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, 2022**

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 **001-38416**

ORGENESIS INC.
(Exact name of registrant as specified in its charter)

Nevada	**98-0583166**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)

20271 Goldenrod Lane, Germantown, MD 20876
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(480) 659-6404**

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 $0.0001 per share	**ORGS**	**The 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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 common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2022) was $54,809,919, as computed by reference to the closing price of such common stock on The Nasdaq Capital Market on such date.

The registrant had 27,493,123 shares of common stock outstanding as of March 22, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. Certain statements made in this discussion are "forward-looking statements" within the meaning of 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by the Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used herein, the words "anticipate," "believe," "estimate," "expect," "forecast," "future," "intend," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

Unless otherwise indicated or the context requires otherwise, the words "we," "us," "our," the "Company," "our Company" or "Orgenesis" refer to Orgenesis Inc., a Nevada corporation, and our majority or wholly-owned subsidiaries, Orgenesis Korea Co. Ltd. (the "Korean Subsidiary"); Orgenesis Belgium SRL, a Belgian-based entity (the "Belgian Subsidiary"); Orgenesis Services SRL, a Belgian-based entity which was incorporated in 2022 ("Orgenesis Services SRL"); Orgenesis Ltd., an Israeli corporation (the "Israeli Subsidiary"); Orgenesis Maryland LLC (formerly Orgenesis Maryland Inc.), a Maryland limited liability company (the "U.S. Subsidiary"); Orgenesis Switzerland Sarl, (the "Swiss Subsidiary"); Orgenesis Biotech Israel Ltd. ("OBI"); Koligo Therapeutics Inc., a Kentucky corporation ("Koligo"); Tissue Genesis International LLC ("Tissue Genesis") a Texas limited liability company which was incorporated in 2022; Orgenesis Germany GmbH (the "German Subsidiary"); Orgenesis CA, Inc. (the "California Subsidiary"); Mida Biotech BV (the "Dutch Subsidiary") which was purchased in 2022; Orgenesis Australia PTY LTD (the "Australian Subsidiary") which was incorporated in 2022; Orgenesis Italy SRL (the "Italian Subsidiary") which was incorporated in 2022, Theracell Laboratories Private Company ("Theracell Laboratories"), a Greek company that the Company gained control on in December 2022, and Morgenesis LLC, a Delaware limited liability company ("Morgenesis") which was incorporated in 2022.

Forward-looking statements made in this Annual Report on Form 10-K include statements about:

Corporate and Financial

- our ability to generate revenue from the commercialization of our point-of-care cell therapy ("POCare") to reach patients and to increase such revenues;
- our ability to achieve profitability;
- our ability to manage our research and development programs that are based on novel technologies;

- our ability to grow the size and capabilities of our organization through further collaboration and strategic alliances to expand our point-of-care cell therapy business;
- our ability to control key elements relating to the development and commercialization of therapeutic product candidates with third parties;
- our ability to manage potential disruptions as a result of the continued impact of the coronavirus outbreak;
- our ability to manage the growth of our company;
- our ability to attract and retain key scientific or management personnel and to expand our management team;
- the accuracy of estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing; and
- our belief that our therapeutic related developments have competitive advantages and can compete favorably and profitably in the cell and gene therapy industry.

Cell & Gene Therapy Business ("CGT")

- our ability to adequately fund and scale our various collaboration, license, partnership and joint venture agreements for the development of therapeutic products and technologies;
- our ability to advance our therapeutic collaborations in terms of industrial development, clinical development, regulatory challenges, commercial partners and manufacturing availability;
- our ability to implement our POCare strategy in order to further develop and advance autologous therapies to reach patients;
- expectations regarding our ability to obtain and maintain existing intellectual property protection for our technologies and therapies;
- our ability to commercialize products in light of the intellectual property rights of others;
- our ability to obtain funding necessary to start and complete such clinical trials;
- our ability to further our CGT development projects, either directly or through our JV partner agreements, and to fulfill our obligations under such agreements;
- our belief that our systems and therapies are as at least as safe and as effective as other options;
- our relationship with Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") and the growing risk that THM may cancel or, at the very least continue to challenge, the License Agreement with the Israeli Subsidiary;
- the outcome of certain legal proceedings that we are or may become involved in;
- our license agreements with other institutions;
- expenditures not resulting in commercially successful products;
- our dependence on the financial results of our POCare business;
- our ability to complete development, processing and then roll out Orgenesis Mobile Processing Units and Labs ("OMPULs") generate sufficient revenue from our POCare Services; and
- our ability to grow our POCare business and to develop additional joint venture relationships in order to produce demonstrable revenues.

Metalmark Investment Risks

- Morgenesis may not receive the future payments pursuant to the Unit Purchase Agreement with MM OS Holdings, L.P. ("MM"), an affiliate of Metalmark Capital Partners;
- MM may force the sale of Morgenesis under certain conditions which may result in MM receiving a greater value than us and our shareholders;
- MM may, under certain circumstances, assume control of the Board of Managers of our subsidiary, Morgenesis, which would result in our inability to control and direct the activities of such subsidiary;
- MM has the right to buy our units in Morgenesis upon the occurrence of certain events, which could result in us not holding any equity in Morgenesis;
- we may be forced to redeem all of the units of Morgenesis held by MM, which could require substantial cash outlay and would adversely affect our financial position; and
- if MM opts to exchange its Morgenesis units for shares of our common stock, we could potentially issue up to 5,106,596 shares of our common stock to MM, which may result in significant dilution to our existing stockholders.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "Risk Factors" set forth in this Annual Report on Form 10-K for the year ended December 31, 2022, any of which may cause our Company's or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks may cause the Company's or its industry's actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The Company is under no duty to update any forward-looking statements after the date of this report to conform these statements to actual results.

PART I

ITEM 1. BUSINESS

Business Overview

We are a global biotech company working to unlock the potential of cell and gene therapies ("CGTs") in an affordable and accessible format. CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products ("ATMPs"). We are mostly focused on autologous therapies that can be manufactured under processes and systems that are developed for each therapy using a closed and automated approach that is validated for compliant production near the patient for treatment of the patient at the point of care ("POCare"). This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

Advanced Therapy Medicinal Products and POCare Overview

ATMP means one of any of the following medicinal products that are developed and commercialized for human use:

- A *somatic cell therapy medicinal product* ("STMP") that contains cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body;
- A *tissue engineered product* ("TEP") that contains cells or tissues that have been modified so that they can be used to repair, regenerate, or replace human tissue; or
- A *gene therapy medicinal product* ("GTMP") that engineers genes that lead to a therapeutic, prophylactic, or diagnostic effect and, in many cases, work by inserting "recombinant" genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer, or long-term diseases. In this case, a recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources.

It is important to note that, although STMPs and GTMPs currently dominate the market, in order to access the market potential and trends in the future, other cell products are likely to be essential in all of these categories. We believe that autologous therapies represent a substantial segment of the ATMP market. Autologous therapies are produced from a patient's own cells versus allogeneic therapies that are mass-cultivated from donor cells via the construction of master and working cell banks and are then produced on a large scale. Developers and manufacturers of ATMPs (both autologous and allogeneic) currently rely heavily on production using traditional centralized supply chains and manufacturing sites.

CGTs are costly and complex to produce. We also refer to CGTs as "living drugs" since they are based on maintaining the cell's vitality. Therefore, there is no possibility to sterilize the products, since such a process involves killing any living organism. Many of these therapies require sourcing of the patient's cells, engineering them in a sterile environment and then transplanting them back to the patient (so-called "autologous" CGT). This presents multiple logistic challenges as each patient requires their own production batch, and the current processes involve complex laboratory-based types of manipulations requiring highly trained lab technicians. We are leveraging a unique approach to therapy production using our POCare Platform to potentially overcome some of the development and supply chain challenges of affordably bringing CGT to patients.

To achieve these goals, we have developed a collaborative worldwide network of research institutes and hospitals who are engaged in the POCare model ("POCare Network"), and a pipeline of licensed POCare advanced therapies that can be processed and produced under such closed and automated processes and systems ("POCare Therapies"). We are developing our pipeline of advanced therapies and with the goal of entering into out-licensing agreements for these therapies.

We believe that, for this industry to prosper, it must be based on utilizing a standardized platform. Cellular therapies, though defined as drug products, conceptually differ from other drug modalities. The way these drug products are produced is inherently different from producing existing drugs. They are based on reprogramming of cells sourced from the patient or from a donor. They are not composed of purchased chemical components such as typical pharmaceuticals, nor are they harvested in large quantities from genetically engineered cell lines and then sterilized such as typical biotech products. These "living drug" products are, in most cases, produced per patient individually in a highly sterile and controlled environment, and their efficacy is optimized when administered a short time following production as fresh product.

To advance the execution of our goal of bringing such therapies to market, we have designed and built our POCare Platform - a scalable infrastructure of technology and services that ensures a central quality system, replicability and standardization of infrastructure and equipment, and centralized monitoring and data management. The platform is constructed on POCare Centers that serve as hubs that implement locally our POCare quality system, Good Manufacturing Practices ("GMP"), training procedures, quality control testing and incoming supply of materials and oversee the actual production in the Orgenesis Mobile Processing Units & Labs ("OMPULs"). The POCare Platform is operated by Morgenesis, an Orgenesis subsidiary (see below). This platform is utilized by other parties, such as biotech companies and hospitals for the supply of their products. Morgenesis services include adapting the process to the platform and supplying the products ("POCare Services"). These are services for third party companies and for CGTs that are not necessarily based on our POCare Therapies.

POCare Services

The POCare Services that we and our affiliated entities perform include:

- Process development of therapies, process adaptation, and optimization inside the OMPULs, or "OMPULization";
- Adaptation of automation and closed systems to serviced therapies;
- Incorporation of the serviced therapies compliant with GMP in the OMPULs that we designed and built;
- Tech transfers and training of local teams for the serviced therapies at the POCare Centers;
- Processing and supply of the therapies and required supplies under GMP conditions within our POCare Network, including required quality control testing; and
- Contract Research Organization ("CRO") services for clinical trials.

The POCare Services are performed in decentralized hubs that provide harmonized and standardized services to customers ("POCare Centers"). We are working to expand the number and scope of our POCare Centers. We believe that this provides an efficient and scalable pathway for CGT therapies to reach patients rapidly at lowered costs. Our POCare Services are designed to allow rapid capacity expansion while integrating new technologies to bring together patients, doctors and industry partners with a goal of achieving standardized, regulated clinical development and production of therapies.

POCare Services Operations via Subsidiaries

We currently conduct our core business operations ourselves and through Morgenesis and its subsidiaries which are all wholly owned except as otherwise stated below (collectively, the "Subsidiaries"). The following is a description of our Subsidiaries:

Morgenesis LLC

In August 2022, we formed Morgenesis LLC, a subsidiary to hold substantially all the assets of our POCare Services. We formed Morgenesis to streamline all existing POCare Service business units into one unified entity, bringing together a full-service range of solutions for therapeutic developers for point of care treatments. The newly formalized service offering provides solutions from initial process development, regulatory strategy and implementation, "OMPULization" which includes cGMP process development, closing/automating the process, and with the end goal of optimizing full cGMP processing and supply of therapeutic product to patients at the point of care. We currently own 76.9% of Morgenesis.

