended December 31, 2020, representing an income increase of $0.4 million, or 145%. This increase was related to a $0.9 million increase in other income resulting from the 2020 reversal of an approximate $0.5 million revenue loss contingency recorded in 2019, and $0.05 million in foreign exchange gains realized upon the dissolution of BioLab 612, offset by a $0.5 million decrease in other income resulting from changes in the market value of our warrant liability.

**Liquidity and Capital Resources**

We have incurred net losses of approximately $169.1 million from our inception through December 31, 2020. Historically, we have not generated, and do not expect to generate in the immediate future, revenue from sales of product candidates. Since our founding in 2003, we have funded our operations through a variety of means:

- From inception through December 31, 2020, we have raised $147.9 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $7.3 million in net proceeds from the issuance of long-term debt instruments;
- DoD and the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, have funded grants and contracts totaling $48.4 million for the development of entolimod for its biodefense indication;
- The Russian Federation has funded a series of contracts totaling $17.3 million, based on the exchange rates in effect on the date of funding. These contracts included requirements for us to contribute matching funds, which we have satisfied with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses;
- We have been awarded $4.0 million in grants and contracts not described above, all of which has been recognized at December 31, 2020;

- Incuron was formed to develop and commercialize the Curaxins product line, including its lead oncology drug candidate CBL0137. In 2015, we sold our ownership interest for approximately $4.0 million and retained a 2% royalty interest in the CBL0137 technology; and

- Panacela was formed to develop and commercialize preclinical compounds, which were transferred to Panacela through assignment and lease agreements. Rusnano contributed $9.0 million to Panacela and CBLI contributed $3.0 million plus intellectual property to Panacela. As of the date of this filing, CBLI owns 67.57% of Panacela.

We have incurred cumulative net losses and expect to incur additional losses related to our R&D activities. We do not have commercial products and have limited capital resources. As of December 31, 2020, we had $2.3 million in cash, cash equivalents and short-term investments which are expected to fund our projected operating requirements and allow us to fund our operating plan, in each case, into April 2022. Since December 31, 2020, we raised additional capital as a result of the registered direct offering we completed on February 23, 2021, resulting in net proceeds to us of approximately $12.7 million. However, until we are able to commercialize our product candidates at a level that covers our cash expenses, we will need to raise substantial additional capital, which we may be unable to raise in sufficient amounts, when needed and at acceptable terms. Additionally, the continued spread of COVID-19 and uncertain market conditions may limit the Company's ability to access capital. Our plans with regard to these matters may include seeking additional capital through debt or equity financing in public or private transactions, the sale or license of drug candidates, or obtaining additional research funding from the U.S. or Russian governments. There can be no assurance that we will be able to obtain future financing on acceptable terms, or at all, or that we can obtain additional government financing for our operations. If we are unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

In addition, the COVID-19 pandemic may negatively impact our ability to complete our planned preclinical and clinical trials, our ability to obtain approval of any product candidates from FDA or other regulatory authorities and our workforce and therefore our research and development activities. This may ultimately have a material adverse effect on our liquidity, although we are unable to make any prediction with certainty given the rapidly changing nature of the pandemic and governmental and other responses to it.

***Operating Activities***

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **Variance** |
| Net cash used in operating activities | $ (2,372,985) | $ (2,663,389) | $ 290,404 |
| Net cash provided by investing activities | 55,443 | 156,783 | (101,340) |
| Net cash provided by financing activities | 3,165,640 | - | 3,165,640 |
| Effect of exchange rate change on cash and equivalents | (27,804) | 15,496 | (43,300) |
| Increase (decrease) in cash and cash equivalents | 820,294 | (2,491,110) | 3,311,404 |
| Cash and cash equivalents at beginning of period | 1,126,124 | 3,617,234 | (2,491,110) |
| Cash and cash equivalents at end of period | $ 1,946,418 | $ 1,126,124 | $ 820,294 |

***Operating Activities***

Net cash used in operations decreased by $0.3 million to $2.4 million for the year ended December 31, 2020 from $2.7 million for the year ended December 31, 2019. Net cash used in operating activities for the period ending December 31, 2020 consisted of a reported net loss of $2.4 million, which was further increased by $0.1 million of net non-cash operating activities, and decreased by $0.1 million due to changes in operating assets and liabilities. The $0.1 million of net non-cash operating activities consisted principally of changes in the valuation of our warrant liability offset by the gain on extinguishment of a 2019 revenue loss contingency. The net $0.1 million change in operating assets and liabilities was due to a continued decrease in working capital relating to accounts receivable and accounts payable. Net cash used in operating activities for the period ending December 31, 2019 consisted of reported net loss of $2.7 million, which was further increased by $0.1 million of net non-cash operating activities and offset by a $0.1 million change in operating assets and liabilities. The net non-cash operating activities of $0.1 million consisted principally of changes in the valuation of our warrant liability. The net $0.1 million change in operating assets and liabilities consisted primarily of an increase in accrued expenses related to a revenue loss contingency.

***Investing Activities***

Net cash provided by investing activities decreased by $0.1 million to $0.1 million for the year ended December 31, 2020 from $0.2 million for the year ended December 31, 2019. The net cash provided by investing activities for the years ended December 31, 2020 and 2019 consisted primarily of the net sales of short-term investments.

***Financing Activities***

Net cash provided by financing activities increased by $3.2 million to $3.2 million for the year ended December 31, 2020 from $0.0 million for the year ended December 31, 2019. Net cash provided by financing activities for the year ended December 31, 2020 consisted of proceeds from issuance of common stock and the exercise of warrants.

**Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements at December 31, 2020.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not required for smaller reporting company filers.

**Item 8. Financial Statements and Supplementary Data**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and
Stockholders of Cleveland BioLabs, Inc. and Subsidiaries

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Cleveland BioLabs, Inc. and Subsidiaries (the “Company”) as of December 31, 2020 and 2019, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows, for each of the years in the two-year period ended December 31, 2020, and the related notes and schedules (collectively referred to as the “financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity’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.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) related to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

*Going Concern:*
The Company has incurred losses each year from inception through December 31, 2020, and continues to have negative cash flow from operations. However, management believes, based on the current projections, including the impact of the February 2021 equity raise, that the Company will have enough funds to ensure continuing operations as a stand-alone entity for a period of at least one year from the issuance of these financial statements.

We determined the Company's ability to continue as a going concern is a critical audit matter due to the estimation and uncertainty regarding the Company's future cash flows and the risk of bias in management's judgments and assumptions in their determination. Our audit procedures related to the Company's assertion on its ability to continue as a going concern included the following, among others:

- We gained an understanding of the internal controls over the Company's going concern evaluation, including the inputs and assumptions used in forecasted results.
- We reviewed Company's records and made specific inquiries of management to assess if there are additional factors that contribute to the uncertainties disclosed which included a possible merger with a Company that issued 2019 financial statements included a going concern exception.
- We assessed whether the Company's determination that there is no substantial doubt about the entity's ability to continue as a going concern was adequately disclosed, including adequate disclosure of detail related to management's plan.
- We tested the reasonableness of the forecasted operating expenses, and uses and sources of cash used in management's assessment of whether the Company has sufficient liquidity to fund operations for at least one year from the financial statement issuance date. This testing included inquiries with management, comparison of prior period forecasts to actual results, consideration of positive and negative evidence impacting management's forecasts, the Company's financing arrangements in place as of the report date, market and industry factors and consideration of the Company's relationships with its financing partners.

/s / Meaden & Moore, Ltd.

MEADEN & MOORE, Ltd.

We have served as the Company's auditor since 2005.

Cleveland, Ohio
March 22, 2021

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,946,418 | $ 1,126,124 |
| Short-term investments | 324,870 | 452,301 |
| Accounts receivable | 11,512 | 378,865 |
| Other current assets | 31,506 | 45,381 |
| Total current assets | 2,314,306 | 2,002,671 |
| Equipment, net | 3,715 | 15,514 |
| Other long-term assets | - | 18,667 |
| Total assets | $ 2,318,021 | $ 2,036,852 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 167,773 | $ 263,573 |
| Accrued expenses | 136,838 | 782,579 |
| Accrued warrant liability | - | 6,414 |
| Total current liabilities | 304,611 | 1,052,566 |
| Non-current liabilities | - | - |
| Commitments and contingencies (Note 9) | - | - |
| Total liabilities | 304,611 | 1,052,566 |
| Stockholders' equity: | | |
| Preferred stock, $.005 par value; 1,000,000 shares authorized as of December 31, 2020 and December 31, 2019, 0 shares issued and outstanding as of December 31, 2020 and December 31, 2019 | - | - |
| Common stock, $.005 par value; 25,000,000 shares authorized as of December 31, 2020 and December 31, 2019, 13,376,062 and 11,298,239 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively | 66,876 | 56,487 |
| Additional paid-in capital | 166,762,778 | 163,161,523 |
| Accumulated other comprehensive loss | (685,680) | (568,030) |
| Accumulated deficit | (169,104,029) | (166,705,572) |
| Total Cleveland BioLabs, Inc. stockholders' deficit | (2,960,055) | (4,055,592) |
| Noncontrolling interest in stockholders' deficit | 4,973,465 | 5,039,878 |
| Total stockholders' equity | 2,013,410 | 984,286 |
| Total liabilities and stockholders' equity | $ 2,318,021 | $ 2,036,852 |

*See Notes to Consolidated Financial Statements*

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | For the Year Ended December 31, 2020 | 2019 |
|---|---|---|
| Revenues: | | |
| Grants and contracts | $ 262,942 | $ 1,113,421 |
| Operating expenses: | | |
| Research and development | 691,070 | 1,656,427 |
| General and administrative | 2,158,423 | 1,817,830 |
| Total operating expenses | 2,849,493 | 3,474,257 |
| Loss from operations | (2,586,551) | (2,360,836) |
| Other income (expense): | | |
| Interest and other income (expense) | 518,118 | (404,722) |
| Foreign exchange gain (loss) | 56,690 | (1,329) |
| Change in value of warrant liability | (426,130) | 72,223 |
| Total other income (expense) | 148,678 | (333,828) |
| Net loss | (2,437,873) | (2,694,664) |
| Net loss attributable to noncontrolling interests | 39,416 | 47,677 |
| Net loss attributable to Cleveland BioLabs, Inc. | $ (2,398,457) | $ (2,646,987) |
| Net loss available to common stockholders per share of common stock, basic and diluted | $ (0.19) | $ (0.23) |
| Weighted average number of shares used in calculating net loss per share, basic and diluted | 12,396,628 | 11,298,239 |

*See Notes to Consolidated Financial Statements*

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

| | For the Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Net loss including noncontrolling interests | $ (2,437,873) | $ (2,694,664) |
| Other comprehensive income (loss): | | |
| Realized foreign currency translation | (57,936) | — |
| Foreign currency translation adjustment | (86,711) | 64,923 |
| Comprehensive loss including noncontrolling interests | (2,582,520) | (2,629,741) |
| Comprehensive loss attributable to noncontrolling interests | 66,413 | 26,094 |
| Comprehensive loss attributable to Cleveland BioLabs, Inc. | $ (2,516,107) | $ (2,603,647) |

*See Notes to Consolidated Financial Statements*

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | For the Year Ended December 31, 2020 | 2019 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $ (2,437,873) | $ (2,694,664) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 11,446 | 13,782 |
| Gain on equipment disposal | — | (50,200) |
| Noncash compensation | 13,500 | — |
| Realized foreign currency translation | (57,938) | — |
| Accrued liability extinguishment | (501,892) | — |
| Change in value of warrant liability | 426,130 | (72,223) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable and other current assets | 380,146 | (68,478) |
| Other long-term assets | 18,667 | 11,871 |
| Accounts payable and accrued expenses | (225,171) | 196,523 |
| Net cash used in operating activities | (2,372,985) | (2,663,389) |
| Cash flows from investing activities: | | |
| Purchase of short-term investments | (679,174) | (1,243,508) |
| Sale of short-term investments | 734,617 | 1,351,639 |
| Proceeds from sale of equipment | — | 50,200 |
| Purchase of equipment | — | (1,548) |
| Net cash provided by investing activities | 55,443 | 156,783 |
| Cash flows from financing activities: | | |
| Issuance of common stock, net of offering costs | 2,783,425 | - |
| Exercise of warrants | 382,215 | - |
| Net cash provided by financing activities | 3,165,640 | - |
| Effect of exchange rate change on cash and equivalents | (27,804) | 15,496 |
| Increase (decrease) in cash and cash equivalents | 820,294 | (2,491,110) |
| Cash and cash equivalents at beginning of period | 1,126,124 | 3,617,234 |
| Cash and cash equivalents at end of period | $ 1,946,418 | $ 1,126,124 |
| Supplemental disclosure of cash flow information: | | |
| Supplemental schedule of non-cash financing activities: | | |
| Cashless exercise of warrants | $ 432,504 | $ — |