During November 2022, we and MM OS Holdings, L.P. ("MM"), an affiliate of Metalmark Capital Partners ("Metalmark"), entered into a series of definitive agreements intended to finance, strengthen and expand our POCare Services business (the "Metalmark Investment"). Pursuant to a unit purchase agreement (the "UPA"), MM agreed to purchase 3,019,651 Class A Preferred Units of Morgenesis (the "Class A Units"), which represents 22.31% of the outstanding equity interests of Morgenesis following the initial closing, for a purchase price of $30.2 million, comprised of (i) $20 million of cash consideration and (ii) the conversion of $10.2 million of MM's then-outstanding senior secured convertible loans previously entered into with MM. Under certain conditions related to Morgenesis' performance among others, MM has agreed to make future payments of up to $20 million in cash for additional Class A (or Class B) Units, and/or make a one-time cash payment of $10 million to Orgenesis (the "Earnout Payment"). In connection with the entry into of the UPA, we, Morgenesis and MM entered into the Second Amended and Restated Limited Liability Company Agreement (the "LLC Agreement") providing for certain restrictions on the disposition of Morgenesis securities, the provisions of certain options and rights with respect to the management and operations of Morgenesis, a right for MM to exchange any units of Morgenesis for shares of Orgenesis common stock and certain other rights and obligations. In addition, MM was provided certain protective rights in Morgenesis.

We transferred the following subsidiaries to Morgenesis, and the proceeds of the investment will generally be used to fund the activities of Morgenesis and its consolidated subsidiaries.

- Orgenesis Maryland LLC, which is the center of POCare Services activity in North America and is currently focused on setting up and providing POCare Services and cell-processing services to the POCare Network.
- Tissue Genesis International LLC, which was formed in Texas in 2022, is currently focused on development of our technologies and therapies.
- Orgenesis Services SRL, which was incorporated in 2022 and is currently focused on expanding our POCare Network in Belgium.
- Orgenesis Germany GmbH, which is currently focused on providing CRO services to the POCare Network.
- Orgenesis Korea Co. Ltd., which is a provider of cell-processing and pre-clinical services in Korea. The Company owns 94.12% of the Korean Subsidiary.
- Orgenesis Biotech Israel Ltd., which is a provider of process development and cell-processing services in Israel.

In December 2022, we (through our subsidiary Morgenesis) gained control over Theracell Laboratories, a Greek company currently focused on expanding our POCare Network. (See notes 12 and 13)

Integration of Custom Fit Solutions within the POCare Center

Our aim is to provide a pathway to bring ATMPs in the cell and gene therapy industry from research to patients worldwide through our POCare Platform. We define point of care as a process of collecting, processing, and administering cells as close as possible to the clinical setting. We believe that this approach is an attractive proposition for CGT during the clinical development stage and even more so upon market approval therapies. This will potentially help to minimize or eliminate the need for cell transportation, which is a high-risk and costly aspect of the supply chain, further allowing flexible production and patient treatment and reduce the cost and lengthy timelines associated with building additional clean rooms and complex tech transfers between production sites.

We believe that the existing industry paradigm in which each therapy developer invests in setting up unique infrastructure such as specialized clean rooms and production facilities is inefficient. The cost of construction, regulatory authorization and maintenance of these facilities is not only prohibitive but extremely difficult and lengthy to replicate, allowing no economies of scale. We have based the design of our POCare Platform on the concept of standardizing infrastructure by providing flexible building blocks through the POCare Centers and OMPULs, which allows for quick expansion at multiple locations.

- Local Decentralization: POCare Centers are set up in preferred regions, based on nearby hospitals' capacity needs, and support the POCare Services model by providing POCare Services.
- Global Harmonization: The POCare Platform overcomes conventional processing challenges by enabling high quality standards and sterile, scalable onsite processing of CGTs orchestrated by the POCare Centers to service local hospitals. Processing infrastructure is harmonized and reproducible using the OMPUL. The use of an OMPUL can shorten implementation time from approximately 18-24 months to approximately 3-9 months, offers a more cost-effective environment and enables local scalability by connecting additional OMPULs. The network structure is supported and connected by the centralization of the harmonized best industry practices and standards to meet the highest quality standards ("QMS", Quality Management System). Further global harmonization is implemented through standardization of the training programs, centralized data management and a unified supply chain.
- OMPULization of Therapies: Strong process development capabilities are critical for any CGT to scale. All therapeutic candidates must undergo some level of process development to move from the discovery phase to the clinical phase, if only to establish the same protocols under GMP. The POCare Platform takes process development to the next level, implementing a process we call OMPULization. OMPULization includes unitizing the process to the exact specifications of the OMPUL so it can be rapidly implemented in OMPULs around the world. In addition, OMPULization incorporates the latest technology solutions to close and automate the process whenever possible.

Integrated closed and automated processing systems require fewer full-time employees ("FTEs") to produce GMP batches, resulting in lower cost of goods and a process that has the ability to scale in sync with market demand. Full automation may not be necessary for all clinical phases, but it is important to plan for future incorporation. To this end, we have invested time and capital into evaluating relevant technology for CGT processing and have developed proprietary equipment that did not exist in the marketplace.

We aim to build value in various aspects of our company ranging from supply related processes including development and distribution systems, clinical and regulatory services, engineering and devices such as OMPULs discussed below and delivery systems. Therapies serviced include immuno-oncology, anti-aging, metabolic, dermatology, orthopedic, as well as regenerative technologies.

The POCare Platform is a unique globally harmonized and decentralized CGT-processing infrastructure that offers cost-effective processing capacities with ease for scalability and reproducibility. By producing personalized cell and gene therapies (CGTs) utilizing the POCare Platform, we are able to add new capacity within months instead of years. Over time, we have worked to develop and validate POCare Technologies that can be combined within mobile production units for advanced therapies.

We have made significant investments in the implementation of several therapy types in OMPULs and have made significant progress in the validation, risk analysis, regulatory and other related tasks relating to the OMPULs. We are setting up the OMPULs through our POCare Centers. OMPULs are designed for the purpose of validation, development, performance of clinical trials, manufacturing and/or processing of potential or approved cell and gene therapy products in a safe, reliable, and cost-effective manner at the point of care, as well as the manufacturing of such CGTs in a consistent and standardized manner in all locations. The design delivers a potential industrial solution for us to deliver CGTs to most clinical institutions at the point of care.

Above are diagrams of an OMPUL and partial interior for illustrative purposes only.

We have finalized or are in the process of finalizing the development of several POCare Centers and adapting to the local requirements of each POCare Center with the target of achieving a capacity to process and supply CGTs per production contracts. As we expand operations, we expect that the OMPUL setup costs will decline over time. Most of our POCare revenue to date is in support of the implementation of technologies and therapies in the OMPULs and production at the POCare Sites.

We have established POCare Centers in several locations globally, in which we perform process development and manufacturing activities for several types of CGT products. For example, in Israel, our POCare Center includes process development and QC labs, as well as OMPULs located at a hospital site in the center of Israel and an additional OMPUL in preparation for an additional hospital. In these OMPULs, we currently manufacture TILs and CAR-T therapies for our customers. In Greece, our POCare Center includes three OMPULs installed in place and a process development lab, currently servicing two customers. Our POCare Center in Maryland, USA, includes an operating process development lab. We are also establishing cleanroom-based facility funded by a government grant. In Spain we have an OMPUL producing a clinical grade product.

POCare Services Development Facilities

OBI

OBI is our specialized process and technology development wholly-owned subsidiary focused on custom-made process development, upscaling design from lab to industry innovation and automation procedures, which are extremely essential in the cell therapy industry. OBI is located in Bar-Lev Industrial Park utilizing the exclusive Israeli innovative ecosystem and highly experienced and talented associates including Ph.D. holders and biotechnology engineers. The center provides end to end solutions to cell therapy industrialization, process development capabilities and proficiency, custom-made engineering and a unique platform for creative design and process optimization. OBI occupies 1,300 square meters of labs and offices resulting in an efficient and unique environment for cell therapy development. In connection with the Masthercell Sale completed in 2020, for a period of three years in the European Union and five years in the United States and the rest of the world from the closing date of the Masthercell Sale, we agreed that OBI will not manufacture products on a contract basis for third-party customers in any jurisdiction other than the State of Israel, but it may conduct such CDMO business in the State of Israel, solely for customers located within the State of Israel or with respect to therapies intended for distribution solely within the State of Israel. The Masthercell sale agreement stipulated that OBI may also conduct, worldwide, (i) point-of-care system, point-of-care products, point-of-care systems, point-of-care processing, and point-of-care development services for the development, manufacturing or processing of therapeutics, processes, systems and technologies to treat patients in a point-of-care clinical, hospital or institutional setting, any future point-of-care services substantially related to the foregoing, and advanced therapy medicinal products either proprietary to us or our affiliates or proprietary to a third-party partner (including a joint venture partner) or collaborator, which includes research, development, systems, manufacturing and processing of therapeutic technology products, systems, and processes, methods or services and (ii) research, manufacturing, development and other activities related to the research, development, manufacturing, discovery and commercialization of therapeutic products or technologies, and processes, systems, methods or services thereof for its own account or in order to make such products or services available for the account of their third-party partners (including joint venture partners) or collaborators (including such therapeutic products, processes or technologies in which we or one of our affiliates has an economic interest or any relationship with any third-party or that are created, developed, manufactured or sold by a joint venture, partnership or collaboration between us or any of our affiliates and a third-party (individually and collectively, “Permitted Business”).

The Korean Subsidiary

The Korean Subsidiary has a particular focus on developing innovative cell therapies for our customers. In connection with the Masthercell Sale completed in 2020, for a period of three years in the European Union and five years in the United States and the rest of the world from the closing date of the Masthercell Sale, we agreed that the Korean Subsidiary will not manufacture cell and gene products on a contract basis for third-party customers in any jurisdiction other than South Korea, but it may conduct CDMO business in South Korea, solely for customers located within South Korea and with respect to therapies intended for distribution solely within South Korea, provided that the Korean Subsidiary may conduct Permitted Business.

Tissue Genesis International

The Tissue Genesis Icellator™ is used to isolate stromal and vascular fraction cells ("SVF") from a patient's own (autologous) adipose tissue (fat). The Tissue Genesis Icellators, associated disposable kits, and our proprietary enzyme Adipase™, are made by contract manufacturers and warehoused at our ISO 13485-certified and FDA-registered facility in Texas. From this facility we fill orders for our customers all around the world and maintain research and development labs to support continued product development.

Tissue Genesis International ("TGI") has expanded its development pipeline from the Icellator to additional systems for automation of Cell and Gene Therapy and incorporation of these various platforms into the OMPULs.

On the Icellator front, in 2022 TGI continued to service our existing customers both domestically and abroad, added new customers, increased revenue from sales, extended shelf-life of existing Icellator inventory, continued Adipase development, and engaged in production of a new lot of disposables.

TGI includes the integration of our development projects, foremost among them the Control Tower for automation of cGMP cell and gene therapy inside the OMPULs. In 2022 TGI brought this project into the ISO quality system and engaged with contract engineering firms with the requisite experience and that meet our stringent quality assurance standards.

Orgenesis Services SRL

Orgenesis Services SRL specializes on developing innovative cell therapies for our customers. The subsidiary benefits both from its central position in Europe and its being in the leading Walloon biotech cluster. It occupies innovative facilities for the development and quality control of therapies in R&D and GMP grades.

Theracell Laboratories

Theracell Laboratories, located in Greece, specializes on developing and processing innovative cell therapies for our customers. It was designated as a "Priority Investment of Strategic National Importance" by Enterprise Greece, the official Greek national investment and trade promotion agency, which is responsible for the allocation of Greek government funding. As a result of this designation, Theracell will be inducted into Greece's fast-track licensing and approval process. This is expected to help advance development and clinical use of our CGT at POCare, subject to regulatory requirements.

Notable 2022 POCare Services Activities

In 2022, we continued to focus on setting up our regional POCare activities. This included the setup of POCare Centers that oversee regional development and GMP services, local OMPUL deployment and supply of products to the local clinical centers. We are in the process of expanding the capacity of our POCare Centers in Maryland, Boston, California, Belgium, Greece, Slovenia, Israel, Italy, Spain and Korea. Future set-up plans include potential sites in the U.S. and EU where we already have initial activity such as in Germany and Texas, as well as in Australia and China.

As part of our POCare Services, we have developed the relevant GMP processes for a variety of therapies such as CAR-T, TILs, NK and MSC based therapies. We have developed OMPULs with the required systems for production of CAR-T, TILs and MSC products, and are working on several other therapies intended for clinical testing. TIL, CAR-Ts and MSCs were already produced in the OMPULs for our customers. We have worked closely with technology partners to adapt various systems for closed system production of the above products and continue our collaboration efforts to develop fully automated systems for integration in the OMPULs.

We expanded our collaboration with UC Davis and have completed the first production batch of GMP grade lentivirus to be utilized for clinical grade production of CAR-Ts. We intend to expand the collaboration to establish and validate the decentralized model of OMPUL placement in compliance with regulatory requirements. The parties aim to commercialize and install OMPULs at other sites within the State of California. We have expanded our partnership with Johns Hopkins University and are setting up a GMP facility with the support of a grant from Maryland. We are providing products to several hospitals in the U.S., are working closely with leading hospitals in Spain and Italy and are working closely with clinicians from hospitals in Israel, where we have deployed our OMPULs to set up additional clinical sites where we can provide POCare Services for our customers and partners. Based on the requests of our customers and partners, we have expanded our POCare Services to include CRO services.

We have collaborated closely with our Greek partner, Theracell, and have set up a partnership in Greece focusing on delivering advanced therapies to Greek hospitals. The Greek government has granted our Greek joint venture entity a “fast track” status and a supportive financial grant.

Our POCare Services are expanding to additional geographies, and we are providing services to the U.S., EU, and Asia.

POCare Therapies

The global CGT market is growing at a rapid pace, now with over 2,000 active clinical trials (ARM H1 2022 Report), including 200+ in Phase III and 254 new clinical trials in 2022 (ARM State of the Industry Briefing). Several biotech companies developing CGTs have been acquired by large pharma (Gilead Sciences acquired Kite Pharma, Roche acquired Spark Therapeutics, Bayer acquired AskBio) for several billion dollars before generating their first revenues. According to an article by McKinsey & Company from April 2020, CGT products account for 12 percent of the industry’s clinical and 16 percent of the preclinical pipeline. 16 of the world’s largest 20 biopharma companies now have CGT assets in their product portfolios.

This is a relatively new field, developing quickly in the last decade. The initial development of these therapies began at clinical research centers, based on attempts of researchers and clinicians to incorporate the scientific knowledge that accumulated from the biotechnology industry, including advancements in genetic engineering of cells, cell sourcing, tissue engineering and the medical advancements of immunology. In the early years of development, it was not even clear if such therapies would be considered a clinical treatment (such as a bone marrow transplant) or drug product such as a recombinant protean. In the last decade there has been much development in the regulatory framework required to bring such products to market, but still there is vagueness in some markets and unique regulatory pathways (such as the legal framework in the EU for hospital exemption allowing hospitals who wish to provide such therapies to their patients to take responsibility for treating patients). Though the biotech industry has embraced this new modality of drug development, they face many challenges. The pharma and biotech companies are used to centralized production and providing shelf products that can be stored and made available on demand. Their development and production teams are eager to fit these therapies into the existing well-known paradigms. This has proven to be extremely challenging, and the result has been approvals of products such as CAR-Ts for blood cancers and products for treatment of genetic diseases costing hundreds of thousands of dollars, or even over a million dollars per patient. The capacity to produce such products is limited and though they are considered a breakthrough in terms of clinical results, the high cost has been prohibitive of market acceptance.

While the biotech industry struggles to determine the best way to lower cost of goods and enable CGTs to scale, the scientific community continues to advance and push the development of such therapies to new heights. Clinicians and researchers are excited by all the new tools (new generations of industrial viruses, big data analysis for genetic and molecular data) and technologies (CRISPR, mRNA, etc.) available (often at a low cost) to perform advanced research in small labs. Most new therapies arise from academic institutes or small spinouts from such institutes. Though such research efforts may manage to progress into a clinical stage, utilizing lab based or hospital-based production solutions they lack the resources to continue the development of such drugs to market approval.

Historically, drug/therapeutic development has required investments of hundreds of millions of dollars to be successful. One significant cause for the high cost is that each therapy often requires unique production facilities and technologies that must be subcontracted or built. Further the cost of production during the clinical stage is extremely expensive, and the cost of the clinical trial itself is very high. Given these financial restraints, researchers and institutes hope to out- license their therapeutic products to large biotech companies or spin-out new companies and raise large fundraising rounds. However, in many cases they lack the resources and the capability to de-risk their therapeutic candidates enough to be attractive for such fundings or partnership.

Our POCare Network is an alternative to the traditional pathway of drug development. Orgenesis works closely with many such institutes and is in close contact with researchers in the field. The partnerships with leading hospitals and research institutes gives us a deep insight as to the developments in the field, as well as the market potential, the regulatory landscape and optimal clinical pathway to potentially bring these products to market.

The ability to produce these products at low cost, allows for an expedited development process and the partnership with hospitals around the globe enables joint grants and lower cost of clinical development. The POCare Therapies division reviews many therapies available for out licensing and select the ones which they believe have the highest market potential, can benefit the most from a point of care approach and have the highest chance of clinical success. It assesses such issues by utilizing its global POCare Network and its internal knowhow accumulated over a decade of involvement in the field.

The goal of this in-licensing is to quickly adapt such therapies to a point-of- care approach through regional partnerships, and to out-license the products for market approval in preferred geographical regions. This approach lowers overall development cost, through minimizing pre-clinical development costs incurred by us, and through receiving of the additional funding from grants and/or payments by regional partners.

Our Therapies development subsidiaries are:

- Koligo Therapeutics, Inc., a Kentucky corporation, which is a regenerative medicine company, specializing in developing personalized cell therapies. It is currently focused on commercializing its metabolic pipeline via the POCare Network throughout the United States and in international markets.

- Orgenesis CA, Inc. a Delaware corporation, which is currently focused on development of our technologies and therapies in California.

- Orgenesis Belgium SRL which is currently focused on product development. Since its incorporation the subsidiary has received grant awards of over Euro 18 million from the Walloon region for several projects (DGO6 grants). We intend to continue applying for the Walloon Region support of our future pre-clinical and clinical development plans.

- Orgenesis Switzerland Sarl, which is currently focused on providing group management services.

- MIDA Biotech BV, which was acquired in 2022 and is currently focused on research and development activities, was granted a 4 million Euro grant under the European Innovation Council Pathfinder Challenge Program which supports cutting-edge science and technology. The grant is for technologies enabling the production of autologous induced pluripotent stem cells (iPSCs) using microfluidic technologies and artificial intelligence (AI).

- Orgenesis Italy SRL which was incorporated in 2022 and is currently focused on R&D activities. Orgenesis has joined an Italian consortium dedicated to the implementation of a research program in the field of gene therapy and drug development with RNA technology. The program is sponsored by the Italian national recovery and resilience plan “strengthening of research structures and creation of national R&D champions on key enabling technologies.

- Orgenesis Ltd., an Israeli subsidiary which is focused on R&D and a provider of R&D management services for out licenced products. Israel as a hub for biotech research and pioneers in this field

- Orgenesis Australia PTY LTD, which was incorporated in 2022 and is currently focused on the development of the Company's technologies and therapies.

Therapies in Development

Our cell and gene therapies pipeline includes investigational therapies and next-generation technologies that have the power to transform the way cancer and other unmet clinical needs are treated. Our pipeline is predominantly comprised of personalised autologous cell therapies, implying that patients receive cells that originate from their own body, virtually eliminating the risk of an immune response and rejection. Our promising pipeline focuses on advanced therapy medicinal products is originated from solid internal proprietary, joint ventures and in-licensing agreements with biotech companies and leading research institutes. Our main therapeutic fields encompass cell-based immuno-oncology, cell-based drug delivery platforms, regenerative medicine, anti-viral and autoimmune disease.

The following table summarizes our therapies in development, which are discussed in detail below:

Therapy	**Development Stage**	**Indication**
HiCAR-T	IND enabling studies	B-ALL, B-cell Lymphoma
CeCART	Pre-clinical	Solid Tumors
T-LOOP	IND enabling studies	Solid Tumors
Intra Nasal Delivery of Cell based Immunotherapy	Pre-Clinical	Drug delivery technology, Glioblastoma
MSCP	Pre-clinical	Wound healing and Psoriasis
EVRD	Pre-clinical	CKD
MDVAC	IND enabling studies	Pancreatic Cancer
AutoSVF	Clinical development	Systemic ARDS , vascular disorders
CellFix	Clinical use	Cartilage Defects
KYSLECEL (see 1 below)	Market approval in the US	TP-IAT
KT-DM-103 and KT-CP-203 (3D-Printed Pancreatic Islets) (see 2 below)	Own development	Type 1 diabetes and chronic pancreatitis
RanTop, Ranpirnase Topical Formulation (see 3 below)	Clinical Stage	Anti-viral/ Immune oncology
Autovac (see 4 below)	Pre-clinical	Autologous viral vaccine
Bioxomes (see 5 below)	Pre-clinical	Drug Delivery Technology
MSPP	Pre-clinical	Urinary Incontinence

1. KYSLECEL® (Autologous Pancreatic Islets)

The patient's own pancreatic islets, comprised of the cells that secrete insulin to regulate blood sugar, form KYSLECEL, a minimally manipulated autologous cell-based product, produced according to current good tissue practices (cGTP), available in the United States and regulated by the U.S. Food and Drug Administration ("FDA"). The target population of KYSLECEL is chronic or acute recurrent pancreatitis patients after total pancreatectomy (TP-IAT), who are in need of insulin secretory capacity preservation.

To gain insight into KYSLECEL patient outcomes, an observational study is expected to be initiated in the United States. In addition, to promote process development and marketing of KYSLECEL in the European Union, substantial efforts are being invested. In this regard, designated teams are being trained by Orgenesis, to manage the introduction of KYSLECEL into new markets by supporting tech transfer, as well as working on the automation of the manufacturing process. We are also considering new potential indications, as well as promoting the development of new additional biological product.

2. KT-DM-103 and KT-CP-203 (3D-Printed Pancreatic Islets)

Orgenesis, through the acquisition of Koligo, has exclusively licensed patents and technology from the University of Louisville Research Foundation, related to the revascularization and 3D printing of cells and tissues intended for transplantation ("3D-V" technology platform). Utilizing this technology, potential autologous and allogeneic pancreatic islet transplants may be implemented to treat type 1 diabetes (KT-DM-103), and chronic pancreatitis (KT-CP-203). In addition to pancreatic islet transplantation, the 3D-V technology platform may also support improved transplantation of other cell and tissue types.

3. RanTop, Ranpirnase Topical Formulation

We are developing a novel topical gel formulation of an active RNA-degrading enzyme, called Ranpirnase. Ranpirnase combats viral infections by targeting double-stranded RNA including miRNA precursors, via RNA degradation catalysis. Topical Ranpirnase demonstrated good tolerability and preliminary clinical efficacy in the treatment of HPV-associated external anogenital warts (EGW) in a Phase 2a clinical study conducted in Bolivia.

Following FDA positive pre-IND feedback, a dermal toxicology feasibility study was conducted, showing that Ranpirnase gel formulation was well-tolerated in repeated daily topical administration. Additionally, a sensitive Ranpirnase blood concentration bioanalytical method was established, needed for determining systemic exposure in toxicology studies for IND filing.

We have demonstrated in laboratory experiments the feasibility of Ranpirnase encapsulation in the Orgenesis Bioxome delivery platform, as well as an encapsulation-enhanced Ranpirnase anti-viral activity in an *in vitro* test. Following identification of an optimal cell source, the combined product will be further developed for oncological indications.