*See Notes to Consolidated Financial Statements*

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

| | Common Stock | | Treasury Stock | | Additional Paid-in |
|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital |
| Balance at December 31, 2018 | 11,298,239 | $ 56,487 | - | $ - | $ 163,161,523 |
| Exercise of warrants | - | - | - | - | - |
| Net loss | - | - | - | - | - |
| Foreign currency translation | - | - | - | - | - |
| Balance at December 31, 2019 | 11,298,239 | 56,487 | - | - | 163,161,523 |
| Exercise of warrants | 555,945 | 2,780 | - | - | 811,939 |
| Net loss | - | - | - | - | - |
| Realized foreign currency translation | - | - | - | - | - |
| Foreign currency translation | - | - | - | - | - |
| Issuance of common stock, net of offering costs | 1,521,878 | 7,609 | - | - | 2,789,316 |
| Balance at December 31, 2020 | 13,376,062 | $ 66,876 | - | $ - | $ 166,762,778 |

| | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Noncontrolling Interests | Total |
|---|---|---|---|---|
| Balance at December 31, 2018 | $ (611,370) | $ (164,058,585) | $ 5,065,972 | $ 3,614,027 |
| Exercise of warrants | - | - | - | - |
| Net loss | - | (2,646,987) | (47,677) | (2,694,664) |
| Foreign currency translation | 43,340 | - | 21,583 | 64,923 |
| Balance at December 31, 2019 | (568,030) | (166,705,572) | 5,039,878 | 984,286 |
| Exercise of warrants | - | - | - | 814,719 |
| Net loss | - | (2,398,457) | (39,416) | (2,437,873) |
| Realized foreign currency translation | (57,936) | - | - | (57,936) |
| Foreign currency translation | (59,714) | - | (26,997) | (86,711) |
| Issuance of common stock, net of offering costs | - | - | - | 2,796,925 |
| Balance at December 31, 2020 | $ (685,680) | $ (169,104,029) | $ 4,973,465 | $ 2,013,410 |

*See Notes to Consolidated Financial Statements*

**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Description of Business

Cleveland BioLabs, Inc. ("**CBLI**" or the "**Company**") is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor ("**TLR**") activators has applications in radiation protection and oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a medical radiation countermeasure and other indications in radiation oncology.

CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. CBLI conducts business in the United States (" **U.S.**") and in the Russian Federation ("**Russia**") through two subsidiaries: one wholly-owned subsidiary, BioLab 612, LLC (**"BioLab 612"**), which began operations in 2012 and was dissolved in November 2020; and Panacela Labs, Inc. ("**Panacela**"), which was formed by us and Joint Stock Company "RUSNANO" (" **Rusnano**"), our financial partner in the venture, in 2011. In addition, during October 2020, CBLI formed High Street Acquisition Corp. as a wholly-owned subsidiray to facilitate the merger more fully discussed below. Unless otherwise noted, references to the "Company," "we," "us," and "our" refer to Cleveland BioLabs, Inc. together with its subsidiaries.

The Company also has an investment in Genome Protection, Inc. (" **GPI**") that is recorded under the equity method of accounting in the accompanying financial statements. The Company has not recorded its 50% share of the losses of GPI through December 31, 2020 as the impact would have reduced the Company's equity method investment in GPI below zero, and there are no requirements to fund the Company's share of these losses or contribute additional capital as of the date of these statements.

On October 16, 2020, the Company, High Street Acquisition Corp. (" **Merger Sub**"), a Delaware corporation and a wholly owned subsidiary of the Company, and Cytocom, Inc., a Delaware corporation ("**Cytocom**"), entered into an Agreement and Plan of Merger (the " **Merger Agreement**"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cytocom, with Cytocom continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "**Merger**"). Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each outstanding share of Cytocom common stock, each outstanding share of Cytocom preferred stock that was not, by its terms, converted into shares of Cytocom common stock immediately prior to the effective time of the merger, and each vested restricted stock unit of Cytocom will be converted into the right to receive a number of shares of the Company's common stock determined by the application of an exchange formula set forth in the Merger Agreement. The exchange formula provides that the total number of shares of the Company's common stock to be issued as merger consideration for the Cytocom's capital stock will, upon issuance, be equal to approximately 61% of the outstanding shares of the combined company's common stock. Accordingly, under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former Cytocom stockholders are expected to own approximately 61% of the outstanding shares of the combined company's common stock on a fully diluted basis and stockholders of the Company as of immediately prior to the Merger are expected to own approximately 39% of the outstanding shares of the combined company's common stock on a fully diluted basis. Certain adjustments to this ratio will be made in respect of each party's net cash at the time of the closing of the Merger, as determined in accordance with the Merger Agreement. Each unvested Cytocom restricted stock unit award will be converted into a restricted stock unit award of the Company. Immediately following the effective time of the Merger, the board of directors of the Company will consist of seven members, three of whom will be designated by the Company and four of whom will be designated by Cytocom. In addition, upon the closing of the Merger, Cytocom's Chief Executive Officer, Michael Handley, will serve as Chief Executive Officer of the combined company. The closing of the Merger is subject to the satisfaction or waiver of certain conditions including, among other things, (i) the required approvals by the Company's stockholders, (ii) the accuracy of the respective representations and warranties of each party, subject to certain materiality qualifications, (iii) compliance by the parties with their respective covenants, (iv) the absence of any law or order preventing the Merger and related transactions, (v) the shares of the Company's common stock to be issued in the Merger being approved for listing (subject to official notice of issuance) on Nasdaq as of the closing and (vi) a registration statement on Form S-4 having become effective in accordance with the provisions of the Securities Act of 1933, as amended, and not being subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to such registration statement that has not been withdrawn. In connection with the merger, CBLI filed a registration statement on Form S-4 with the Securities and Exchange Commission on February 16, 2021 containing a proxy statement for the special meeting of stockholders required to obtain approval of the issuance of shares of the Company's common stock in the Merger and a prospectus registering the issuance of such shares. The registration statement has not yet been declared effective by the Securities and Exchange Commission.

On February 19, 2021, the Company entered into a Securities Purchase Agreement (the " **Purchase Agreement**") for the sale of 2,000,000 shares (the "**Shares**") of common stock at a purchase price of $7.00 per share, in a registered direct offering. The closing of the sale of the Shares under the Purchase Agreement occurred on February 23, 2021. The gross proceeds to the Company from the transaction were approximately $14 million, before deducting the placement agent's fees and other estimated offering expenses. Under the Company's engagement letter (the "**Engagement Letter**") with H.C. Wainwright & Co., LLC ("**Wainwright**"), pursuant to which Wainwright agreed to serve as exclusive placement agent for the issuance and sale of the Shares, the Company also issued to designees of Wainwright warrants to purchase up to 150,000 shares of Common Stock (the "**Placement Agent Warrants**"). Subject to certain ownership limitations, the Placement Agent Warrants are immediately exercisable at a price of $8.75 per share of Common Stock, subject to customary adjustments as provided under the terms of the Placement Agent Warrants. The Warrants are exercisable for five years from the commencement of sales of the shares being offered.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Consolidation***

The accompanying consolidated financial statements include the accounts of CBLI, BioLab 612 through the dissolution date in November 2020, and Panacela. All significant intercompany balances and transactions have been eliminated in consolidation. These financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States ("**GAAP**").

At December 31, 2020, we had cash, cash equivalents, and short-term investments of $2.3 million. Of that total, $0.3 million was restricted for the use of our consolidated joint venture, Panacela, leaving $2.0 million available for general use, which management believes in connection with the February 2021 common stock issuance will be sufficient to support CBLI's operations through April 2022. To ensure continuing operations beyond that point, management is evaluating all opportunities, including investments from non-controlling interests, the sale or license of our drug candidates, the issuance of additional equity, and securing additional revenues from the U.S. or Russian governments. These financial statements have been prepared under the assumption that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. As it relates to Cytocom, their financial statements issued for the year ended December 31, 2019 raised substantial doubt about Cytocom's ability to continue as a going concern given current debt levels and planned operating cash outflows through 2020. It is uncertain what impact a planned merger with Cytocom would have on the proposed new consolidated entity's ability to generate sufficient cash flows in order to sustain operations. For further information on the proposed operating results and cash flows of a merged entity, refer to Registration Statement on Form S-4 filed with the SEC on February 16, 2021.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Cash and Cash Equivalents***

The Company had $1.9 million and $1.1 million of cash and cash equivalents at December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, $0.015 million of the Company’s cash and cash equivalents were held in Russian banks, all of which was denominated in rubles.

***Short-Term Investments***

The Company’s short-term investments are classified as and held to maturity and recorded at amortized cost. Short-term investments consist of $0.3 million in certificates of deposit with maturity dates beyond three months and less than one year and are owned by Panacela. These investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Realized gains and losses, and interest and dividends on short-term investments are recorded in our Statements of Operations as Interest and Other Income. The cost of securities sold is based on the specific identification method.

***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to a significant concentration of credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains cash balances with financial institutions in excess of insured limits.

As of December 31, 2020, the Company held less than 1% of its cash and cash equivalents in accounts located outside of the United States.

As of February 8, 2021, the Dollar:Russian Ruble exchange rate increased to 75.1107, resulting in a decrease of $0.0002 million to the Company’s cash and cash equivalents as compared to December 31, 2020.

***Significant Customers and Accounts Receivable***

The following table presents our revenue by customer, on a proportional basis, for the periods indicated:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | Variance |
| U.S. Department of Defense | 81.2% | 64.5% | 16.7% |
| Incuron, Inc | 18.8% | 35.5% | -16.7% |
| | 100.0% | 100.0% | 0.0% |

Although the Company anticipates future DoD contract and grant revenues, since we have no active agreements there is no guarantee that these revenue streams will continue in the future.

The Company extends unsecured credit to its government customers under normal trade agreements and contracted terms, which generally require payment within 30 days. Accounts receivable consist of amounts due under contracts and grants from these customers, along with amounts receivable under subleases at our Buffalo, New York office facility. The allowance for doubtful accounts was $0.1 million and $0.0 million at December 31, 2020 and December 31, 2019, respectively.

***Equipment***

Equipment is stated at cost, net of accumulated depreciation. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repair and maintenance costs are expensed as incurred.

Equipment is depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

| **Asset Category** | **Estimated Useful Life (in Years)** |
|---|---|
| Laboratory equipment | 5 |
| Furniture and fixtures | 5 |
| Computer equipment | 3 |

***Impairment of Long-Lived Assets***

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

***Intellectual Property***

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred, since the recoverability of such expenditures is uncertain. Upon marketability approval by the FDA, or a respective foreign regulatory governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

***Accrued Warrant Liability***

Certain warrants are accounted for as derivative instruments in accordance with the Financial Accounting Standards Board Accounting Standards Codification (the "**Codification**") on derivatives and hedging as the warrant holders, under certain change of control situations, could require settlement in cash. As such, the warrants were initially recorded as liabilities based on their fair values on the date of issuance. Subsequent changes in the value of the warrants are recorded in the Statements of Operations as "Change in value of warrant liability."

The Company's remaining outstanding warrants were treated as equity upon issuance and continue to be treated as equity since they do not contain any mandatory redemption features or other provisions that would require a different classification of these warrant instruments outside of permanent equity.

***Foreign Currency Translation***

The Russian ruble is the functional currency of our foreign subsidiaries, which are all located in the Russian Federation. Assets and liabilities of these companies are translated into U.S. dollars at the period-end exchange rate. Income and expense items are translated at the average exchange rates during the period. The net effect of this translation is recorded in the consolidated financial statements as accumulated other comprehensive income (loss). As a result of the dissolution of BioLab 612 in November 2020, accumulated foreign currency translation in the amount of $57,936 was realized, and recorded to foreign exchange gain in the Statements of Operations.

***Other Comprehensive Income (Loss)***

The Company applies the Codification on comprehensive income that requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The following table presents the changes in accumulated other comprehensive loss for the year ended December 31, 2020.

| | Gains and (losses) on foreign exchange translations | Total |
|---|---|---|
| Beginning balance | $ (568,030) | $ (568,030) |
| Realized foreign currency translation | (57,936) | (57,936) |
| Foreign currency translation | (59,714) | (59,714) |
| Ending balance | $ (685,680) | $ (685,680) |

***Revenue Recognition***

The Company generates grant and contract revenue from two different types of contractual arrangements: cost reimbursement grants and contracts, and fixed-price grants and contracts. Costs consist primarily of internal labor charges, subcontractors and materials, as well as an allocation of fringe benefits, overhead and general and administrative expenses. Under cost reimbursement grants and contracts, revenue is recognized during the period that the associated research and development costs are incurred. Under fixed-price grants and contracts, revenue is recognized using the percentage-of-completion method. The assumptions and estimates used in determination of the percentage-of-completion are developed in coordination with the principal investigator performing the work.