4. Autologous Cell-Based Vaccine for protecting against SARS-CoV-2

AutoVac is an autologous, pan-antigenic vaccine platform. The vaccine is based on the use of a specific target for *ex vivo* induction of autologous cell-based vaccine that enables rapid response in times of a viral outbreak. As initial proof of concept, we are validating this novel cell-based vaccine platform against Coronavirus disease 2019 (COVID-19). Preliminary *in vitro* results demonstrated successful immune cell activation, correlated with antigen expression. Currently, additional pre-clinical immunogenicity studies are planned for regulatory submission support, as well as regulatory and clinical strategy finalization. In addition, other viral pathogens are tested, to confirm specificity, and robustness of this vaccine platform.

5. Bioxomes™ as a cell-based delivery product

Exosomes are small, membrane-enclosed extracellular vesicles, involved in cell-to-cell interactions. Exosomes may serve as a valuable therapeutic modality, given their ability to transfer a wide variety of therapeutic payloads among cells that can affect a cell in multiple ways, and can be designed to reach specific cell types. Bioxomes are biocompatible and serve as GMP/GLP-compliant exosome-like membrane nanostructures that can be produced from various cell types. To this end, we have developed a proprietary large-scale GMP-compatible manufacturing process for preparation of Bioxome, from human adipose cells, fibroblasts, blood cells, as well as plant cells.

Additionally, preliminary biodistribution studies demonstrated specific organ tropism, as well as enhanced skin penetration, when applied topically. Further biodistribution and bioavailability studies with Bioxomes, encapsulated with selected therapeutic cargos are on-going to confirm efficacy and safety. Bioxomes are planned to be utilized as the next generation biological delivery platform for Immuno-oncology indications. Currently, the regulatory strategy is being finalized according to US FDA requirements.

Strategic CGT Therapeutics Collaborations

Collaborations, partnerships, joint ventures and license agreements are key components of our POCare strategy.

Our POCare technology collaborators and partners include Ori Biotech, Accellix, Columbia University in the City of New York, Caerus Therapeutics Corporation, UC Davis, The Johns Hopkins University, The Weizman Institute of Science and others.

In addition, we have collaborations and joint ventures for developing POCare Therapies in jurisdictions throughout the world, including various countries in North America, Europe, Latin America, Asia, and Australia. Such partnerships include in-licensing and out-licensing of therapies, service contracts from the partners under co-development agreements, and development and manufacturing agreements for POCare products supplied regionally. For more information, see note 12, “Collaboration and Licensing Agreements” of the “Notes to the Financial Statements” included in Item 8.

Current POCare Therapies Development Facilities

Koligo

Koligo maintains commercial production facilities for KYSLECEL at an FDA-registered establishment in Indiana. Koligo is also developing new technologies such as bio-degradable 3D structure to deliver islets & other cell/tissue. Koligo also maintains development labs at its Indiana location to support continued development.

The Belgian Subsidiary

The Belgian Subsidiary specializes in developing and validating proprietary and licensed advanced cell and gene therapies such as the Muscle-derived Mesenchymal Stem Cells therapy for the treatment of SUI. The subsidiary benefits both from its central position in Europe and its being in the leading Walloon biotech cluster. Located near Namur, at Novalis Science Park, the Belgian Subsidiary collaborates with leading medical and academic facilities which enables it to cover the drug product life cycle from research to clinical stage through pre-clinical and quality control.

The subsidiary employs talented and highly experienced staff and collaborators.

Mida

Mida specializes in developing and validating proprietary and licensed advanced cell and gene therapies such IPS based therapies and AI.

The Israel Subsidiary

The Israel subsidiary occupies 400 square meters of labs and offices in Nes Ziona, Israel.

Revenue Model, Business Development and Licenses

Our POCare Platform is comprised of three enabling components: a multitude of licensed cell based POCare Therapies to be produced in closed, automated POCare Technology systems across a collaborative POCare Network. Our therapies include, but are not limited to, autologous, cell-based immunotherapies, therapeutics for metabolic diseases, anti-viral diseases, and tissue regeneration. We are establishing and positioning the business to bring point-of-care therapies to patients in a scalable way working directly with hospitals and through regional JV partners and JVs active in autologous cell therapy product development, including facilities in various countries in North America, Europe, Asia, the Middle East, and Australia. Our goal through the POCare Platform is to enable a rapid, globally harmonized pathway for these therapies to reach large numbers of patients at lowered costs through efficient, and decentralized production. Our POCare Network brings together industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies.

We are focused on technology in licensing and therapeutic collaborations, and we out-license therapies marketing rights and manufacturing rights to partners and/or to the JVs. In many cases, the JVs are responsible for the preparation of clinical trials, local regulatory approvals and regional marketing activities. Such licensing includes exclusive or nonexclusive, sublicensable, royalty bearing rights and license to the Orgenesis Background IP as required to manufacture, distribute and market and sell Orgenesis products within the relevant territories. In consideration of the rights and the licenses so granted, we receive a royalty in the range of ten percent of the net sales generated by the JV Entity and/or its sublicensees (as applicable) with respect to the Orgenesis products.

Further to revenues generated from out-licensing, we generate revenues from POCare Services and sales which is comprised of:

- R&D development services provided to out-licensing partners

We have signed POCare development services Master Services Agreements (“MSAs”) with our JV partners. In terms of the MSAs, we provide certain broadly defined development services that relate to our licensed therapies designed to develop or enhance the therapy with the objective of preparing it for clinical use. Such services, per therapy, include regulatory services, pre-clinical studies, intellectual property services, development services, and GMP process translation. We also provide support services to our customers.

- Hospital supply

Hospital services includes the sale or lease of products and the performance of processing services to our POCare hospitals or other medical providers. We either work directly with hospitals or receive payments through our regional JV partnerships.

- Cell process development revenue

We provide cell process development services in some regions to third party customers. Those services are unique to the customers who retain the ownership of the intellectual property created through the process.

- POCare cell processing

We provide distributed cell processing services for third party customers at POCare Centers in close proximity to patients.

Our POCare revenue is as follows:

	Years Ended December 31,	
Revenue stream:	**2022**	**2021**
	(in thousands)	
POCare development services	$ 14,894	$ 32,192
Cell process development services and hospital services	11,212	3,310
POCare cell processing	9,919	-
Total	$ 36,025	$ 35,502

Competition in the Cell Therapy Field

The biopharmaceutical industry is intensely competitive. There is continuous demand for innovation and speed, and as the cell-based therapies market evolves, there is always the risk that a competitor may be able to develop other compounds or drugs that are able to achieve similar or better results for indications. Potential competition includes major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of these competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations with established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Currently, we are not aware of any other companies pursuing a business model similar to what we are developing under our POCare Platform. However, our competitors in the CGT field who are significantly larger and better capitalized than us could undertake strategies similar to what we are pursuing and even develop them at a much more rapid rate. These potential competitors include the same multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions that are operating in the CGT field. In that respect, smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Intellectual Property

We will be able to protect our technology and products from unauthorized use by third parties only to the extent it is covered by valid and enforceable claims of our patents or is effectively maintained as trade secrets. Patents and other proprietary rights are thus an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

In addition, we own or have exclusive rights to thirty-six (36) United States patents, seventy-five (75) foreign-issued patents, eighteen (18) pending patent applications in the United States, seventy-one (71) pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, North Korea, Panama, Russia, Singapore, South Africa, and South Korea, and eleven (11) international Patent Cooperation Treaty (“PCT”) patent applications. These patents and patent applications relate, among others, to (1) dendritic cell based (whole cell) vaccines, and their use for treating cancer and viral diseases; (2) compositions comprising Ranpirnase and other ribonucleases and their use for treating viral diseases; (3) tumor infiltrating lymphocytes (TILs) and their use for treating cancer; (4) compositions comprising immune cells, ribonucleases, or antibodies for treating COVID-19; (5) therapeutic compositions comprising exosomes, bioxomes, and redoxomes; (6) bioreactors for cell culture and automated devices for supporting cell therapies; (7) chimeric antigen receptors (CARs); (8) adoptive immunotherapy using neurotransmitters; (9) Mobile Processing Units; (10) Axial Stem Cells; (11) Cell-delivery devices; (12) scaffolds, including alginate and sulfated alginate scaffolds, and bioconjugates comprising sulfated polysaccharides and diverse bioactive peptides, and uses thereof; and (13) skin diseases treatment and anti-aging compositions.

We have a granted U.S. patent, a pending U.S. patent application and pending U.S. provisional patent applications directed, among others, to dendritic cell-based (whole cell) vaccines, and their use for treating cancer and viral diseases. If issued, any patents based on these applications will expire in 2037. The granted U.S. patent will expire in 2037.

We have pending U.S. patent applications directed, among others, to compositions comprising Ranpirnase and other ribonucleases for the treatment of viral diseases. If issued, any patents based on these applications will expire between 2031 and 2040. Counterpart patents applications were filed in Australia, Canada, China, Europe, Hong Kong, Japan, Israel, Mexico, New Zealand, South Korea, Russian Federation, Singapore, and South Africa. If issued, any patents based on these applications will expire between 2035 and 2041. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

We have pending U.S. patent applications directed, among others, to therapeutic compositions comprising exosomes, bioxomes, and redoxomes. If issued, any patents based on these applications will expire between 2029 and 2041. Counterpart patents applications were filed in Australia, Brazil, Canada, China, Europe, India, Israel, Japan and South Korea. If issued, any patents based on these applications will expire in 2039. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

We have pending U.S. patent applications directed, among others, to compositions comprising ribonucleases and antibodies or bioxomes, and their use for treating viral diseases, including COVID-19. If issued, any patents based on these applications will expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations. A counterpart patent application was filed in Israel.

We have a pending International PCT application directed, among others, to compositions comprising immune cells for treating COVID-19. If converted into national phase applications and issued, any patents based on these applications will expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending International PCT application, pending U.S. patent applications, and pending U.S. provisional patent applications directed, among others, to bioreactors for cell culture and automated devices for supporting cell therapies. If issued, any patents based on these applications will expire between 2027 and 2042. Counterpart patent applications were filed in Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, Mexico, South Africa, Taiwan, Thailand, and Vietnam.

We have a pending International PCT application directed, among others, to tumor infiltrating lymphocytes (TILs) and their use for treating cancer. If converted into national phase applications and issued, any patents based on these applications will expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending U.S. patent application directed, among others, to compositions comprising mesenchymal stem cells, and their use for treating solid tumors. If issued, any patent based on this application would expire in 2040. Counterpart patent applications were filed in China, Europe, and Israel. If issued, any patents based on these applications would expire in 2040. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending International PCT application directed, among others, to methods of treating cancer or CNS-related diseases by intranasal administration of an oncolytic virus. If converted into national phase applications and issued, any patents based on these applications will expire in 2043, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have four pending U.S. provisional patent applications and a pending U.S. patent application directed, among others, to chimeric antigen receptors (CARs), and their use for treating malignancies. If issued, any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a granted patent and a pending U.S. patent application directed, among others, to adoptive immunotherapy using neurotransmitters. If issued, any patent based on this application would expire in 2039. Counterpart patent applications were filed in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, Russian Federation, Singapore, and South Korea. If issued, any patents based on these applications would expire in 2039. These expiration dates do not include any patent term extensions that might be available following the grant of marketing authorizations. The granted U.S. patent will expire in 2024.

We have a pending International PCT application and a pending U.S. patent application directed, among others, to mobile processing laboratories configured for performing there within a cell therapy process. Any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending U.S. patent application directed, among others, to Axial Stem Cells, their preparation, and uses in treatment or diagnostics of neurodegenerative diseases, bone or cartilage disorders, muscle disorders, and in regenerative treatment of tissues or organs. Counterpart patent applications were filed in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, Russian Federation, and South Korea. If issued, any patents based on these applications would expire in 2042, without including any patent term extensions that might be available following the grant of marketing authorizations.