***Research and Development***

Research and development ("**R&D**") costs are expensed as incurred. R&D costs primarily consist of salaries, fringe benefits, and stock-based compensation for our clinical and scientific personnel along with a ratable share of our facility expenses. Other R&D expenses include fees paid to research-oriented consultants, outside service providers, costs of materials used in clinical trials, and other research activities.

***Accounting for Stock-Based Compensation***

The Cleveland BioLabs, Inc. Equity Incentive Plan, adopted in 2018 (the **"Plan"**), authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. As of December 31, 2020, an aggregate of 597,557 shares of common stock were authorized for issuance under the Plan, of which a total of approximately 515,493 shares of common stock remained available for future awards. In addition, a total of 76,064 shares of common stock reserved for issuance were subject to currently outstanding stock options granted under the Plan as in effect prior to the 2018 amendment and restatement. A single participant cannot be awarded more than 100,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by the Company's board of directors or its management delegates.

The 2013 Employee Stock Purchase Plan (**"ESPP"**) provides a means by which eligible employees of the Company and certain designated related corporations may be given an opportunity to purchase shares of common stock. As of December 31, 2020, there were 725,000 shares of common stock reserved for purchase under the ESPP. The number of shares reserved for purchase under the ESPP increases on January 1 of each calendar year by the lesser of (i) 10% of the total number of shares of common stock outstanding on December 31st of the preceding year, or (ii) 100,000 shares of common stock. The ESPP allows employees to use up to 15% of their compensation to purchase shares of common stock at an amount equal to 85% of the fair market value of the Company's common stock on the offering date or the purchase date, whichever is less.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted where the vesting period is based on length of service or performance, while a Monte Carlo simulation model is used for estimating the fair value of stock options with market-based vesting conditions. No options were granted during the years ended December 31, 2020 and 2019.

***Income taxes***

No income tax expense was recorded for the years ended December 31, 2020 and 2019 as the Company did not have taxable income for any of the years presented. A full valuation allowance has been recorded against the Company's net deferred tax asset.

***Earnings (Loss) per Share***

Basic net loss per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

The Company has excluded the following securities from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

| | As of December 31, | |
|---|---|---|
| **Common Equivalent Securities** | **2020** | **2019** |
| Warrants | 371,340 | 327,253 |
| Options | 76,064 | 136,105 |
| Total | 447,404 | 463,358 |

***Recently Issued Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ( **"FASB"**) or other standard-setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

**3. Fair Value Measurements**

The Company measures and records warrant liabilities at fair value in the accompanying financial statements. Fair value is defined 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, includes:

- Level 1 – Observable inputs for identical assets or liabilities such as quoted prices in active markets;
- Level 2 – Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 – Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2020 and 2019:

| | As of December 31, 2020 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Short-term investments | $ - | $ 324,870 | $ - | $ 324,870 |
| Total assets | $ - | $ 324,870 | $ - | $ 324,870 |
| **Liabilities:** | | | | |
| Accrued warrant liability | $ - | $ - | $ - | $ - |

| | As of December 31, 2019 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Short-term investments | $ - | $ 452,301 | $ - | $ 452,301 |
| Total assets | $ - | $ 452,301 | $ - | $ 452,301 |
| **Liabilities:** | | | | |
| Accrued warrant liability | $ - | $ - | $ 6,414 | $ 6,414 |

The Company has certain warrants that could require settlement in cash if a fundamental transaction occurs, as defined in the respective agreements. These agreements specify that any amount due to warrant holders as a result of a fundamental transaction would be based on the Black-Scholes pricing model.

The following are the assumptions used to measure the accrued warrant liability as of and during the years ended December 31, 2020 and 2019:

"Risk-free interest rate" means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

"Expected dividend yield" means the anticipated dividend return for an investor over the expected life. For the Company, this amount is zero as it is not anticipated that dividends will be paid for the foreseeable future.

"Expected life" means the period of time that options granted are expected to remain outstanding, based wholly on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not have adequate historical exercise information to estimate the expected life the options granted.

"Expected volatility" means a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Expected volatility is based on the Company's historical volatility.

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Stock Price | $ 3.45 | $ 0.60 |
| Exercise Price | $ 20.40 | $ 3.64 - 20.40 |
| Term in years | 0.04 | 1.04-1.60 |
| Volatility | 69.29% | 84.59 - 98.24% |
| Annual rate of quarterly dividends | 0% | 0% |
| Discount rate- bond equivalent yield | 0.00% | 1.58 - 1.59% |

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurement of the accrued warrant liability for the years ended December 31, 2020 and 2019:

| | Year Ended December 31, 2020 |
|---|---|
| Beginning Balance | $ 6,414 |
| Total (gains) or losses, realized and unrealized, included in earnings (1) | 426,130 |
| Settlements | (432,544) |
| Balance at December 31, 2020 | $ - |

| | Year Ended December 31, 2019 |
|---|---|
| Beginning Balance | $ 78,637 |
| Total (gains) or losses, realized and unrealized, included in earnings (1) | (72,223) |
| Balance at December 31, 2019 | $ 6,414 |

*(1) Unrealized gains or losses related to the accrued warrant liability were included as change in value of warrant liability.*

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of December 31, 2020 and 2019, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability measurement to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. The following table summarizes the unobservable inputs into the fair value measurements:

| | December 31, 2020 | | | |
|---|---|---|---|---|
| **Description** | **Fair Value** | **Valuation Technique** | **Unobservable Input** | **Range in years** |
| Accrued warrant liability | $ - | Black-scholes pricing model | Expected term | 0.04 |

Management believes the value of the accrued warrant liability is more sensitive to changes in the Company's stock price at the end of the respective reporting period as opposed to changes in the expected term. However, given the limited term remaining on the warrants recorded as liability instruments, a 10% increase or 10% decrease in the expected term or Company's stock price would not have changed the accrued warrant liability as of December 31, 2020.

The carrying amounts of the Company's remaining financial instruments, which include cash, short-term investments, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

**4. Equipment**

The following table summarizes the value of the Company's equipment as of December 31, 2020 and 2019:

| | As of December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Computer equipment | $ 89,362 | $ 98,307 |
| Lab equipment | 39,651 | 39,651 |
| Furniture | 3,100 | 3,100 |
| | 132,113 | 141,058 |
| Less accumulated depreciation | (128,398) | (125,544) |
| Equipment, net | $ 3,715 | $ 15,514 |

**5. Stockholders' Equity**

During June 2020, the Company raised $2.8 million in net proceeds from the issuance of 1,515,878 shares of common stock and warrants to purchase 871,630 shares of common stock. These warrants were recorded as a equity instrument and valued at $1.0 million at the date of issuance utilizing the following Black-Scholes assumptions.

| | June 3, 2020 |
|---|---|
| Stock Price | $ 1.65 |
| Exercise Price | $2.03 - $2.62 |
| Term in years | 5.00 |
| Volatility | 98.20% |
| Annual rate of quarterly dividends | 0% |
| Discount rate- bond equivalent yield | 0.38% |

Issuance costs amounted to $391,581.

***Warrants***

In connection with sales of the Company's common stock and the issuance of debt instruments that have since been repaid, warrants were issued. The warrants expire between one and seven years from issuance from the date of grant and are subject to the terms applicable in each agreement. The following table sets forth the changes in the number of warrants outstanding for the periods presented:

| | Number of Warrants | Weighted Average Exercise Price |
|---|---|---|
| Outstanding at December 31, 2018 | 528,054 | $ 10.90 |
| Forfeited, Canceled | (200,801) | 14.18 |
| Outstanding at December 31, 2019 | 327,253 | 8.89 |
| Granted | 871,630 | 2.11 |
| Exercised | (827,543) | 2.03 |
| Outstanding at December 31, 2020 | 371,340 | $ 7.28 |

***Equity Incentive Plan***

The following is a summary of option award activity under the Plan for the year ended December 31, 2020:

| | Year ended December 31, 2020 | | | |
|---|---|---|---|---|
| | Total Stock Options Outstanding | Weighted Average Exercise Price per Share | Nonvested Stock Options | Weighted Average Grant Date Fair Value per Share |
| December 31, 2019 | 136,105 | $ 40.07 | — | $ — |
| Forfeited, Canceled | (60,041) | 56.19 | — | — |
| December 31, 2020 | 76,064 | $ 27.35 | — | $ — |

The following is a summary of outstanding stock options under the Plan as of December 31, 2020:

| | Stock Options Outstanding | Vested Stock Options |
|---|---|---|
| Quantity | 76,064 | 76,064 |
| Weighted-average exercise price | $ 27.35 | $ 27.35 |
| Weighted Average Remaining Contractual Term (in Years) | 3.24 | 3.24 |
| Intrinsic value | $ 12,300 | $ 12,300 |

For the years ended December 31, 2020 and 2019, the Company granted no stock options. The total intrinsic value of options exercised for the years ended December 31, 2020 and 2019 was $0. As of December 31, 2020, there was no total compensation cost not yet recognized related to unvested stock options.

**6. Significant Alliances and Related Parties**

***Roswell Park Cancer Institute***

The Company has entered into several agreements with Roswell Park Cancer Institute (" **RPCI**"), including various sponsored research agreements, an exclusive license agreement and clinical trial agreements for the conduct of the Phase 1 entolimod oncology study, and the Phase 1 CBL0137 intravenous administration study. Additionally, our Chief Scientific Officer, Dr. Andrei Gudkov, is the Senior Vice President of Basic Research at RPCI.

The Company incurred $1,197 and $67,896 in expense to RPCI related to research grants and agreements for the years ended December 31, 2020 and 2019, respectively. The Company had $0 and $345 included in accounts payable owed to RPCI at December 31, 2020 and 2019, respectively.

***The Cleveland Clinic***

CBLI entered into an exclusive license agreement, or the License, with The Cleveland Clinic (" **CCF**") pursuant to which CBLI was granted an exclusive license to CCF's research base underlying our therapeutic platform and certain product candidates in development by Panacela. CBLI has the primary responsibility to fund all newly developed patents, however, CCF retains ownership of those patents covered by the agreement. CBLI also agreed to use commercially diligent efforts to bring one or more products to market as soon as practical, consistent with sound and reasonable business practices and judgments. In consideration for the License, CBLI agreed to issue CCF common stock and make certain milestone, royalty and sublicense royalty payments. Milestone payments, which may be credited against future royalties, amounted to $0 for the years ended December 31, 2020 and 2019. No royalty or sublicense royalty payments were made to CCF during the two-year period ended December 31, 2020.

The Company also recognized $0 and $30,710 as research and development expense to CCF for the years ended December 31, 2020 and 2019, respectively. The Company had $0 included in accrued expenses payable at December 31, 2020 and 2019.

***Buffalo BioLabs and Incuron***

Our Chief Scientific Officer, Dr. Andrei Gudkov, has business relationships with several entities with which we transact business, the most significant of which is Buffalo BioLabs ("**BBL**"), where Dr. Gudkov was a founder and currently serves as its Principal Scientific Adviser. Pursuant to a master services agreement we have with BBL, the Company recognized $0 and $124 as research and development expense to BBL for the years ended December 31, 2020 and 2019, respectively. We also recognized $0 and $23,106 from BBL as sublease and other income for the years ended December 31, 2020 and 2019, respectively, of which $6,285 and $6,285 is included in accounts receivable at December 31, 2020 and 2019, respectively.

Dr. Gudkov is also an uncompensated member of the board of directors for Incuron. Pursuant to master service and development agreements we have with Incuron, the Company performs various research, business development, clinical advisory, and management services to Incuron. We recognized revenue of $49,357 and $395,544 from Incuron for the years ended December 31, 2020 and 2019, respectively. In addition, we also recognized $0 and $2,268 from Incuron as sublease and other income for the years ended December 31, 2020 and 2019, respectively. Pursuant to these agreements, we had accounts receivable of $0 and $99,285 from Incuron at December 31, 2020 and 2019, respectively.

***IP Bayramov Roman***

The liquidator of our subsidiary, BioLab 612, LLC, also provides accounting services through a separate legal entity to Panacela Labs, LLC. Professional fee expense to this firm, IP Bayramov Roman, amounted to $16,679 and $18,537 for the years ended December 31, 2020 and 2019, respectively.

***Genome Protection***

GPI incurred $53,760 and $196,975 in consultant expenses with members of the Company's management team for the years ended December 31, 2020 and 2019, respectively. The Company recognized $0 and $7,409 as sublease and other income from GPI for the year ended December 31, 2020 and 2019, respectively. We had accounts receivable of $0 and $3,700 at December 31, 2020 and 2019, respectively.

***Board of Directors***

The Company approved two cash awards to members of the Board of Directors during 2020 in the amount of $150,000. We had accounts payable to one Board of Directors member in the amount of $117,500 as of December 31, 2020.

**7. Income Taxes**

The Company accounts for income taxes using the asset and liability method. Deferred taxes are determined by calculating the future tax consequences attributable to differences between the financial accounting and tax bases of existing assets and liabilities. A valuation allowance is recorded against deferred tax assets when, in the opinion of management, it is more likely than not that the Company will not be able to realize the benefit from its deferred tax assets.

The Company files income tax returns, as prescribed by the national, state and local jurisdictions in which it operates. The Company's uncertain tax positions are related to tax years that remain subject to examination and are recognized in the financial statements when the recognition threshold and measurement attributes are met. Interest and penalties related to tax deficiencies and uncertain tax positions are recorded as income tax expense.

Loss from continuing operations consists of the following:

| | For the Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| US operations | $ (2,352,514) | $ (2,562,960) |
| Foreign operations | (85,359) | (131,704) |
| | $ (2,437,873) | $ (2,694,664) |

The provision for income taxes charged to continuing operations is $0 for all periods presented.

Deferred tax assets (liabilities) were comprised of the following as of the periods presented below:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Deferred tax assets: | | |
| Operating loss carryforwards | $ 36,791,000 | $ 36,449,000 |
| Accrued expenses and stock compensation | 5,922,000 | 5,940,000 |
| Tax credit carryforwards | 4,045,000 | 4,017,000 |
| Intellectual property | 2,460,000 | 4,049,000 |
| Equipment | 40,000 | 71,000 |
| Other | 36,000 | - |
| Total deferred tax assets | 49,294,000 | 50,526,000 |
| Deferred tax liabilities | - | - |
| Net deferred tax asset | 49,294,000 | 50,526,000 |
| Valuation allowance | (49,294,000) | (50,526,000) |
| | $ — | $ — |

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate of 21% for the year ended December 31, 2020 and December 31, 2019 to the pretax loss from continuing operations as a result of the following differences:

| | For the Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Tax at the U.S. statutory rate | $ (512,000) | $ (566,000) |
| Change in value of warrant liability | 89,000 | (15,000) |
| Valuation allowance | 289,000 | 581,000 |
| Merger facilitative costs | 134,000 | — |
| | $ — | $ — |

At December 31, 2020, the Company had U.S. federal net operating loss carryforwards of approximately $148.0 million, of which $139.7 million begins to expire if not utilized by 2023, and $8.3 million, which has no expiration, and approximately $4.3 million of tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has state net operating loss carryforwards of approximately $93.8 million, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $0.3 million, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich on July 9, 2015 resulted in Mr. Davidovich owning 60.2% of the Company, at that time. We therefore believe it highly likely that this transaction will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code. Consequently, our ability to utilize approximately $124.8 million of U.S. federal net operating loss carryforwards, $3.65 million of U.S. tax credit carryforwards, approximately $73.4 million of state net operating loss carryforwards, and $324,000 of state tax credit carryforwards, all of which occurred prior to July 9, 2015, are limited. As such, a significant portion of these carryforwards will likely expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carryforwards.

ASC 740 requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of a deferred tax asset is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. In making this determination, management considers all available positive and negative evidence affecting specific deferred tax assets, including the Company's past and anticipated future performance, the reversal of deferred tax liabilities, length of carry-back and carry-forward periods and the implementation of tax planning strategies. Based on all available evidence, management has determined that a full valuation allowance was necessary at December 31, 2020 and 2019.

The Company files U.S. federal income tax returns, along with various state and foreign income tax returns. All federal, state and foreign tax returns for the years ended December 31, 2019, 2018 and 2017 are still open for examination.

The following presents a roll-forward of the unrecognized tax benefits and the associated interest and penalties:

| | Unrecognized Tax Benefits | Interest and Penalties |
|---|---|---|
| Balance at January 1, 2019 | $ 504,000 | $ - |
| Deferred tax position | 6,000 | - |
| Balance at December 31, 2019 | 510,000 | - |
| Deferred tax position | 4,000 | - |
| Balance at December 31, 2020 | $ 514,000 | $ - |

**8. Employee Benefit Plan**

CBLI maintains an active defined contribution retirement plan for its employees, referred to herein as the Benefit Plan. All employees satisfying certain service requirements are eligible to participate in the Benefit Plan. The Company makes matching cash contributions each payroll period, up to 4% of employees' salaries. The Company's expense relating to the Benefit Plan was $15,741 and $33,325 for the years ended December 31, 2020, and 2019, respectively.

**9. Commitments and Contingencies**

The Company is a party to various legal actions and administrative proceedings arising in the normal course of business. In the opinion of Company's management, resolution of these matters is not anticipated to have a material adverse effect on the Company.

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include fixed obligations to sponsor research and development activities, make minimum royalty payments for licensed patents and pay additional amounts that may be required upon the achievement of scientific, regulatory and commercial milestones, including milestones such as the submission of an IND to the FDA and the first commercial sale of the Company's products in various countries. As of December 31, 2020 the Company is uncertain as to whether any of these contingent events will become realized. There were no milestone payments or royalties on net sales accrued for any of these agreements as of December 31, 2020 and 2019.

From time-to-time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company recorded a revenue loss contingency of $544,000 in the fourth quarter of 2019 related to deposits paid to a supplier in support of our JWMRP contract which the Company may have been responsible for repaying to the DoD. This amount was recorded as an accrued expense in the December 31, 2019 Consolidated Balance Sheet. During July 2020, the Company settled with the supplier for repayment of the deposit. The Company used the proceeds from the return of the deposit to repay the DoD in settlement of any outstanding contingent event. Accordingly, the Company recorded an extinguishment of the accrued liability to other income in the amount of $501,892 during June 2020.

During 2019, the Company identified that it had experienced cost overruns in the amount of $472,310 on certain governmental contracts with the Department of Defense. The Company had already received reimbursement from the Department of Defense for these overruns, and anticipated that the overruns would be eligible for application against cost under-spending on other tasks under the government contract. Accordingly, no loss contingency was recorded in 2019. During 2020, upon further discussions with the Department of Defense, this matter was resolved in favor of the Company, and ultimately no loss contingency or revenue reduction was required to be recorded.

As of December 31, 2020, the Company had no unconditional purchase obligations for goods and services.

*Operating Leases*

The Company leases laboratory facilities and office facilities at various locations on a month to month basis. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. For the years ended December 31, 2020 and 2019, total rent expense related to the Company's operating leases was $19,286 and $202,891, respectively.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

**Effectiveness of Disclosure Controls and Procedures**

Our management, with the participation of our Vice President of Finance (performing the functions of the Company's principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "**Exchange Act**"), as of December 31, 2020. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Vice President of Finance (performing the functions of the Company's principal executive officer and principal financial officer) concluded that, as of such date, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our Vice President of Finance (performing the functions of the Company's principal executive officer and principal financial officer), as appropriate to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of management, including our Vice President of Finance (performing the functions of the Company's principal executive officer and principal financial officer), we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control – Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

**Remediation of Previously Reported Material Weakness**

Management has implemented changes to strengthen our internal controls over the monitoring of revenue recognition and the prevention or detection of material misstatements on a timely basis related to contract compliance and proper revenue recognition. These changes were intended to address the material weakness identified during the year ended December 31, 2019 and to enhance our overall control environment and include the ongoing activities described below.

Management has performed a comprehensive review of all contracts to which the Company is party, including a review of underlying schedules, to ensure a more complete understanding of these agreements to ensure compliance and proper application of revenue recognition principles. Upon completion of this review, management implemented certain system controls to ensure compliance and prevent the recognition of revenue in excess of specific elements of the contract agreements. In addition, new processes have been implemented related to periodic invoicing and revenue recognition analysis designed to detect any potential issues and correct as applicable.

We believe the measures described above facilitated the remediation of the material weakness identified during the year ended December 31, 2019 and strengthened our internal control over financial reporting. We are committed to continuing to improve our internal control processes and will continue to review, optimize and enhance our financial reporting controls and procedures. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify, or, in appropriate circumstances, not complete, certain of the remediation measures described above.

**Changes in Internal Control over Financial Reporting**

Other than the mitigating controls discussed above, there was no change in our internal control over financial reporting during the year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

#### The Board of Directors

Set forth below are the names of all of the persons serving as our directors as of the date of this Annual Report on Form 10-K, their ages, their offices in the Company, if any, their principal occupations or employment for the past five years, the length of their tenure as directors and the names of other public companies in which such persons hold or have held directorships during the past five years. Additionally, information about the specific experience, qualifications, attributes or skills that led to our Board's conclusion at the time of filing of this Annual Report on Form 10-K that each nominee should serve as a director is set forth below. There are no family relationships between or among any director, executive officer or person nominated or chosen by the Company to become a director or executive officer.

| Name | Age | Position with the Company |
|---|---|---|
| Alexander Andryuschechkin (1) | 37 | Director |
| Anna Evdokimova | 45 | Director |
| Ivan Fedyunin | 33 | Director |
| Randy S. Saluck (1) | 55 | Director |
| Daniil Talyanskiy | 36 | Director |
| Lea Verny (1) | 55 | Chair of the Board |

1. Member of the Audit Committee, the Compensation Committee, and the Nominating and Corporate Governance Committee.

*Alexander Andryuschechkin*. Mr. Andryushechkin was appointed to the Company's Board to fill a vacancy in July 2016. He currently serves as the Chief Financial Officer and a board member of Generium JSC, a private biotech pharmaceutical manufacturing company based in the Russian Federation. He also currently serves as the Chief Financial Officer of IBC Generium LLC, a private pharmaceutical research and development company based in the Russian Federation. He has served as a board member of Affitech A/S since 2017. From 2012 to 2016, Mr. Andryushechkin was the Head of Finance of ASG LLC, a manufacturing company, where he was responsible for corporate finance and investment management. From 2010 to 2016, Mr. Andryushechkin was a member of the board of Festival City LLC, a real estate development company, where he focused on business development activities. From 2012 to 2014, Mr. Andryushechkin was Chairman of the Board ASTOR CJSC, where he focused on financial management. Mr. Andryushechkin graduated from the Omsk State University with a Master's Degree in Economics in 2005 and a post-graduate degree in Economics and Management in 2008. Mr. Andryushechkin's experience in corporate finance and financial management, including investment management and business valuation, make him an important asset to our Board.

*Anna Evdokimova*. Ms. Evdokimova was appointed to the Company's Board in 2015. Ms. Evdokimova has served as Venture Capital Investment Director of Millhouse LLC, an asset management company, since May 2015 and served as the Deputy Head of Corporate Finance from 2006 to May 2015. She also has served on the board of directors of Russia Forest Product since 2008, on the board of directors of Novotalk since 2015, on the board of directors of Anyclip Ltd since 2015, on the board of directors of Storedot since 2016, and on the board of directors of each of SaferPlace, Oncotartis Inc., and Incuron Inc. since 2018. From 2002 to 2004, Ms. Evdokimova worked as the Head of Corporate Finance of a major Russian oil and gas company, Slavneft. In 1998, Ms. Evdokimova joined Russian-listed oil major Sibneft and served as Head of Export Finance through 2002. Ms. Evdokimova holds a Bachelor's degree from Moscow State Linguistic University and a Master's of Business Administration in finance from Fordham University. Ms. Evdokimova was originally appointed to our Board, and was subsequently selected as a director nominee in each successive election thereafter through 2019 under the terms of the Securities Purchase Agreement, dated as of June 24, 2015 (the "**Davidovich Purchase Agreement**"), between the Company and David Davidovich, our largest stockholder, which granted to him the right to designate a majority of the nominees who stand for election to our Board during the time he held a majority of our outstanding common stock, subject to the terms and conditions of the Davidovich Purchase Agreement. Ms. Evdokimova's experience in international finance, particularly with respect to entities operating within the Russian Federation, make her an important asset to our board.

*Ivan Fedyunin*. Mr. Fedyunin was appointed to the Company's Board to fill a vacancy in August 2018. Since 2017, he has served as an expert in healthcare and life science investments at Millhouse LLC, an asset management company, where his responsibilities include evaluating companies for investment consideration and portfolio management. From October 2014 through April 2017, Mr. Fedyunin served as R&D director of Pharmapark LLC, a private Russian pharmaceutical company, where his responsibilities included the supervision of the research and development department. From February 2013 through April 2017, he was a chief operating officer of Promogen-Mab LLC, a drug development company, where he supervised research and development and had a senior management role. Since June of 2017, Mr. Fedyunin has served on the boards of directors of Melcap Systems Ltd., BrainQ Technologies Limited, Vigorous Solutions Ltd., and Ocular Discovery Ltd., each of which is a private company in the medical device, biopharmaceutical or pharmaceutical space based in the State of Israel. In 2012, Mr. Fedyunin earned his PhD degree in biochemistry from Potsdam University, Germany while working at both Potsdam University and Max Planck Institute of Colloids and Interfaces. Mr. Fedyunin graduated from the Moscow State University, Russia with a major in biochemistry in 2008. Mr. Fedyunin was originally appointed to our Board, and was subsequently selected as a director nominee in each successive election thereafter through 2019, under the terms of the Davidovich Purchase Agreement with Mr. Davidovich, our largest stockholder, which granted to him the right to designate a majority of the nominees who stand for election to our Board, during the time he held a majority of our outstanding common stock, subject to the terms and conditions of the Davidovich Purchase Agreement. Mr. Fedyunin's experience in portfolio management makes him an important asset to our Board.