We have a pending U.S. provisional patent application and a pending PCT application, directed, among others, to a composition comprising topiramate and bioxome, redoxome, HA, extracellular vesicles (EV), or PRP extracellular vesicles and its use for the treatment of a dermatological condition. If converted into national phase applications and issued, any patents based on these applications would expire in 2042 and 2043, without including any patent term extensions that might be available following the grant of marketing authorizations.

The Israeli Subsidiary has exclusive rights to eight (8) United States patents, thirty (30) foreign-issued patents, one (1) pending patent application in the United States, and six (6) pending patent applications in foreign jurisdictions, including Brazil, Canada, Europe, and Israel. These patents and patent applications relate, among others, to the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β-cell-like phenotype and function and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis. Granted U.S. patents, which are directed to trans-differentiation to pancreatic β-cell-like phenotype and function cells and to their use in the treatment of degenerative pancreatic disorders, including diabetes, pancreatic cancer and pancreatitis, will expire between 2024 and 2040. Counterpart patents granted in Austria, Australia, Belgium, China, Eurasia, France, Germany, Greece, Israel, Switzerland, Japan, Mexico, Panama, Singapore, South Korea, and the United Kingdom, will expire between 2024 and 2035.

We also own IP and related Extracellular Vesicle (“EV”) Technology pursuant to an EV purchase agreement (the “EV Agreement”). Pursuant to the EV Agreement, we received all of the rights in EV technology purchased. In addition, we received an exclusive worldwide license to use the EV IP technology for any purpose.

Government Regulation

Development Business

We are required to comply with the regulatory requirements of various local, state, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products, where our OMPULs are established or where we plan to supply products. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with GMPs, labeling and distribution, import and export, facility registration or licensing, and product registration and listing. As a result, our facilities are subject to regulation in Israel and South Korea. We are also required to comply with environmental, health and safety laws and regulations, as discussed below. These regulatory requirements impact many aspects of our operations, including manufacturing, developing, labeling, packaging, storage, distribution, import and export and record keeping related to customers’ products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve facilities for manufacturing products or products for commercialization.

Both of our products and our customers’ products must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities that have jurisdiction in the countries in which our and our customers’ products are intended to be marketed may delay or put on hold clinical trials, delay approval of a product or determine that the product is not approvable. The regulatory agencies can delay approval of a drug if our manufacturing facilities or OMPULs are not able to demonstrate compliance with cGTPs, pass other aspects of pre-approval inspections (i.e., compliance with filed submissions) or properly scale up to produce commercial supplies. The government authorities having jurisdiction in the countries in which our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product is deemed adulterated or misbranded. In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional fees. This may require a change in our manufacturing techniques or additional capital investments in our facilities.

Certain products manufactured by us involve the use, storage and transportation of toxic and hazardous materials. Our operations are subject to extensive laws and regulations relating to the storage, handling, emission, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities.

Prevailing legislation tends to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

Our development operations involve the controlled use of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

The costs associated with complying with the various applicable local, state, national and international regulations could be significant and the failure to comply with such legal requirements could have an adverse effect on our results of operations and financial condition. See “Risk Factors — Risks Related to Development and Regulatory Approval of Our Therapies and Product Candidates — Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.” for additional discussion of the costs associated with complying with the various regulations.

POCare Therapies Portfolio

Our therapeutic product portfolio pipeline is diverse and addresses various unmet clinical needs. It is predominantly comprised of personalized autologous cell therapies, implying that patients receive cells that originate from their own body, virtually eliminating the risk of an immune response and rejection and thus easing various regulatory hurdles. In addition, by leveraging our vast experience and proven track record in developing and optimizing cell processing, these selective therapies are adapted to be produced in closed, automated systems, reducing the need for high grade cleanroom environments. The systems enable each stage of the manufacturing process (cell sorting, expansion, genetic modifications, quality control) to be optimized in order to substantially reduce the cost burden for patients and making the therapies widely accessible. Notably, our therapeutic pipeline is developed by researchers from our network and are subsequently out-licensed and validated in multi-center clinical trials conducted across point of care partner sites leveraging the robustness of our POCare Network. Once approved these therapies are distributed to leading medical institutions globally within our network and thus granting the inventors a royalty-based commercialization horizon.

Regulatory Process in the United States

Our potential product candidates are subject to regulation as a biological product under the Public Health Service Act and the Food, Drug and Cosmetic Act. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product:

- Pre-clinical laboratory and animal tests conducted in compliance with Good Laboratory Practice, or GLP, requirements to assess a drug’s biological activity and to identify potential safety problems, and to characterize and document the product’s chemistry, manufacturing controls, formulation, and stability;

- Submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before clinical testing in humans can start;
- Obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce biologic drug candidates into humans in clinical trials;
- Conducting adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with Good Clinical Practice, or GCP, requirements;
- Compliance with current GMP regulations and standards;
- Submission to the FDA of a Biologics License Application ("BLA") for marketing that includes adequate results of pre-clinical testing and clinical trials;
- The FDA reviews the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and
- Obtaining FDA approval of the BLA, including inspection and approval of the product manufacturing facility as compliant with GMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent. The FDA may also require post marketing testing and surveillance of approved products or place other conditions on the approvals.

Regulatory Process in Europe

In the European Union ("EU") somatic cell and gene therapy products are called Advanced Therapy Medicinal Product (ATMPs). Since January 2022 the Clinical Trial Regulation (EU) 536/2014 regulates the application of medicinal products including ATMPs to humans immediately effective in all member states. In conjunction with Regulation 536/2014 the EU commission has released two delegated acts regulating manufacturing of investigational as well as marketed AMPs. For products that are regulated as an ATMP,
Regulation requires:

- Compliance with current GMP regulations and standards, as described in the delegated acts;
- Filing a Clinical Trial Application ("CTA");
- in EU member states and EEA countries according to regulation 536/2014 via CTIS (Clinical Trial Information System) allowing a harmonized approval process among all member states (including multinational clinical trials);
- Obtaining approval by ethic committees responsible for medical institutions;
- Adequate and well-controlled clinical trials according to GCP standards protecting the well-being of a study participant and establishing the safety and efficacy of the product for its intended use;
- Centralized submission procedure for ATMPs via EMA for Marketing Authorization; and
- Review and approval of the Marketing Authorization Application.

As in the U.S., prior to the general regulatory process of a new biologic products, we will prosecute an Orphan Drug Designation for treatment of patients with established "Diabetes Mellitus" induced by total pancreatectomy. In the EU, in order to be qualified, the prevalence must be below 5 per 10,000 of the EU population, except where the expected return on investment is insufficient to justify the investment.

Authorized orphan medicines benefit from 10 years of protection from market competition with similar medicines with similar indications once they are approved. Companies applying for designated orphan medicines pay reduced fees for regulatory activities. This includes reduced fees for protocol assistance, marketing-authorization applications, inspections before authorization, applications for changes to marketing authorizations made after approval, and reduced annual fees.

Exemption from the centralized procedure was introduced into the ATMP Regulation to allow marketing of certain ATMPs in individual EU member states. The so-called "hospital exemption" can only be applied for custom-made ATMPs used in a hospital setting for a specific patient by a treating physician. In addition, a competent authority must authorize hospital exemption for ATMPs. Hospital exemption products must comply with the same national requirements concerning quality, traceability and pharmacovigilance that apply to authorized medicinal products. The "hospital exemption" has to be applied for individually in each EU member state according to national procedures and control measures.

Clinical Trials

Typically, both in the U.S. and the EU, clinical testing involves a three-phase process, although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, comparative trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA or EMA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, as well as clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA or EMA.

The FDA has granted Orphan Drug designation for our AIP cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from TP due to chronic pancreatitis. The FDA's Orphan Drug Designation Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States. Orphan designation qualifies the sponsor of the drug for various development incentives, including eligibility for seven years of market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and other potential assistance in the drug development process.

Human Capital Resources

As of December 31, 2022, we had an aggregate of 167 employees working at our company and Subsidiaries. In addition, we retain the services of outside consultants for various functions including clinical work, finance, accounting and business development services. Most of our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that we have good relations with our employees.

Compensation and Benefits

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Biotechnology companies both large and small compete for a limited number of qualified applicants to fill specialized positions. To attract qualified applicants, we offer a total rewards package consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation to select employees. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance.

Diversity, Equity and Inclusion

Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values. This is reflected in our numbers with our total workforce being approximately 53% women, 11% ethnically diverse and 50% over the age of 40.

Health, Wellness and Safety

We believe that the safety and health of our employees and their families is essential to our business. Our culture is driven by a desire to do what is right, and we strive to support the well-being of our employees. We prioritize the safety and well-being of our employees as they face both mental and physical challenges related to the COVID-19 pandemic. Our employees have demonstrated great resilience during the pandemic, and we continue to provide resources to support their well-being. Beginning in March 2020, we have supported our employees and government efforts to curb the COVID-19 pandemic through a multi-faceted communication, infrastructure, and behavior modification and enforcement effort that includes:

- establishing clear and regular COVID-19 policies, safety protocols, and updates to all employees;
- strongly encouraging all office-based employees to work from home; and
- implementing protocols to address actual and suspected COVID-19 cases and potential exposure.

Our financial, medical, and mental health benefits that were already in place prior to the COVID-19 pandemic were designed to help employees through crisis, and we further expanded our offerings to create appropriate "work from home" conditions for success and wellness, including purchasing additional IT equipment and office supplies and increasing communications related to our mental health benefits. In particular, we offered sessions on mindfulness to further support the mental health of our employees.

Environmental, Social and Governance

Our commitment to integrating sustainability across our organization begins with our Board of Directors, or the Board. The Nominating and Governance Committee of the Board has oversight of strategy and risk management related to Environmental, Social and Governance, or ESG. All employees are responsible for upholding our core values, including to communicate, collaborate, innovate and be respectful, as well as for adhering to our Code of Ethics and Business Conduct, including our policies on bribery, corruption, conflicts of interest and our whistleblower program. We encourage employees to come to us with observations and complaints, ensuring we understand the severity and frequency of an event in order to escalate and assess accordingly. Our Chief Compliance Officer strives to ensure accountability, objectivity, and compliance with our Code of Conduct. If a complaint is financial in nature, the Audit Committee Chair is notified concurrently, which triggers an investigation, action, and report.

We are committed to protecting the environment and attempt to mitigate any negative impact of our operations. We monitor resource use, improve efficiency, and at the same time, reduce our emissions and waste. We are systematically addressing the environmental impacts of the buildings we rent as we make improvements, including adding energy control systems and other energy efficiency measures. Waste in our own operation is minimized by our commitment to reduce both single-use plastics and operating paper-free, primarily in a digital environment. We have safety protocols in place for handling biohazardous waste in our labs, and we use third-party vendors for biohazardous waste and chemical disposal.

Corporate and Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are available free of charge though our website (*http://www.orgenesis.com*) as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (the "SEC"). Except as otherwise stated in these documents, the information contained on our website or available by hyperlink from our website is not incorporated by reference into this report or any other documents we file, with or furnish to, the SEC.

Our common stock is listed and traded on the Nasdaq Capital Market under the symbol "ORGS."

As used in this Annual Report on Form 10-K and unless otherwise indicated, the term "Company" refers to Orgenesis Inc. and its Subsidiaries. Unless otherwise specified, all amounts are expressed in United States Dollars.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- Our POCare business has a limited operating history and an unproven business model and faces significant challenges as the cell therapy industry is rapidly evolving. Our prospects may be considered speculative and any failure to execute our business strategy could adversely impact our business.

- Our management, as of December 31, 2022, and our independent registered public accounting firm, in its report on our financial statements as of and for the fiscal year ended December 31, 2022, have concluded that there is substantial doubt as to our ability to continue as a going concern.

- We are not profitable as of December 31, 2022, have limited cash flow and, unless we increase revenues and take advantage of any commercial opportunities that arise to expand our POCare business, the perceived value of our company may decrease and our stock price could be affected accordingly.