*Randy S. Saluck*. J.D., MBA, Mr. Saluck previously served as one of our directors from May 2013 until April 2016 and was subsequently reappointed to the Board in July 2016 to fill a vacancy. Since 2017, Mr. Saluck has been the Chief Executive Officer and a Director of Libertas Funding LLC, a company focused on providing funding for small businesses. From 2015 to 2018, Mr. Saluck has been part-time Chief Financial Officer and General Counsel of Convexity Scientific, LLC., a private medical device company on whose board he served from February 2016 to October 2017 as a director. From 2005 to 2017, Mr. Saluck was the Managing Member of Mortar Rock Capital Management, LLC and the Portfolio Manager of Mortar Rock Capital LP, a value-oriented investment fund. From 2014 to 2018, Mr. Saluck has served as the part-time Chief Strategic Officer of Accelerated Pharma, Inc., a company focused on genomic technology to develop drugs for oncology and other indications. From 2002 to 2005, Mr. Saluck was a portfolio manager at the investment fund of Meisenbach Capital, LP and, from 2000 to 2002, Mr. Saluck was a senior analyst at Tyndall Partners, LLC, which invested in value-oriented equities and distressed debt. Prior thereto, Mr. Saluck was an investment banker focused on mergers and acquisitions involving a variety of industries at Salomon Brothers Inc. Before becoming an investment banker, Mr. Saluck was a corporate and securities attorney, working at Cahill Gordon & Reindel LLP and then Tenzer Greenblatt LLP. As an attorney, Mr. Saluck worked with numerous small capitalization companies assisting them in the execution of their financing and strategic plans. He received a Bachelor's degree from the University of Pennsylvania, a Juris Doctor degree from the University of Virginia and an MBA from the Wharton School of the University of Pennsylvania with a concentration in finance and accounting. Mr. Saluck provides our board with stockholder perspective and experience in public finance and investor relationships.

*Daniil Talyanskiy*. Mr. Talyanskiy was appointed to the Company's Board in July 2016 to fill a vacancy. He has served as the First Deputy CEO and Chief Business Officer of IBC Generium LLC, a private pharmaceutical research and development company based in the Russian Federation, since 2011. Since 2017, Mr. Talyanskiy has served as a board member of Generium JSC, a private biotech pharmaceuticals manufacturing company based in the Russian Federation for which he has also served as First Deputy CEO since 2013. He has also served as a Board Member of Affitech A/S and Oncotartis Inc. since 2017. He was also a member of the Supervisory Board of co.don AG (CNWKk.DE), a regenerative pharmaceuticals manufacturing company from 2015 to 2016. Prior to joining IBC Generium LLC, from 2008 to 2011, Mr. Talyanskiy was the Head of Corporate University in UIC Oboronprom JSC. From 2006 to 2008, Mr. Talyanskiy worked in various investment companies as an Investment Manager. Mr. Talyanskiy graduated from the Togliatti Academy of Management with a Master's Degree in Management in 2007. Mr. Talyanskiy's experience in business development of pharmaceuticals make him an important asset to our Board.

*Lea Verny*. Ms. Verny was first elected to the Company's Board in April 2016 and has served as board chair since July 2016. She has collaborated with London-based SP Angel Corporate Finance LLP on a variety of projects including private equity, corporate finance and advisory, and project finance, since 2008. Prior to that, Ms. Verny served as a private banker with Banque Pictet, Switzerland. From 2001 to 2007, Ms. Verny was a Director in Corporate Finance and Advisory of HSBC Bank plc in London and served as a Head of Investment Banking with HSBC Bank in Russia. From 1997 to 2001, Ms. Verny was a representative of the HSBC Investment Bank plc in Russia. From 1995 to 1997, Ms. Verny had established and served as a Director of the Russian European Center for Economic Policy, the European Commission's TACIS Program's funded organization that, through teams of Western experts, provided economic policy advice to Russian authorities. Since December 2016, Ms. Verny has served as a director for Zoltav Resources, Inc., a Russian-focused oil and gas exploration and production company. Ms. Verny holds a Bachelor's degree in Statistics and International Relations from the Hebrew University in Jerusalem as well as a Master in Business Administration Degree from INSEAD in France. Ms. Verny was originally selected as a nominee for election to our Board, and was subsequently selected as a director nominee in each successive election thereafter through 2019, under the terms of the Davidovich Purchase Agreement with Mr. Davidovich, our largest stockholder, which granted to him the right to designate a majority of the nominees who stand for election to our Board, during the time he held a majority of our outstanding common stock, subject to the terms and conditions of the Davidovich Purchase Agreement. Ms. Verny's international banking experience makes her an important asset to our Board and Audit Committee.

**Executive Officers**

The following table sets forth certain information regarding our executive officers. The Board elects officers annually and such executive officers serve at the discretion of the Board. There are no family relationships among any of our directors or executive officers.

| Name | Age | Position |
|---|---|---|
| Langdon Miller, MD | 67 | Chief Medical Officer |
| Andrei Gudkov, Ph.D., D. Sci. | 64 | Chief Scientific Officer |
| Christopher Zosh | 45 | Interim Principal Executive Officer and Principal Financial Officer; Vice President of Finance |

*Langdon L. Miller, MD.* Dr. Miller has been Chief Medical Officer since 2015, and from 2015 through mid-2020 he also served as our President. He previously served as a strategic adviser to the Company beginning in 2014. Dr. Miller has maintained a drug development consultancy, Sound Clinical Solutions, SP, located in Seattle, WA since 2013 and, through his consultancy, has served as a consulting Chief Medical Officer to Oncternal Therapeutics, Inc., located in San Diego, CA, from August 2016 through April 2018. Since April 2018, Dr. Miller has also served as Executive Vice President and Chief Medical Officer of VelosBio Inc., a private biopharmaceutical company that was acquired by Merck & Co in December 2020 and now is a wholly owned subsidiary of Merck & Co. Dr. Miller has served on the board of Dunn Gardens, a private, not-for-profit organization, since 2013 and was appointed to the board of Swedish Club, a private, not-for-profit organization in April of 2019. Dr. Miller has more than 25 years of experience in the design and conduct of translational and clinical drug development programs in oncology (both in hematological and solid tumors) and orphan diseases (including cystic fibrosis, muscular dystrophy, and hemophilia). He has worked in all phases (phase 1-4) of drug development, from first-in-human studies through pivotal registration-directed trials to medical affairs programs and has filed multiple INDs, CTAs, NDAs and orphan drug applications. Dr. Miller played major roles in the development of filgrastim and sargramostim, in the regulatory approvals of irinotecan, exemestane, epirubicin, dexrazoxane, sunitinib, and idelalisib in several cancers, and in validating new endpoints for Duchenne muscular dystrophy and cystic fibrosis. He has extensive experience in the generation, analysis, presentation, and justification of drug development programs before regulatory authorities, advisory committees, investigators, investors, and business development partners. He has authored over 100 regulatory documents and publications. Dr. Miller has held leadership positions in government and in large and small biopharmaceutical companies. He was a Senior Investigator at the National Cancer Institute from 1989 to 1995 before transitioning to industry at the Pharmacia Corporation, where he held positions of increasing responsibility from 1995 to 2003, eventually heading oncology drug development there as Clinical Vice President, Global Clinical Research. He built the clinical development team at PTC Therapeutics where he was Chief Medical Officer from 2003 to 2010 before moving to Calistoga Pharmaceuticals as Executive Vice President of Research and Development from 2010 to 2011. Upon Calistoga's acquisition by Gilead Sciences, he became Vice President of Clinical Research Oncology at Gilead Sciences from 2011 to 2013. He holds a Doctorate in Medicine from Northwestern University and completed his residency in internal medicine at the University of Minnesota and an oncology fellowship at Stanford University.

*Andrei Gudkov, Ph.D., D. Sci.* Dr. Gudkov has served as our Chief Scientific Officer since our inception in June 2003 and served as a director from our inception in June 2003 until April 2016. From 2007 to 2019, Dr. Gudkov served as Senior Vice President of Basic Science at Roswell Park Comprehensive Cancer Center (Roswell Park) and since 2019 he has served as Senior Vice President of Research Technology and Innovation at Roswell Park. Since 2007, he has served as Chairman of the Department of Cell Stress Biology at Roswell Park. He also serves as a Director for Everon Biosciences, Inc., Oncotartis Inc., Incuron Inc., Panacela Labs, Inc., and Chief Science Officer of Genome Protection, Inc., an anti-aging drug development company jointly owned by the Company. From 2001 to 2007, he was Chairman of the Department of Molecular Biology at the Lerner Research Institute at the Cleveland Clinic and Professor of Biochemistry at Case Western Reserve University. Prior to this, he was a tenured faculty member in the Department of Molecular Genetics at the University of Illinois at Chicago, where his lab concentrated on the development of new functional gene discovery methodologies and the identification of new candidate cancer treatment targets. Before immigrating to the United States in 1990, Dr. Gudkov worked at The National Cancer Research Center in Moscow, where he led a broad research program focused on virology and cancer drug resistance. Dr. Gudkov holds a Ph.D. and D. Sci. Degree in Experimental Oncology from the Cancer Research Center (Moscow, Russia).

*Christopher Zosh* has served as Vice President of Finance of the Company since January 1, 2019 and in December 2019, was designated by our Board as our interim principal executive officer and principal financial officer. Prior to that, he served as Acting Finance Director of the Company, from July 2017 through December 2018, and Senior Accountant, from June 2014 through June 2017, where his responsibilities have included overseeing the Company's internal accounting and financial reporting functions. Since July 1, 2017, he has also served on the board of directors of Panacela Labs, Inc., a joint venture between the Company and Joint Stock Company "Rusnano," a Russian investment fund, in which the Company holds a 66.77% equity interest. Prior to joining the Company, Mr. Zosh held several positions over his fourteen-year career with Sodexo, a facilities management and food service company to schools, universities, hospitals, senior living communities, venues and other vital industries, the most recent of which was Financial Accounting Analyst. In addition, Mr. Zosh served as an Orthopedic Specialist in the United States Army Reserves. He holds a bachelor's degree in business administration with a concentration in accounting from the State University of New York at Buffalo.

**Code of Ethics for Senior Executives and Financial Officers, Code of Business Conduct and Ethics for Directors and Code of Conduct**

The Board has adopted a Code of Ethics for Senior Executives and Financial Officers that is specifically applicable to executive officers and senior financial officers, including our principal executive officer and principal financial officer. Additionally, the Board has adopted the Code of Business Conduct and Ethics for Directors that is specifically applicable to our directors. Both the Code of Ethics for Senior Executives and Financial Officers and the Code of Business Conduct and Ethics for Directors are posted on our website, www.cbiolabs.com, under the link "Investors" and the section therein titled "Corporate Governance." We have also adopted a Code of Conduct in order to promote honest and ethical conduct and compliance with the laws and governmental rules and regulations to which we are subject. The Code of Conduct is applicable to all of our employees, officers and directors, and is posted on our website, www.cbiolabs.com, under the link "Investors" and the section therein titled "Corporate Governance." The Company intends to satisfy the requirement to disclose any amendment to, or waivers from, a provision of its code of ethics by posting such information at this same website.

**Corporate Governance**

***Audit Committee.***

Our Company has a separately designated standing audit committee (the " **Audit Committee**"). Our Audit Committee met four times during fiscal year 2020. This committee currently has three members, Messrs. Saluck (Chair) and Andryuschechkin and Ms. Verny, each of whom is independent under the rules of the Nasdaq Capital Market.

The Board has determined that Mr. Saluck is an "audit committee financial expert," as the Securities and Exchange Commission has defined that term in Item 407 of Regulation S-K.

Our Audit Committee generally has direct responsibility and oversight for our accounting policies and internal controls, financial reporting practices, and legal and regulatory compliance. More specifically, the Audit Committee is responsible for reviewing and discussing the annual audited financial statements and disclosures with management and our independent auditor; reviewing the financial statements and disclosures provided in our quarterly and periodic reports with management and the independent auditor; and overseeing the external audit coverage, including appointment and replacement of the independent auditor and pre-approval of all audit and non-audit services to be performed by the independent auditor.