- Our research and development efforts on novel technology using cell-based therapy and our future success is highly dependent on the successful development of that technology.

- We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

- Our success will depend on strategic collaborations with third parties to develop and commercialize therapeutic product candidates, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

- Our business has been affected by the COVID-19 pandemic and may be significantly adversely affected by a resurgence of the COVID-19 pandemic or if other events out of our control disrupt our business or that of our third-party partners.

- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

- Our success depends on our ability to develop and roll out our OMPULs.

- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

- We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

- There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

- Our product candidates are biologics, and the manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities.

- Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

- We currently have no marketing and sales organization and have no experience in marketing therapeutic products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

- There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

- We face significant competition from other biotechnology and pharmaceutical companies, many of which have substantially greater financial, technical and other resources, and our operating results will suffer if we fail to compete effectively.

- We are highly dependent on key personnel who would be difficult to replace, and our business plans will likely be harmed if we lose their services or cannot hire additional qualified personnel.

- Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

- Third parties to whom we may license or transfer development and commercialization rights for products covered by intellectual property rights may not be successful in their efforts and, as a result, we may not receive future royalty or other milestone payments relating to those products or rights.

- Morgenesis may not receive the future payments pursuant to the Unit Purchase Agreement with MM.

- MM may force the sale of Morgenesis under certain conditions which may result in MM receiving a greater value than us and our shareholders.

- MM may, under certain circumstances, assume control of the Board of Managers of our subsidiary, Morgenesis, which would result in our inability to control and direct the activities of such subsidiary.

- MM has the right to buy our units in Morgenesis upon the occurrence of certain events, which could result in us not holding any equity in Morgenesis.

- We may be forced to redeem all of the units of Morgenesis held by MM, which could require substantial cash outlay and would adversely affect our financial position.

- If MM opts to exchange its Morgenesis units for shares of our common stock, we could potentially issue up to 5,106,596 shares of our common stock to MM, which may result in significant dilution to our existing stockholders.

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company's common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

Risks Related to Our Company and POCare Business

Our POCare business has a limited operating history and an unproven business model and faces significant challenges as the cell therapy industry is rapidly evolving. Our prospects may be considered speculative and any failure to execute our business strategy could adversely impact our operations and the price of our common stock.

Our POCare business has a limited operating history and an unproven business model. Our plans to continue to grow our POCare cell therapy business and to further the development of ATMPs are subject to significant challenges. Although we have sufficient capital resources for the next 12 months and the foreseeable future, we may not be able to implement our POCare business or commence clinical trials or respond to competitive pressures due to other non-financial factors beyond our control. Our failure to effectively execute our business strategy could adversely affect our ability to successfully grow our POCare business and develop cell therapy product candidates, which could cause the value of your investment in our common stock to decline.

Our management, as of December 31, 2022, and our independent registered public accounting firm, in its report on our financial statements as of and for the fiscal year ended December 31, 2022, have concluded that there is substantial doubt as to our ability to continue as a going concern.

Our audited financial statements for the fiscal year ended December 31, 2022 were prepared assuming that we will continue as a going concern. The going concern basis of the presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from our inability to continue as a going concern. As of December 31, 2022, our management concluded that, based on expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern for the twelve months after the date the financial statements were issued. Our ability to continue as a going concern is subject to our ability to raise additional capital through equity offerings or debt financings. The Unit Purchase Agreement between us and MM requires MM to make up to two additional payments to Morgenesis if certain specified Net Revenue targets (as defined in the Unit Purchase Agreement) are satisfied by Morgenesis during each of years 2022 and 2023, as described in more detail in this report. For each of those fiscal years in which such specified Net Revenue targets are satisfied by Morgenesis, MM will be obligated to pay an additional $10 million to Morgenesis shortly after the end of that fiscal year. However, we may not be able to secure additional financing in a timely manner or on favorable terms, if at all, and may not receive any such future payments under the Unit Purchase Agreements if the required milestones are not met. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our stockholders may lose some or all of their investment in us. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We are not profitable as of December 31, 2022, have limited cash flow and, unless we increase revenues and take advantage of any commercial opportunities that arise to expand our POCare business, the perceived value of our company may decrease and our stock price could be affected accordingly.

For the year ended December 31, 2022 and as of the date of this report, we assessed our financial condition and concluded that based on current and projected cash resources and commitments, there is a substantial doubt about the Company's ability to continue as a going concern to meet the Company's current operations for the next 12 months from the date of this report. Our auditor's report for the year ended December 31, 2022 includes a going concern opinion on the matter. Management is unable to predict if and when we will be able to generate significant revenues or achieve profitability. Our plan regarding these matters is to continue improving the net results in our POCare business into fiscal year 2023. There can be no assurance that we will be successful in increasing revenues, improving our POCare results or that the perceived value of our Company will increase. In the event that we are unable to generate significant revenues in our POCare business, our stock price could be adversely affected.

Our research and development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our cell therapy technology creates significant challenges with respect to product development and optimization, manufacturing, government regulation and approval, third-party reimbursement and market acceptance. For example, the FDA and EMA have relatively limited experience with the development and regulation of cell therapy products and, therefore, the pathway to marketing approval for our cell therapy product candidates may accordingly be more complex, lengthy and uncertain than for a more conventional product candidate. The indications of use for which we choose to pursue development may have clinical effectiveness endpoints that have not previously been reviewed or validated by the FDA or EMA, which may complicate or delay our effort to ultimately obtain FDA or EMA approval. Because this is a new approach to treating diseases, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA, EMA and other regulatory authorities that have very limited experience with the commercial development of our technology for treating different diseases;
- developing and deploying consistent and reliable processes for removing the cells from the patient engineering cells ex vivo and infusing the engineered cells back into the patient;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our products;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- maintaining a system of post marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process.

Our efforts to overcome these challenges may not prove successful, and any product candidate we seek to develop may not be successfully developed or commercialized.

Kyslecel may not achieve patient or market acceptance, which could have a material adverse effect on our business.

Our commercialization strategy for Kyslecel relies on medical specialists, medical facilities and patients adopting TP-IAT with Kyslecel as an accepted treatment for chronic pancreatitis. However, medical specialists are historically slow to adopt new treatments, regardless of perceived merits, when older treatments continue to be supported by established providers. Overcoming such resistance often requires significant marketing expenditure or definitive product performance and/or pricing superiority. The cost of allocating resources for such requirements might severely impact the potential for profitability of Kyslecel.

There is no guarantee that physician or patient acceptance of TP-IAT with Kyslecel will be substantial. Further, there is no guarantee that Koligo will be able to achieve patient acceptance or obtain enough customers (clinical providers) to meet its sales objectives. If we do not meet our sales objectives, our business prospects and financial performance will be materially and adversely affected.

Further, we are partially reliant on published clinical trials and scientific research conducted by third parties to justify the patient benefit and safety of TP-IAT with Kyslecel and, as such, we rely, in part, on the accuracy and integrity of those third-parties to have reported the results and correctly collected and interpreted the data from all clinical trials conducted to date. If published data turn out to later be incorrect or incomplete, our business prospects and financial performance may be materially and adversely affected.

The therapeutic efficacy of Ranpirnase and our other product candidates is unproven in humans, and we may not be able to successfully develop and commercialize Ranpirnase or any of our other product candidates.

Ranpirnase and our other product candidates are novel compounds and their potential benefit as antiviral drugs or immunotherapies is unproven. Ranpirnase and our other product candidates may not prove to be effective against the indications for which they are being designed to act and may not demonstrate in clinical trials any or all of the pharmacological effects that have been observed in preclinical studies. As a result, our clinical trial results may not be indicative of the results of future clinical trials.

Ranpirnase and our other product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If Ranpirnase or any of our other product candidates is associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon the development of such product candidate or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Because of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop or commercialize Ranpirnase or any of our other product candidates, in which case our business will be harmed.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2022, we had 167 employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. This lack of long-term experience working together may adversely impact our senior management team’s ability to effectively manage our business and growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

We may require additional capital to support our business, and this capital may not be available on acceptable terms or at all.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and to grow our POCare cell therapy business and to further the development of ATMPs. Accordingly, we may need to engage in equity or debt financings to secure additional funds.

Capital and credit market conditions, adverse events affecting our business or industry, the tightening of lending standards, rising interest rates, negative actions by regulatory authorities or rating agencies, or other factors also could negatively impact our ability to obtain future financing on terms acceptable to us or at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to support our business growth and respond to business challenges could be significantly limited. In addition, the terms of any additional equity or debt issuances may adversely affect the value and price of our common stock, our results of operations, financial condition and cash flows.

If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any financing secured by us in the future could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions.

Our operations may be adversely affected by ongoing developments in the Ukraine and Russia.

In December 2020, we signed an agreement with a company one of whose principal places of business is in Russia that include collaboration in point of care development in Russia, as well as the development and commercialization of potential key technologies for our clinical development and manufacturing projects. The United States, EU, UK, Canada and Japan have imposed sanctions against and export controls involving Russia, and other potential retaliatory measures could be taken by the United States and other countries. At this time, we cannot predict the outcome of developments in Russian and the Ukraine on these agreements.

Currency exchange fluctuations may impact the results of our operations.

The results of our operations are affected by fluctuations in currency exchange rates in both sourcing and selling locations. Our results of operations may still be impacted by foreign currency exchange rates, primarily, the euro-to-U.S. dollar exchange rate. In recent years, the euro-to-U.S. dollar exchange rate has been subject to substantial volatility which may continue, particularly in light of recent political events regarding the European Union, or EU. Because we do not hedge against all of our foreign currency exposure, our business will continue to be susceptible to foreign currency fluctuations.

We have entered into collaborations and joint ventures and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have entered into collaborations and joint ventures and may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners for which the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. The success of our existing and future collaboration arrangements and strategic partnerships, which include research and development services by our collaborators to improve our intellectual property, will depend heavily on the efforts and activities of our collaborators and may not be successful. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our success will depend on strategic collaborations with third parties to develop and commercialize therapeutic product candidates, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

A key aspect of our strategy is to seek collaborations with partners, such as a large pharmaceutical organization, that are willing to further develop and commercialize a selected product candidate. To date, we have entered into a number of collaborative arrangements with cell therapy organizations. By entering into any such strategic collaborations, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product developed outside of the collaboration;

- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture or obtain the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into additional collaborations on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support. If we are not successful in attracting a partner and entering into a collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

Our business has been affected by the COVID-19 pandemic and may be significantly adversely affected by a resurgence of the COVID-10 pandemic or if other events out of our control disrupt our business or that of our third-party partners.

A continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results. We have experienced and may in the future experience disruptions from a resurgence of COVID-19 to our business in a number of ways, including:

- Delays in supply chain and manufacturing, including the suspension of cell transport, limitations on transfer of technology, shutdown of manufacturing facilities and delays in delivery of supplies and reagents;

- Delays in discovery and preclinical efforts;

- Changes to procedures or shut down, or reduction in capacity, of clinical trial sites due to limited availability of clinical trial staff, reduced number of inpatient intensive care unit beds for patients receiving cell therapies, diversion of healthcare resources away from clinical trials and other business considerations;

- Limited patient access, enrollment and participation due to travel restrictions and safety concerns, as well as housing and travel difficulties for out-of-town patients and relatives; and

- Changes in regulatory and other requirements for conducting preclinical studies and clinical trials during the pandemic.

In addition, we currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials, ship investigation drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party in our supply chain for materials is adversely impacted by effects from a resurgence of the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted and our costs could be increased, limiting our ability to manufacture our product candidates for our clinical trials and planned future clinical trials and conduct our research and development operations as planned.

In addition, our business could be significantly adversely affected by other business disruptions to us or our third-party partners or collaborators that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our partners and collaborators, contract manufacturing organizations (CMOs) and other contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredients are generally considered to offer the strongest protection of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use or any method of manufacturing. While we have issued patents in the United States, we cannot be certain that the claims in our issued patent will not be found invalid or unenforceable if challenged.