***Compensation Committee*.**

Our Compensation Committee was just reconstituted following the Company no longer qualifying as a "controlled company" in 2020, so it did not meet during fiscal year 2020. This committee currently has three members, Alexander Andryuschechkin, Randy Saluck and Lea Verny, each of whom is independent under the rules of the Nasdaq Capital Market.

The Compensation Committee determines and approves the compensation level of executive officers based on an evaluation of their performance in light of our goals and objectives. The Compensation Committee also considers our performance and relative stockholder return, the level and value of similar incentive awards prevalent in the industry, and awards given to executive officers in past years. The Compensation Committee also has the authority to recommend to the Board compensation for directors and the form of this compensation. The Compensation Committee makes recommendations to the full Board with respect to the adoption, amendment, termination, or replacement of both incentive compensation plans and equity-based plans. The Compensation Committee has the power to retain professionals to assist in the evaluation of director and executive compensation, and has the sole authority to retain and terminate any such professional and to approve the professional's fees. The Compensation Committee may also establish subcommittees of entirely independent directors to evaluate special or unique matters.

For a discussion concerning the processes and procedures for determining executive and director compensation, see " *Narrative Disclosure to Summary Compensation Table"* and " *Executive Officer and Director Compensation*."

***Nominating and Corporate Governance Committee*.**

Our Nominating and Corporate Governance Committee was just reconstituted following the Company no longer qualifying as a "controlled company" in 2020, so it did not meet during fiscal year 2020. The Nominating and Corporate Governance Committee has three members, Alexander Andryuschechkin, Randy Saluck and Lea Verny, each of whom is independent under the rules of the Nasdaq Capital Market.

The Nominating and Corporate Governance Committee generally has responsibility for identifying candidates who are eligible under the qualification standards set forth in our Corporate Governance Guidelines and recommending such eligible individuals to serve as members of the Board. It also makes recommendations to the Board concerning the structure and membership of other Board committees. The Nominating and Corporate Governance Committee is also charged with considering matters of corporate governance generally and reviewing and recommending to the Board, periodically, our corporate governance principles.

In addition, under our current corporate governance policies, the Nominating and Corporate Governance Committee may consider candidates recommended by stockholders as well as from other sources such as other directors or officers, third party search firms or other appropriate sources. For all potential candidates, the Nominating and Corporate Governance Committee may consider all factors it deems relevant, such as a candidate's personal integrity and sound judgment, business and professional skills and experience, independence, knowledge of the industry in which we operate, possible conflicts of interest, diversity, the extent to which the candidate would fill a present need on the Board, and concern for the long-term interests of the stockholders. In general, persons recommended by stockholders will be considered on the same basis as candidates from other sources.

**Item 11. Executive Compensation**

**Summary Compensation Table**

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2020 and 2019 to our (1) Chief Medical Officer, (2) Chief Science Officer, and (3) Vice President of Finance.

| Name and Principal Position | Year | Salary ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|
| **Langdon L. Miller** | 2020 | 23,100 | - | 23,100 |
| Chief Medical Officer | 2019 | 73,725 | - | 77,625 |
| **Andrei Gudkov** | 2020 | 26,055 | - | 26,055 |
| Chief Science Officer | 2019 | 66,138 | - | 66,138 |
| **Christopher Zosh** | 2020 | 116,769 | 4,671(1) | 121,440 |
| *Vice President of Finance* (principal executive officer and principal financial officer)* | 2019 | 92,463 | 11,031(2) | 103,494 |

1. Includes Company 401(k) matching contributions.
2. Includes Company 401(k) matching contributions and quarterly bonus payments.

* Following the resignation of the Company's former chief executive officer, which became effective as of December 13, 2019, Christopher Zosh was designated by the Board as interim Principal Executive Officer and Principal Financial Officer on December 13, 2019.

**Narrative Disclosure to Summary Compensation Table**

***Langdon L. Miller, MD***

On August 10, 2020, the Company entered into a Consulting Agreement (the "Miller Consulting Agreement") with Sound Clinical Solutions, SP, a consulting services provider of which Dr. Langdon Miller, the Company's Chief Medical Officer, is sole proprietor. The Miller Consulting Agreement replaced Dr. Miller's previous employment agreement, which expired in accordance with its terms in July 2020. Under the Miller Consulting Agreement, Dr. Miller continues to serve the Company as Chief Medical Officer as an independent contractor, and not an employee, for the term of six months, unless extended by mutual agreement of the Company and Dr. Miller, or earlier terminated. The Company has agreed to pay Dr. Miller, through his consultancy, the rate of $350 per hour for his services, which will be focused on clinical development responsibilities associated with the development of the Company's principal drug candidate, entolimod, as a medical radiation countermeasure, and such other duties and responsibilities associated with his continued services as Chief Medical Officer. In addition, Dr. Miller may be reimbursed for pre-approved travel expenses. Both Dr. Miller and the Company may terminate the Miller Consulting Agreement for convenience upon 14 days' prior written notice. Upon termination, the Company will pay all fees owed to Dr. Miller for services rendered prior to the termination date, but he will not be entitled to any severance or other post-termination payments. The Miller Consulting Agreement also contains customary confidentiality and inventions and proprietary information provisions.

**Andrei Gudkov, Ph.D., D. Sci.**

On October 11, 2020, the Company entered into a Consulting Agreement (the "Gudkov Consulting Agreement") with Dr. Andrei Gudkov, Ph.D., D. Sci., the Company's Chief Scientific Officer. The Gudkov Consulting Agreement replaces Dr. Gudkov's previous employment agreement, which expired in accordance with its terms in July 2020. Under the Gudkov Consulting Agreement, Dr. Gudkov will continue to serve the Company as Chief Scientific Officer as an independent contractor, and not an employee, for the term of six months, unless extended by mutual agreement of the Company and Dr. Gudkov, or earlier terminated. The Company has agreed to pay Dr. Gudkov, through his consultancy, the rate of $225 per hour for his services, which will be focused on clinical development responsibilities associated with the development of the Company's principal drug candidate, entolimod, as a medical radiation countermeasure, and such other duties and responsibilities associated with his continued services as Chief Scientific Officer. In addition, Dr. Gudkov may be reimbursed for pre-approved travel expenses. Both Dr. Gudkov and the Company may terminate the Gudkov Consulting Agreement for convenience upon 14 days' prior written notice. Upon termination, the Company will pay all fees owed to Dr. Gudkov for services rendered prior to the termination date, but he will not be entitled to any severance or other post-termination payments. The Gudkov Consutling Agreement also contains customary confidentiality and inventions and proprietary information provisions.

**Christopher Zosh**

On December 13, 2019, the Company appointed Christopher Zosh, who was serving in the capacity of Vice President of Finance, to serve as the Company's interim principal executive officer, principal financial officer and principal accounting officer while the Company's board of directors continues its search for a permanent Chief Executive Officer. Mr. Zosh succeeds Yakov Kogan, whose resignation as Chief Executive Officer became effective on December 13, 2019.

Mr. Zosh is currently an at-will employee of the Company, and as such, is eligible to participate in the Company's plans and arrangements that do not discriminate in scope, terms or operation in favor of executive of officers or directors and that are generally available to all salaried employees of the Company. There were no immediate changes to Mr. Zosh's compensation package in connection with his designation as principal executive officer, principal financial officer and principal accounting officer. His current base annual salary is $115,000

**Outstanding Equity Awards at Fiscal Year-End**

The following table shows grants of stock options outstanding on the last day of the fiscal year ended December 31, 2020, including both awards subject to performance conditions and non-performance-based awards, to each of the executive officers named in the Summary Compensation Table. There were no stock option exercises by any of our named executive officers during the fiscal year ended December 31, 2020. There were no outstanding stock awards that were not then exercisable to the executive officers named in the Summary Compensation Table on the last day of the fiscal year ended December 31, 2020. All balances shown in the table below have been adjusted to account for the 1:20 reverse split of the Company's common stock that was effected on January 28, 2015. All awards are fully vested.

| | | Option Awards | |
|---|---|---|---|
| **Name** | **Number of Securities Underlying Unexercised Options Exercisable (#)** | **Option Exercise Price ($)** | **Option Expiration Date** |
| **Langdon L. Miller** | 10,000 | 3.00 | 5/4/2025 |
| **Andrei Gudkov** | 6,250 | 3.20 | 4/22/2025 |
| | 7,500 | 13.60 | 3/13/2024 |
| | 4,203 | 30.80 | 5/12/2023 |
| | 2,813 | 67.00 | 1/22/2022 |
| | 7,481 | 143.20 | 3/20/2021 |
| **Christopher Zosh** | 125 | 10.40 | 6/16/2024 |
| | 300 | 3.20 | 4/22/2025 |

**Director Compensation**

Of the directors on our Board during fiscal 2020, Ms. Evdokimova and Mr. Fedyunin (together, the "Millhouse Directors") are each employees of Millhouse LLC, an asset management company of which Mr. Davidovich, our largest stockholder, serves as the Chief Executive Officer. Ms. Evdokimova and Mr. Fedyunin were selected as director nominees under the terms of the Davidovich Purchase Agreement with Mr. Davidovich, which granted him the right to designate a majority of the nominees who stand for election to our Board during the time he held a majority of our outstanding common stock. The Millhouse Directors are each paid employees of Millhouse LLC, and were employed by Millhouse LLC prior to the time of their original appointment or election to the Board. The Millhouse Directors, along with Messrs. Andryuschechkin and Talyanskiy, do not receive compensation for board service from the Company; however the remaining two board members do receive compensation for board service. The following is a description of the cash compensation arrangements under which the other directors are currently compensated for board and committee services.

| Position | Annual Fee | Compensated Directors |
|---|---|---|
| Board Member | $ 30,000 | Ms. Verny, Mr. Saluck |
| Board Chair | 5,000 | Ms. Verny |
| Audit Committee Chair | 5,000 | Mr. Saluck |

In addition to annual cash compensation listed above, the Company from time to time compensates members of the Board with special cash awards for distinguished service. In 2020, the Board approved two such awards to members of the Board, Ms. Verny was awarded $100,000 and Mr. Saluck was awarded $50,000.

In addition to annual cash compensation, the Company from time to time compensates members of the Board with equity in the form of options to purchase shares of our common stock. In 2020, the Company did not grant stock options to any member of the Board for services performed since our 2020 Annual Meeting. Each of our directors is also reimbursed for reasonable out-of-pocket expenses incurred in attending our board or board committee meetings.

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2020 to each of our directors by the Company.

| **Name** | **Paid or earned in cash ($)** | **Total ($)** |
|---|---|---|
| **Randy S. Saluck, J.D., MBA (1)** | 85,000 | 85,000 |
| **Lea Verny (2)** | 135,000 | 135,000 |
| **Anna Evdokimova (2)** | - | - |
| **Ivan Fedyunin (2)** | - | - |
| **Ivan Persiyanov (2)** | - | - |

| | | |
|---|---|---|
| **Alexander Andryuschechkin (2)** | - | - |
| **Daniil Talyanskiy (2)** | - | - |

1. As of December 31, 2020, Mr. Saluck held 20,250 options that are all exercisable and fully vested.
2. Mmes. Verny, Evdokimova and Messrs. Fedyunin, Andryushechkin and Talyanskiy held no stock options or other equity awards as of December 31, 2020.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of December 31, 2020 for (a) the executive officers named in the Summary Compensation Table in the section titled "Item 11 - *Executive Compensation*," (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) stockholders that beneficially owned more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by a person or group within 60 days of December 31, 2020 pursuant to the exercise of options or warrants to be outstanding and beneficially owned by such person or group for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 13,376,062 shares of common stock outstanding on December 31, 2020.

| Name | Outstanding Shares Beneficially Owned | Rights to Acquire Beneficial Ownership | | Total Shares Beneficially Owned | Percent |
|---|---|---|---|---|---|
| **5% or greater shareholders** | | | | | |
| David Davidovich[(1)] | 6,459,948 | — | | 6,459,948 | 48.29% |
| James W. Harpel[(2)] | 1,205,979 | — | | 1,205,979 | 9.02% |
| **Directors and Named Executive Officers** | | | | | |
| Alexander Andryuschechkin | — | — | | — | * |
| Anna Evdokimova | — | — | | — | * |
| Ivan Fedyunin | — | — | | — | * |
| Randy S. Saluck, J.D., MBA | 140 | 20,250 | (3) | 20,390 | * |
| Daniil Talyanskiy | — | — | | — | * |
| Lea Verny | — | — | | — | * |
| Andrei Gudkov, Ph.D., D. Sci. | 75,869 | 28,247 | | 104,116 | * |
| Langdon L. Miller, MD | — | 10,000 | (4) | 10,000 | * |
| Christopher Zosh | — | 425 | (5) | 425 | * |
| **All current executive officers and directors as a group (9 persons)** | **76,009** | **58,922** | | **134,931** | **1.00%** |

* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) David Davidovich reported sole voting and dispositive power with respect to 6,459,948 shares of our common stock in a Statement on Schedule 13D filed with the SEC on July 21, 2015. Mr. Davidovich's address is APT 3, 21 Manresa Road, London, United Kingdom, SW3 SLZ.