We cannot be certain that the claims in our issued United States methods of use patents will not be found invalid or unenforceable if challenged.

We cannot be certain that the pending applications covering among others the bioconjugates comprising sulfated polysaccharides; Ranpirnase and other ribonucleases for treating viral diseases; therapeutic compositions comprising exosomes, bioxomes, and redoxomes; bioreactors for cell culture, automated devices for supporting cell therapies, and point-of-care systems; immune cells, ribonucleases, or antibodies for treating COVID-19; or chimeric antigen receptors (CARs); will be considered patentable by the United States Patent and Trademark Office (USPTO), and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Even if our patent applications covering these inventions issue as patents, the patents protect specific products and may not be enforced against competitors making and marketing a product that has the same activity. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. These types of patents may not be enforced against competitors making and marketing a product that provides the same activity but is used for a method not included in the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when products are approved by the FDA, that certain third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). In such lawsuit, we or our licensees may incur substantial expenses defending our rights or our licensees' rights to commercialize such product candidates, and in connection with such lawsuit and under certain circumstances, it is possible that we or our licensees could be required to cease or delay the commercialization of a product candidate and/or be required to pay monetary damages or other amounts, including royalties on the sales of such products. Moreover, any such lawsuit may also consume substantial time and resources of our management team and board of directors. The threat or consequences of such a lawsuit may also result in royalty and other monetary obligations being imposed on us, which may adversely affect our results of operations and financial condition.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Because most of our products have not reached commercial stage, we do not currently need to carry clinical trial or extensive product liability insurance. In the future, our inability to obtain additional sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Such insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage.

It may be difficult to enforce a U.S. judgment against us, our officers and directors and the foreign persons named in this Annual Report on Form 10-K in the United States or in foreign countries, or to assert U.S. securities laws claims in foreign countries or serve process on our officers and directors and these experts.

While we are incorporated in the State of Nevada, currently a majority of our directors and executive officers are not residents of the United States, and the foreign persons named in this Annual Report on Form 10-K are located outside of the United States. The majority of our assets are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or foreign court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in foreign countries in which we operate. Foreign courts may refuse to hear a claim based on a violation of U.S. securities laws on the grounds that foreign countries are not necessary the most appropriate forum in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that foreign law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by foreign countries law. There is little binding case law in foreign countries addressing the matters described above.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, for example, effective May 25, 2018, the GDPR replaced the prior EU Data Protection Directive (95/46) that governed the processing of personal data in the European Union. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data and increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

Adoption of the GDPR increased our responsibility and liability in relation to personal data that we process and may require us to put in place additional mechanisms to ensure compliance. Any failure to comply with the requirements of GDPR and applicable national data protection laws of EU member states, could lead to regulatory enforcement actions and significant administrative and/or financial penalties against us (fines of up to Euro 20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher), and could adversely affect our business, financial condition, cash flows and results of operations.

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential information. Our information technology systems are potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, vendors, or from attacks by malicious third parties. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination or misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material effect on our business, financial position, results of operations and/or cash flow.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, and terrorism or disease outbreaks (such as the recent outbreak of COVID-19, or the novel coronavirus).

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we are unable to integrate acquired businesses effectively, our operating results may be adversely affected.

From time to time, we seek to expand our business through acquisitions. We may not be able to successfully integrate acquired businesses and, where desired, their product portfolios into ours, and therefore we may not be able to realize the intended benefits. If we fail to successfully integrate acquisitions or product portfolios, or if they fail to perform as we anticipate, our existing businesses and our revenue and operating results could be adversely affected. If the due diligence of the operations of acquired businesses performed by us and by third parties on our behalf is inadequate or flawed, or if we later discover unforeseen financial or business liabilities, acquired businesses and their assets may not perform as expected. Additionally, acquisitions could result in difficulties assimilating acquired operations and, where deemed desirable, transitioning overlapping products into a single product line and the diversion of capital and management's attention away from other business issues and opportunities. The failure to integrate acquired businesses effectively may adversely impact our business, results of operations or financial condition.

Risks Related to Our OMPULs

We may not be able to operate our OMPULs in all cities or desired locations and the sizes and use of our laboratories in such OMPULs may be restricted due to zoning, environmental, medical waste, or other licensing regulations.

We may be subject to local zoning ordinances or other similar restrictions that may limit where the OMPULs can be located and the extent of their size and use. In addition, international, federal, state and local environmental and other administrative and licensing regulations could restrict the ability of the OMPULs to connect with local power, water, sewer, and other infrastructure. Our success depends on our ability to develop and roll out our OMPULs which may become more difficult or more expensive by such applicable regulations. Changes in any of these regulations could require us to close or move our OMPULs which would affect our ability to conduct and grow our business.

If our existing OMPULs facilities become damaged or inoperable or if we are required to vacate our existing facilities, our ability to perform our tests and pursue our research and development efforts may be jeopardized.

We currently perform a majority of tests relating to our POCare Services out of our OMPULs. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for us to operate for some period of time. In addition, since there is no lengthy history of use of OMPULs and the OMPULs are still in the development stage, we are unable to predict the normal wear and tear on such OMPULs or how many years each OMPUL will remain operational.

The inability to perform our tests or to reduce the backlog that could develop if our facilities are inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation. Furthermore, our OMPUL facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facilities, or to locate and qualify new facilities.

We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

Changes in the price and availability of our raw materials could be detrimental to our OMPUL operations.

Supply chain issues, including limited supply of certain raw material or supply interruptions, delays or shortages of material may disrupt our daily operations as the OMPULs may be unable to retain an inventory of materials required to maintain operations or to build or repair OMPULs.

We are dependent on skilled human capital for our OMPULs.

Our ability to innovate and execute is dependent on the ability to hire, replace, and train skilled personnel. The employment market suffers from shortage of candidates that may continue in future years and cause delays and inabilities to execute our plans. Additionally, based on current trends in the US labor market, there could be a shortage of available trained staff for the OMPULs in the United States. Staff retention could also be a significant operational issue.

If we are unable to successfully secure our locations and premises, we may be unable to operate out of our OMPULs or keep our employees and laboratory equipment safe.

In certain cities and urban markets, homelessness, rising crime rates and decreased police funding, could impact the security of the OMPULs and the safety of employees and patients. If we are unable to successfully secure our OMPULs, our research and development could be negatively impacted.

Our OMPULs are operated in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition, and harm our business.

The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct our OMPUL business include, without limitation:

- federal and state laws governing laboratory testing, including CLIA, and state licensing laws;
- federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including laboratory developed tests, or LDTs;
- federal, state and local laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations; and
- European Union GMP approvals, which may be delayed because of the use OMPULs which could then delay manufacturing for clinical trials.

Risks Related to Our Trans-Differentiation Technologies for Diabetes and the THM License Agreement

THM is entitled to cancel the THM License Agreement.

Pursuant to the terms of the THM License Agreement with THM, Orgenesis Ltd, the Israeli Subsidiary, must develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the development plan. In the event the Israeli Subsidiary fails to fulfill the terms of the development plan under the THM License Agreement, THM shall be entitled to terminate the THM License Agreement by providing the Israeli Subsidiary with written notice of such a breach and if the Israeli Subsidiary does not cure such breach within one year of receiving the notice. THM may also terminate the THM License Agreement if the Israeli Subsidiary breaches an obligation contained in the THM License Agreement and does not cure it within 180 days of receiving notice of the breach. We also run the risk that THM may attempt cancel or, at the very least challenge, the License Agreement with the Israeli Subsidiary as we continue to expand our focus to other therapies and business activities. While we have not received any notice of cancellation of the THM License Agreement, we have received an allegation regarding the scope of the rights by THM that may present future challenges for our Israeli Subsidiary to continue to develop, manufacture, sell and market the products pursuant to the milestones and time schedule specified in the development plan of the THM License Agreement. In addition, THM has filed a complaint against us in the Tel Aviv District Court relating to the scope of such THM license and the royalties and other payments that THM is entitled to thereunder. See “Legal Proceedings” in this Annual Report on Form 10-K. Such complaint may lead to further risk of cancellation of the THM License Agreement.

The Israeli Subsidiary is a licensed technology that demonstrates the capacity to induce a shift in the developmental fate of cells from the liver and differentiating (converting) them into “pancreatic beta cell-like” insulin-producing cells for patients with diabetes. Our intention is to develop our technology to the clinical stage for regeneration of functional insulin-producing cells, thus enabling normal glucose regulated insulin secretion, via cell therapy. By using therapeutic agents that efficiently convert a sub-population of liver cells into pancreatic islets phenotype and function, this approach allows the diabetic patient to be the donor of his/her own therapeutic tissue and to start producing his/her own insulin in a glucose-responsive manner, thereby eliminating the need for insulin injections. Because this is a new approach to treating diabetes, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval regulatory authorities that have very limited experience with the commercial development of the trans-differentiating technology for diabetes;
- developing and deploying consistent and reliable processes for engineering a patient’s liver cells ex vivo and infusing the engineered cells back into the patient;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our products;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- maintaining a system of post marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process.

Risks Related to Development and Regulatory Approval of Our Therapies and Product Candidates

Research and development of biopharmaceutical products is inherently risky.

We may not be successful in our efforts to use and enhance our technology platform to create a pipeline of product candidates and develop commercially successful products. Furthermore, we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties’ patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payers, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA and to a lesser extent by the Drug Enforcement Administration ("DEA") and state government agencies, as well as by varying regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our future products. Under these regulations, we may become subject to periodic inspection of our facilities, procedures and operations and/or the testing of our future products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with current GMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We may also be required to report adverse events associated with our future products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals or other regulatory actions.

The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. If internal compliance programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business.

The European Medicines Agency ("EMA") will regulate our future products in Europe. Regulatory approval by the EMA will be subject to the evaluation of data relating to the quality, efficacy and safety of our future products for its proposed use. The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators.

Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

Further trials and other costly and time-consuming assessments of the product may be required to obtain or maintain regulatory approval. Medicinal products are generally subject to lengthy and rigorous pre-clinical and clinical trials and other extensive, costly and time-consuming procedures mandated by regulatory authorities. We may be required to conduct additional trials beyond those currently planned, which could require significant time and expense. In addition, even after the technology approval, both in the U.S. and Europe, we will be required to maintain post marketing surveillance of potential adverse and risk assessment programs to identify adverse events that did not appear during the clinical studies and drug approval process. All of the foregoing could require an investment of significant time and expense.

We have generated limited revenue from therapeutic product sales, and our ability to generate any significant revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have a limited number of therapeutic products approved for commercial sale, and we have generated only limited revenue from product sales. Our ability to generate revenue of more significant scale and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if more of the product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

When we commence any clinical trials, we may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. We cannot be sure that we will be able to submit an IND, and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- the inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in establishing CMC (Chemistry, Manufacturing, and Controls) which is a cornerstone in clinical study submission and later on, the regulatory approval;
- the FDA not allowing us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;

- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment;
- a result of a new safety finding that presents unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical study operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly;
- if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure to perform in accordance with the FDA's current good clinical practices, or cGCPs, requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of preclinical and clinical studies may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or our third-party manufacturers' facilities with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Further, failure to obtain approval for any of the above reasons may be made more likely by the fact that the FDA and other regulatory authorities have very limited experience with commercial development of our cell therapy for the treatment of Type 1 Diabetes.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

As with most biological drug products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Any of these occurrences may materially and adversely harm our business, financial condition and prospects.

Our product candidates are biologics, and the manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities.