(2) James W. Harpel reported sole voting and dispositive power with respect to 1,009,979 shares of our common stock and shared voting and dispositive power over 196,000 shares of our common stock on Schedule 13G filed with the SEC on February 11, 2021. Mr. Harpel reported that the shares with respect to which he has shared voting and dispositive power are owned by six trusts over which Mr. Harpel has Power of Attorney and shares with the trustees of such trusts the power to vote or dispose the shares held by such trusts. Mr. Harpel's address is Palm Beach Capital, 525 South Flagler Drive, Suite 201, West Palm Beach, FL 33401.

(3) These shares of common stock can be acquired through the exercise of options that are directly owned by Mr. Saluck. Upon acquisition, Mr. Saluck will have sole voting and investment power over such shares.

(4) These shares of common stock can be acquired through the exercise of options that are directly owned by Dr. Miller. Upon acquisition, Dr. Miller will have sole voting and investment power over all such shares.

(5) These shares of common stock can be acquired through the exercise of options that are directly owned by Mr. Zosh. Upon acquisition, Mr. Zosh will have sole voting and investment power over such shares.

***Change of Control of the Company***

On July 9, 2015, we closed a private placement transaction with David Davidovich, a venture capital investor, pursuant to which the Company issued and sold to Mr. Davidovich an aggregate of 6,459,948 shares of the Company's common stock, for an aggregate purchase price of approximately $25 million, or $3.87 per share, under the terms of the Davidovich Purchase Agreement. Under the Davidovich Purchase Agreement, Mr. Davidovich also had the right to nominate for election to the Board a majority of directors until such time when he no longer holds a majority of the issued and outstanding common stock of the Company. As a result of the closing of the issuance and sale of the shares to Mr. Davidovich under the terms of the Davidovich Purchase Agreement, Mr. Davidovich assumed effective control of the Company through his ownership of approximately 60% (since reduced to 48.29% due to the subsequent issuance of additional shares of common stock) of our outstanding shares of common stock and his right to nominate for election to the Board a majority of our directors. As a result of additional issuances of our common stock during the fiscal year ending December 31, 2020, Mr. Davidovich no longer holds a majority of the issued and outstanding common stock of the Company, so although he is still has significant control over the Company through his ownership of a large amount of our common stock, he no longer has the contractual ability under the Davidovich Purchase Agreement to select a majority of the nominees to stand for election to board of directors each year.

In connection with the closing of Mr. Davidovich's purchase, on July 9, 2015, we also entered into a Registration Rights Agreement with Mr. Davidovich (the "Registration Rights Agreement"). Pursuant to the terms of the Registration Rights Agreement, we filed a registration statement under the Securities Act of 1933 registering for resale the shares held by Mr. Davidovich. The registration statement has been declared effective by the SEC and since July 9, 2017 Mr. Davidovich has been able to freely sell some or all of his shares of our common stock, the effect of which sale or sales may be that Mr. Davidovich ceases to control the Company.

On October 16, 2020, as previously disclosed, the Company entered into the Merger Agreement with Merger Sub, and Cytocom, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cytocom, with Cytocom continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger. In consideration of the merger, the Company will issue new shares of its common stock the holders of Cytocom's capital stock. Under the exchange ratio formula set forth in the Merger Agreement, as of immediately after the merger, the former Cytocom stockholders are expected to own approximately 61% of the outstanding shares of the Company's common stock on a fully diluted basis and stockholders of the Company as of immediately prior to the merger are expected to own approximately 39% of the outstanding shares of Company's common stock on a fully diluted basis, subject to certain adjustments. Additionally, beginning at the effective time of the merger, the Board will consist of seven members, three of whom will be designated by the Company and four of whom will be designated by Cytocom, and Cytocom's Chief Executive Officer, Michael Handley, will serve as Chief Executive Officer of the Company. Accordingly, upon closing of the merger, the Company will experience a change of control.

**EQUITY COMPENSATION PLAN INFORMATION**

The following table provides information as of December 31, 2020, regarding shares of common stock that may be issued under the Company's equity compensation plans, including the Cleveland Biolabs, Inc. Equity Incentive Plan, adopted in 2018 (the "Equity Plan"). Information is included for both equity compensation plans approved by the Company's stockholders and not approved by the Company's stockholders (which date back to before the Company became a reporting company under the Exchange Act).

| Plan Category | (a) Number of securities to be issued upon exercise of outstanding options, warrants and rights | (b) Weighted-average exercise price of outstanding options, warrants and rights | (c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| **Equity compensation plans approved by security holders (1)** | 76,064 | 27.35 | 515,493 |
| **Equity compensation plans not approved by security holders** | — | — | — |
| **Total** | 76,064 | 27.35 | 515,493 |

(1) Consists of the Equity Plan.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Pursuant to our written Related Party Transaction Policy, the Audit Committee must provide written approval in advance for any transaction that could involve an actual, potential or perceived conflict of interest, including transactions where employees or directors have a substantial financial interest in any of our competitors, customers or suppliers, or where gifts or loans of value in excess of $200 are received in a year from our suppliers, customers or competitors. The policy also requires advance written approval for any transaction where an employee or director owns a substantial interest in an entity that has a prospective business relationship with, or is a competitor of, us. In determining whether to approve any transaction requiring review under the policy, the Audit Committee considers whether the terms of the transaction are fair and on the same basis as would apply for a non-related party; whether there are business reasons for the Company to enter into the transaction; whether the transaction would impair the independence of an independent director; and whether the transaction would present an improper conflict of interest for a director or executive of the Company. The following is a list of transactions with related persons reviewed and approved by the Audit Committee during the two fiscal years ended December 31, 2020. There were no transactions with related persons required to be reported that were not reviewed and approved by the Audit Committee that were entered into during the year ended December 31, 2020, except that the transactions involving Norma Investments Limited described below were approved by the full Board, with no participation by the interested directors.

**Transactions and Relationships with Dr. Gudkov**

Our Chief Scientific Officer, Dr. Andrei Gudkov, is the Senior Vice President of Basic Science and the Chairman of the Department of Cell Stress Biology at Roswell Park Cancer Institute ("RPCI"). We subcontract Dr. Gudkov's laboratory at RPCI from Health Research Inc. to perform certain research and development studies for us, and also purchase certain core products and services from RPCI, including mice, the housing and storage of mice, irradiator services, DNA sequencing and blood analysis. RPCI also serves as one of our clinical sites. For the aforementioned services, we paid Health Research Inc. approximately $0.00 million and $0.06 million in 2020 and 2019, respectively.

Dr. Gudkov is also an uncompensated member of the board of directors for Incuron, LLC ("Incuron"). Pursuant to master service and development agreements we have with Incuron, the Company performs various research, business development, clinical advisory, and management services for Incuron. We recognized revenue of $0.05 million and $0.4 million from Incuron for the years ended December 31, 2020, and 2019, respectively. In addition, we also recognized $0 and $2,268 from Incuron for sublease and other income for the years ended for the years ended December 31, 2020, and 2019, respectively.

**Transactions and Relationships with GPI and Norma Investments**

As previously disclosed, in the third quarter of 2018, the Company entered into a series of related transactions under which the Company and Everon Biosciences, Inc. ("Everon") licensed and assigned certain intellectual property to Genome Protection, Inc. ("GPI"), a corporation formed by the Company for the purpose of creating a joint venture with Everon. GPI, which is currently 50% owned by the Company and 50% owned by Everon, is undertaking a research and development program aimed at clinical testing of entolimod and GP532 (a variant of our entolimod drug candidate) and the development of medications with anti-aging and other indications associated with genome damage. On August 10, 2018, GPI, Norma Investments Limited, a British Virgin Islands company ("Norma"), the Company and Everon entered into that certain Simple Agreement for Future Equity (the "SAFE"). Norma is controlled by investor Roman Abramovich, who also controls Millhouse Capital, LLC, the employer of three members of the Company's Board at the time the transaction was approved, Anna Evdokimova, Ivan Fedyunin and Ivan Persiyanov, and of which the Company's controlling stockholder is chief executive officer. Ms. Evdokimova and Messrs. Fedyunin and Persiyanov did not participate in the deliberations or vote to approve the Company's entry into the SAFE.

Under the SAFE, GPI granted Norma the right to purchase shares of GPI's capital stock in exchange for the payment of up to $30,000,000, of which $10,500,000 was paid shortly after the execution of the SAFE and the remainder may be paid, if at all, in tranches over time. The SAFE also provides that, upon the closing of a transaction in which GPI raises $3,000,000 or more in equity capital from a third party, Norma has the right to require GPI to issue to it the number of shares obtained by dividing the purchase price paid for the SAFE through such date by 50% of the price per share of the equity securities sold to the third party. If GPI experiences a change of control event or completes a firm commitment initial public offering of securities registered under the Securities Act of 1933, as amended, then GPI will, at Norma's option, either (i) pay to Norma an amount equal to the purchase price paid by Norma through such date under the SAFE plus interest accrued at a rate of 6.33% per year or (ii) issue to Norma shares of its common stock in the number obtained by dividing the purchase price paid by Norma through such date under the SAFE by 50% of the price per share of GPI's common stock based on GPI's valuation immediately preceding the consummation of either the change-of-control event or initial public offering. If GPI is dissolved, terminates its operations, makes a general assignment for the benefit of its creditors or liquidates or winds up its affairs, then GPI must pay Norma an amount equal to the purchase price paid by Norma through such date under the SAFE, prior to any distributions being made to any holders of GPI's capital stock, including the Company. The term of the SAFE is perpetual, terminating only upon the full repayment or conversion of the purchase price paid by Norma to GPI in connection with the events described above.

Under the SAFE, the parties agree that GPI's board of directors (the "GPI Board") will consist of four members, two of whom will be selected by Norma, one of whom will be selected by the Company and one of whom will be selected by Everon. The SAFE also provides that the parties agreed that a quorum of the GPI Board will require that at least one of the directors selected by Norma be present. Additionally, the SAFE sets forth a number of actions that GPI will be prohibited from taking without the unanimous consent of all of the members of the GPI Board, including, among other things, effecting a change of control transaction, terminating its operations, dissolving or liquidating, amending its organizational documents, transferring or licensing its intellectual property or issuing any shares of capital stock. The SAFE sets forth other matters that must be approved by a majority of the members of the GPI Board, including the incurrence of indebtedness exceeding $100,000, granting a lien or other encumbrance on GPI's assets, entering into a related party transaction and hiring, terminating or setting the compensation of executive officers. The Company and Everon have each guaranteed, to the extent of their powers as stockholders of GPI, the due and punctual performance by GPI of all of its obligations under the SAFE, and have also agreed to indemnify, on a joint and several basis, Norma for any losses arising out of any misrepresentation or any material breach of the SAFE, up to the amount of the purchase price paid by Norma under the SAFE.

In connection with the execution of the SAFE, the Company, Everon, GPI and Norma entered into that certain Director Designation Agreement, dated as of August 10, 2018 (the "Director Designation Agreement"), pursuant to which the parties made certain commitments as to voting and transfer of their shares of GPI and GPI's governance. Under the terms of the Director Designation Agreement, the parties agreed that the GPI Board will consist of four members, two of whom will be selected by Norma, one of whom will be selected by the Company and one of whom will be selected by Everon. Each party to the Director Designation Agreement also commits to (i) vote its GPI capital stock for the selected designees of the other parties, (ii) cause the director(s) appointed by it to nominate for election the selected designees of the other parties, (iii) vote its GPI capital stock for the removal of a member of the GPI Board if the party that originally selected such person so requests and (iv) to cause the director(s) appointed by it to vote to fill any vacancy created by the death, resignation or removal of a party's designee director with the replacement designee selected by such party.

Similar to the SAFE, the Director Designation Agreement sets forth a number of actions that GPI will be prohibited from taking without the unanimous consent of all of the members of the GPI Board, including, among other things, effecting a change of control transaction, terminating its operations, dissolving or liquidating, amending its organizational documents, transferring or licensing its intellectual property or issuing any shares of capital stock. The Director Designation Agreement sets forth other matters that must be approved by a majority of the members of the GPI Board, including the incurrence of indebtedness exceeding $100,000, granting a lien or other encumbrance on GPI's assets, entering into a related party transaction and hiring, terminating or setting the compensation of executive officers.

The Director Designation Agreement also contains a right of first refusal in favor of Norma under which if either the Company or Everon desires to sell its shares in GPI to a third party, it must first give notice to Norma, which then has the right to purchase some or all of such shares on the same terms and conditions as the selling stockholder had proposed to sell the shares to a third party. If Norma does not elect to purchase all of the shares that either the Company or Everon proposed to sell, then the Company or Everon, respectively, may sell such shares to the third party. Norma is not, however, required to first offer any shares of GPI it proposes to sell to the Company or Everon before selling such shares to a third party.

The Company recognized $0 and $7,909 in sublease and other income from GPI for the year ended December 31, 2020 and 2019, respectively.

**Parent of Smaller Reporting Company**

We have no parent company, though David Davidovich may be considered to be our parent by virtue of his ownership of 49.29% of our outstanding shares of common stock.

**Independence**

Because David Davidovich held more than 50% of the voting power for the election of our directors until June 2020, the Company was a "controlled company" within the meaning of the NASDAQ Stock Market Rules, and therefore was exempt from a number of corporate governance rules applicable to non-controlled companies. However, as a result of additional issuances of shares of our common stock, Mr. Davidovich now holds less than a majority of our common stock, and, accordingly, we are no longer a "controlled company." Instead, we are now subject to the same corporate governance rules of the NASDAQ Stock Market that apply to any other company that qualifies as a "smaller reporting company" under the rules of the SEC.

Our Board has affirmatively determined that all of our directors are "independent." Mme. Verny and each of Messrs. Saluck and Andryuschechkin are independent under The NASDAQ Stock Market Rules and the Securities Exchange Act of 1934 (the "Exchange Act") for purposes of serving on the Audit Committee. Each of Mme. Evdokimova and Messrs. Persiyanov, Talyanskiy, and Fedyunin are independent under such rules for purposes of general board service.

**Item 14. Principal Accounting Fees and Services**

Meaden & Moore, Ltd. acts as the principal auditor for us and also provides certain audit-related services. We have entered into an engagement agreement with Meaden & Moore, Ltd. that sets forth the terms by which Meaden & Moore, Ltd. will perform audit services for us. That agreement is subject to alternative dispute resolution procedures and an exclusion of punitive damages.

The Audit Committee pre-approves all services provided by Meaden & Moore, Ltd. to us. In pre-approving services, the Audit Committee considers whether such services are consistent with the SEC's rules on auditor independence. The fees for the services provided by Meaden & Moore, Ltd. to us are set forth below.

**Audit Fees**

Audit Fees were $133,300 for the year ended December 31, 2020 and were $115,900 for the year ended December 31, 2019. Audit Fees consisted of work performed in the audit of financial statements and work performed in connection with quarterly financial statement reviews, statutory audits, consultation regarding financial accounting and/or reporting standards, filings with the SEC and comfort letters.

**Audit-Related Fees**

There were no amounts billed by Meaden & Moore, Ltd. for Audit-Related Fees during the years ended December 31, 2020 and December 31, 2019.

**Tax Fees**

There were no amounts billed by Meaden & Moore, Ltd. for Tax Fees during the years ended December 31, 2020 and December 31, 2019.

**All Other Fees**

There were no amounts billed by Meaden & Moore, Ltd. for Other Fees during the years ended December 31, 2020 and December 31, 2019.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this report:

(1) Financial Statements, included in Part II, Item 8. "Financial Statements and Supplementary Data":

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2020 and 2019
Consolidated Statements of Operations for the years ended December 31, 2020 and 2019
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2020 and 2019
Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019
Consolidated Statement of Stockholders' Equity as of December 31, 2020 and 2019
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

None.

(3) Index to Exhibits: The exhibits listed in the following Exhibit Index are filed with this report or, as noted, incorporated by reference herein.

| Exhibit No. | Identification of Exhibit |
|---|---|
| 2.1** | Merger Agreement, dated as of October 16, 2020, among Cleveland Biolabs, Inc., High Street Acquisition Corp. and Cytocom, Inc. (Incorporated by reference to Exhibit 2.1 to Form 8-K filed October 19, 2020). |
| 3.1 | Restated Certificate of Incorporation filed with the Secretary of State of Delaware on March 18, 2010 (Incorporated by reference to Exhibit 3.1 to Form 10-K for the year ended December 31, 2009, filed on March 22, 2010). |
| 3.2 | Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013 (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended June 30, 2013, filed on August 9, 2013). |
| 3.3 | Certificate of Amendment of Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 27, 2015). |
| 3.4 | Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 20, 2016 (incorporated by reference to Exhibit 3.4 to Form 10-Q for the period ended March 31, 2016, filed May 16, 2016). |
| 3.5 | Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 21, 2017 (incorporated by reference to Exhibit 3.5 to Form 10-Q for the period ended March 31, 2017, filed May 15, 2017). |
| 3.6 | Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 9, 2015). |
| 3.7 | Certificate of Amendment of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed on February 9, 2015). |
| 3.8 | Second Amended and Restated By-Laws (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 5, 2007). |
| 3.9 | Amendment to Second Amended and Restated By-Laws of Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 18, 2015). |
| 4.1 | Form of Series A Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 15, 2014). |
| 4.2 | Amendment to Series A Common Stock Purchase Warrant, dated September 4, 2014, by and between Cleveland BioLabs, Inc.,Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (Incorporated by reference to Exhibit 4.1 and Exhibit 4.2 to Form 8-K filed on September 8, 2014). |

| Exhibit No. | Identification of Exhibit |
|---|---|
| 4.3 | Description of Registrant's Securities (Incorporated by reference to Exhibit 4.4 to Form 10-K filed on April 15, 2020). |
| 4.4 | Form of Warrant (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on June 3, 2020). |
| 4.5 | Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.2 to Form 8-K filed on June 3, 2020). |
| 4.6 | Settlement and General Release Agreement, dated as of July 15, 2020, between Cleveland BioLabs, Inc. and Alpha Capital Anstalt (Incorporated by reference to Exhibit 4.3 to Form 10-Q filed on August 14, 2020). |
| 4.7 | Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on February 23, 2021). |
| 10.1 | Registration Rights Agreement, dated February 4, 2015, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 9, 2015). |
| 10.2 | Securities Purchase Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 24, 2015). |
| 10.3 | Registration Rights Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 24, 2015). |
| 10.4† | Second Amendment to Exclusive License Agreement, dated September 22, 2011, by and between The Cleveland Clinic Foundation and the registrant (Incorporated by reference to Exhibit 10.3 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.5 | Sponsored Research Agreement between Cleveland BioLabs, Inc. and Roswell Park Cancer Institute Corporation, effective as of January 12, 2007 (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 12, 2007). |
| 10.6 | Investment Agreement, dated September 19, 2011, by and among Panacela Labs, Inc., the Registrant and Open Joint Stock Company Rusnano (Incorporated by reference to Exhibit 10.1 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.7† | Exclusive License and Option Agreement, dated September 23, 2011, by and between Children's Cancer Institute Australia for Medical Research and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.2 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.8† | Exclusive License and Option Agreement, dated September 23, 2011, by and between Health Research, Inc., Roswell Park Institute Division, Roswell Park Cancer Institute Corporation, and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.4 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.9 | Amended and Restated Exclusive Sublicense Agreement, dated September 23, 2011, by and between Cleveland BioLabs, Inc. and Panacela Labs, Inc. (Incorporated by reference to Exhibit 10.5 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.10 | Assignment Agreement, dated September 23, 2011, by and between Panacela Labs, Inc. and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.7 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |

| Exhibit No. | Identification of Exhibit |
|---|---|
| 10.11 | Royalty Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Incuron LLC (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 4, 2015). |
| 10.12* | Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Appendix A to Proxy Statement on Schedule 14A filed on April 1, 2008). |
| 10.13* | First Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 9, 2010). |
| 10.14* | Second Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 15, 2012). |
| 10.15* | Third Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 17, 2015). |
| 10.16* | Form of Stock Award Grant Agreement (Incorporated by reference to Exhibit 99.2 to Form 8-K filed on June 15, 2012). |
| 10.17* | Form of Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 99.3 to Form 8-K filed on June 15, 2012). |
| 10.18* | Cleveland BioLabs, Inc. 2013 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 20, 2013). |
| 10.19* | First Amendment to Cleveland BioLabs, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on April 17, 2015). |
| 10.20* | 2012 Long-term Executive Compensation Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 15, 2012). |
| 10.21* | Severance Benefit Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 13, 2014). |
| 10.22* | Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 1, 2018). |
| 10.23 | License Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 10, 2018). |
| 10.24 | Assignment Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc. (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 10, 2018). |
| 10.25 | Simple Agreement for Future Equity, dated as of August 10, 2018, among Genome Protection, Inc., Norma Investments Limited, Cleveland BioLabs, Inc. and Everon Biosciences, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 14, 2018). |
| 10.26 | Director Designation Agreement, dated as of August 10, 2018, among Genome Protection, Inc., Everon Biosciences, Inc., Cleveland BioLabs, Inc. and Norma Investments Limited (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 14, 2018). |
| 10.27 | Form of Securities Purchase Agreement, dated as of June 1, 2020, between Cleveland BioLabs, Inc. and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 3, 2020). |
| 10.28 | Consulting Agreement, dated as of August 10, 2020, between Cleveland BioLabs, Inc. and Sound Clinical Solutions, SP (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 14, 2020). |
| 10.29 | Consulting Agreement, dated as of October 11, 2020, between Cleveland BioLabs, Inc. and Andrei Gudkov, Ph.D., D. Sci. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 13, 2020). |
| 10.30 | Form of Voting and Support Agreement (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 19, 2020). |
| 10.31 | Form of Securities Purchase Agreement, dated as of February 19, 2021, between Cleveland BioLabs, Inc. and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 23, 2021). |
| 21.1 | Subsidiaries |
| 23.1 | Consent of Meaden & Moore, Ltd. |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certification of Christopher Zosh |
| 32.1 | Section 1350 Certification. |
| 101.1 | The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K for the quarter and year ended December 31, 2020: (i) Consolidated Balance Sheets at December 31, 2020 and 2019; (ii) Consolidated Statements of Operations for years ended December 31, 2020 and 2019; (iii) Consolidated Statements of Comprehensive Loss for years ended December 31, 2020 and 2019; (iv) Consolidated Statement of Stockholders' Equity for years ended December 31, 2020 and 2019; (v) Consolidated Statements of Cash Flows for years ended December 31, 2020 and 2019; and (vi) Notes to Consolidated Financial Statements as blocks of text. |

† Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

* Indicates management contract or compensatory plan required to be filed as an Exhibit.

** Pursuant to Item 601(a)(5) of Regulation S-K, certain schedules have been omitted. Upon request, a copy of any omitted schedule will be furnished supplementally to the Securities and Exchange Commission.

**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 thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: March 22, 2021

By: /s/CHRISTOPHER ZOSH
Christopher Zosh
Vice President of Finance

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

| Signature | Title | Date |
|---|---|---|
| /S/ Christopher Zosh<br>Christopher Zosh | Vice President of Finance (Principal Executive Officer and Principal Financial Officer) | March 22, 2021 |
| /S/ Lea Verny<br>Lea Verny | Director | March 22, 2021 |
| /S/ Randy Saluck<br>Randy Saluck | Director | March 22, 2021 |
| /S/ Alexander Andryushechkin<br>Alexander Andryushechkin | Director | March 22, 2021 |
| /S/ Anna Evdokimova<br>Anna Evdokimova | Director | March 22, 2021 |
| /S/ Ivan Fedyunin<br>Ivan Fedyunin | Director | March 22, 2021 |
| /S/ Daniil Talyanskiy<br>Daniil Talyanskiy | Director | March 22, 2021 |

Subsidiaries

| **Name** | **Jurisdiction of Incorporation** |
| --- | --- |
| High Street Acquisition Corporation | Delaware |
| Panacela Labs, Inc. | Delaware |
| Panacela Labs LLC | Russian Federation |

MEADEN & MOORE

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and
Stockholders of Cleveland BioLabs, Inc. and Subsidiaries:

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-140687, 333-150542, 333-167415, 333-182466, 333-203631 and 333-225721) and the registration statements on Form S-3 (Nos. 333-192755, 333-202387, 333-209232, and 333-238578) of Cleveland BioLabs, Inc. and Subsidiaries of our report dated March 22, 2021, relating to the consolidated financial statements and financial statement schedules, which appear in this Form 10-K.

MEADEN & MOORE, LTD.

Cleveland, Ohio
March 22, 2021

**Certification**

I, Christopher Zosh, certify that:

1. I have reviewed this annual report on Form 10-K of Cleveland BioLabs, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/22/2021

By: /s/ Christopher Zosh

Christopher Zosh
Vice President of Finance
(Principal Executive Officer and Principal Financial Officer)

**Certification***

In connection with the Annual Report of Cleveland BioLabs, Inc., (the "Company") Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.§ 1350), Christopher Zosh, Vice President of Finance Principal Executive Officer and Principal Financial Officer of the Company, hereby certifies that, to the best of his knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

Date: 3/22/2021

By: /s/ Christopher Zosh
Christopher Zosh
VP of Finance
(Principal Executive Officer and Principal Financial Officer)

* This certification accompanies the Annual Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cleveland BioLabs, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.