If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of liver cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, failures in process testing and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity and tractability of all reagents and viruses involved in the process with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Although we are working to develop commercially viable processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our subsidiaries and joint ventures will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents and viruses, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, viruses, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

There can be no assurance that we will be able to further develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry, and the rapidly evolving market for developing cell-based therapies is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our senior management, particularly our Chief Executive Officer, Vered Caplan. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, most these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of all of these individuals or the lives of any of our other employees.

Risks Related to the Metalmark Investment

Morgenesis may not receive the future payments pursuant to the Unit Purchase Agreement with MM OS Holdings, L.P. ("MM"), an affiliate of Metalmark Capital Partners.

The Unit Purchase Agreement between us and MM (the "UPA") requires MM to make up to two additional payments to Morgenesis if certain specified Net Revenue targets (as defined in the Unit Purchase Agreement) are satisfied by Morgenesis during each of years 2022 and 2023, as described in more detail below. For each of those fiscal years in which such specified Net Revenue targets are satisfied by Morgenesis, MM will be obligated to pay an additional $10 million to Morgenesis shortly after the end of that fiscal year.

If (a) Morgenesis and its subsidiaries generate Net Revenue (as defined in the UPA) equal to or greater than $30,000,000 during the twelve month period ending December 31, 2022 (the "First Milestone") and/or equal to or greater than $50,000,000 during the twelve month period ending December 31 2023 (the "Second Milestone"), and (b) our shareholders approve the LLC Agreement Terms (as defined below under "Principal Terms of the LLC Agreement") on the earlier of (x) the date that is seven (7) months following the initial closing date and (y) the date of our 2023 annual meeting of shareholders (such Orgenesis stockholder approval hereafter being the "Orgenesis Stockholder Approval" and such Orgenesis Stockholder Approval deadline hereafter being the "Stockholder Approval Deadline"), in accordance with applicable law and in a manner that will ensure that MM is able to exercise its rights under the LLC Agreement (as defined below) without any further action or approval by MM, then MM will pay up to $10,000,000 in cash in exchange for 1,000,000 additional Class A Units if the First Milestone is achieved and $10,000,000 in cash in exchange for 1,000,000 Class B Units Preferred Units of Morgenesis (the "Class B Units") if the Second Milestone is achieved. Notwithstanding the foregoing, if the First Milestone is not achieved, but Morgenesis and its subsidiaries generate Net Revenue equal or greater to $13,000,000 for the three months ending March 31, 2023, then MM shall make the first $10,000,000 future investment for 1,000,000 Class A Units described above. In the event we fail to obtain Orgenesis Stockholder Approval by the Stockholder Approval Deadline, we will not be entitled to receive (but MM may, in its sole discretion, elect to make) the first $10,000,000 future investment or the second future $10,000,000 investment. In addition, at any time until the consummation of a Company IPO or Change of Control of Morgenesis (in each case, as defined in the LLC Agreement), MM may, in its sole discretion, elect to invest up to an additional $60,000,000 in Morgenesis (any such investment, an "Optional Investment") in exchange for certain Class C Preferred Units of Morgenesis (the "Class C Units" and, together with the Class A Units and the Class B Units, the "Preferred Units"). $10,000,000 of such Optional Investment shall be to purchase Class C-1 Preferred Units based on an enterprise value of $125,000,000, with such enterprise value adjusted by any net debt as of such time; $25,000,000 of Optional Investment shall be to purchase Class C-2 Preferred Units based on an enterprise value of $156,250,000, with such enterprise value adjusted by any net debt as of such time; and $25,000,000 of Optional Investment shall be to purchase Class C-3 Preferred Units based on an enterprise value of $250,000,000, with such enterprise value adjusted by any net debt as of such time. Further, if, during the twelve month period ending on December 31, 2023, Morgenesis and its subsidiaries generate (i) Net Revenue (as defined in the UPA) equal to or greater than $70,000,000, (ii) Gross Profit (as defined in the UPA) equal to or greater than $35,000,000 and (iii) EBITDA (as defined in the UPA) equal to or greater than $10,000,000, then MM shall make (or cause to be made) a one-time cash payment of $10,000,000 to the Company upon such payment becoming final and binding pursuant to the UPA (the "Earnout Payment").

Accordingly, if our stockholders do not approve the LLC Agreement Terms and do not meet the applicable Net Revenue, Gross Profit or EBITDA targets, Morgenesis will not be eligible to receive the future payments from MM. Further, MM may choose not to make any of the Optional Investments. In addition, under certain circumstances, MM will obtain the right to put to us (or, at our discretion, to Morgenesis if Morgenesis shall then have the funds available to consummate the transaction) its shares in Morgenesis.

MM may force the sale of Morgenesis under certain conditions which may result in MM receiving a greater value than us and our shareholders.

At any time following the earliest to occur of (x) prior to the two year anniversary of the initial closing date under the UPA (the "Initial Two Year Period") or a Material Governance Event (as defined in the LLC Agreement), if MM and we approve a sale of Morgenesis or (y) (i) after the Initial Two Year Period or (ii) after the occurrence of a Material Governance Event, if MM or the Morgenesis Board by Supermajority Vote (as defined in the LLC Agreement) approves a Sale of Morgenesis (an "Approved Sale"), then, subject to notice, MM or Morgenesis can require the members of Morgenesis to sell their units in Morgenesis (the "Drag Along Rights") to the purchaser in the Approved Sale. Notwithstanding the foregoing, we are entitled to advise Morgenesis and the Morgenesis Board of our election to be a potential acquiror of Morgenesis. Notwithstanding the foregoing, if MM falls below 50% of its initial holdings in Morgenesis as specified above, then it is no longer entitled to exercise the Drag Along Right. Notwithstanding the foregoing, prior to the three-year anniversary of the initial closing date (the "Initial Three-Year Period"), MM and Morgenesis will not be entitled to exercise the Drag Along Right unless the valuation of Morgenesis reflected in the sale is equal to or greater than $300,000,000. If we breach our obligation to effectuate an Approved Sale or otherwise the failure of an Approved Sale to be consummated is primarily attributable to our or our affiliates, then (i) the Morgenesis Board shall be appointed as follows: (a) one manager shall be appointed by us, (b) the Industry Expert Manager shall be appointed by MM and (c) three Managers shall be appointed by MM and (ii) MM will have the option to convert all of its Preferred Units into such number of Common Units (as defined below) that represents (on a post-conversion basis) the Applicable Percentage (as defined in the LLC Agreement) of all of the outstanding Common Units (including any Common Units to be issued to MM pursuant to this provision).

While we have the right of first refusal with respect to acquiring Morgenesis in its entirety, if MM elects to exercise such a right and if we are not in the position to acquire Morgenesis, MM may cause the sale of Morgenesis to any third party on terms MM approves on an arm's length basis pursuant to the Drag Along Right, subject to the conditions set forth above. If this occurs, we are contractually obligated to approve such a sale and execute any documents as required by MM. Based on this, there may be a situation where MM approves a sale that is more valuable or beneficial to MM than to our company and our shareholders, and we will not be able to prevent such a transaction. A sale of Morgenesis would have impacts to our POCare Services business as conducted through Morgenesis and to our overall value as a whole.

MM may, under certain circumstances, assume control of the Board of Managers of our subsidiary, Morgenesis, which would result in our inability to control and direct the activities of such subsidiary.

The initial board of managers of Morgenesis (the "Morgenesis Board") is comprised of five (5) managers, three (3) of which were appointed by us, of which one must be an industry expert and will require prior reasonable consultation with MM, and two (2) by MM. If the equity holdings of each of us and MM fall below 25% of their initial holdings in Morgenesis as specified above, each will be entitled to appoint one less manager.

If (i) at any time there is a Material Underperformance Event (as defined in the LLC Agreement), (ii) at any time there is a Material Governance Event, (iii) Morgenesis does not pay in full the aggregate Redemption Price (as defined in the LLC Agreement) to redeem on any Redemption Date (as defined in the LLC Agreement) all Preferred Units to be redeemed on such Redemption Date, (iv) Morgenesis or Orgenesis does not pay in full the aggregate price of the Put Option (as defined in the LLC Agreement), or (v) Orgenesis breaches its obligation to effectuate an Approved Sale (as defined below) or otherwise the failure of an Approved Sale to be consummated is primarily attributable to us or our affiliates, then the Morgenesis Board shall be appointed as follows: (a) one manager shall be appointed by us, (b) the Industry Expert Manager shall be appointed by MM and (c) three Managers shall be appointed by MM.

If this were to occur, MM would control the Board of Directors of Morgenesis and will be entitled to direct its activities and approve any transactions of Morgenesis, even if such transactions provide greater value to MM than they do to us and our shareholders. This lack of control could significantly impact our POCare service activities as conducted through Morgenesis and to our overall value as a whole.

MM has the right to buy our units in Morgenesis upon the occurrence of certain events, which could result in us not holding any equity in Morgenesis.

Upon the occurrence of either (i) a Material Governance Event or (ii) failure of our shareholders to approve the Specified Agreement Terms (as defined in the LLC Agreement) by the Stockholder Approval Deadline, MM is entitled, at its option, to put to us (or, at our discretion, to Morgenesis if we or Morgenesis shall then have the funds available to consummate the transaction) its units or, alternatively, purchase from us its units (such purchase right, being the "MM Call Option"). The purchase price for units of MM or us in Morgenesis under either the put right or the MM Call Option shall be equal to the fair market value of such units as determined by a nationally recognized independent accounting firm selected by MM in its sole discretion; provided, however, that in no event shall the Put Price with respect to Preferred Units be less than $10.00 per Class A Preferred Unit plus the Class A PIK Yield (as defined below) (the "Class A Preferred Unit Original Issue Price"), $10.00 per Class B Preferred Unit plus the Class B PIK Yield (as defined below) (the "Class B Preferred Unit Original Issue Price") or the applicable price per Class C Preferred Unit as set forth in the LLC Agreement (the "Class C Preferred Unit Original Issue Price"), as applicable, to each Preferred Unit. In the event MM does exercise its right following the occurrence of any such event, we shall cease to be an equity owner of Morgenesis and will no longer derive any benefits from this subsidiary or its activities. This would also affect the POCare activities being conducted by us through Morgenesis and our overall value as a whole.

We may be forced to redeem all of the units of Morgenesis held by MM, which could require substantial cash outlay and would adversely affect our financial position.

Each holder of Preferred Units has the right to require Morgenesis to redeem its Preferred Units if holders of at least 50% of the then outstanding Preferred Units deliver written notice to Morgenesis (the "Redemption Request") at any time after (i) the earlier of either (x) November 4, 2027 and (y) the failure to obtain the Orgenesis Stockholder Approval of the LLC Agreement Terms by the Stockholder Approval Deadline, and (ii) receipt by Morgenesis of an offer for a Change of Control from a third party purchaser that is not an affiliate of any unitholder at a valuation of no less than $300,000,000 which Morgenesis has not accepted and completed (the "Proposed Sale"). In the event a Redemption Request is delivered at any time following November 4, 2027, the price per Preferred Unit at which Morgenesis will redeem Preferred Units (the "Redemption Price") will be equal to the applicable Preferred Liquidation Preference Amount (as defined in the LLC Agreement) determined as if a Deemed Liquidation Event (as defined in the LLC Agreement) had occurred on the date the Redemption Request is delivered and as determined by a nationally recognized independent accounting firm selected by MM in its sole discretion. In the event that a Redemption Request is delivered in connection with the failure to obtain the Orgenesis Stockholder Approval of the LLC Agreement Terms by the Stockholder Approval Deadline, the Redemption Price will be equal to the applicable Preferred Liquidation Preference Amount that would have been paid for each Preferred Unit (based on the applicable class of Preferred Unit) if the Proposed Sale had been completed.

Any such redemption would require us to expend substantial cash resources and could have a material adverse effect on our financial position. In addition, our cash reserves at the time of such redemption may be insufficient to satisfy such redemption, in which case we may not be able to continue as a going concern if we are unable to support our operations or cannot otherwise raise the necessary funds to support our operations.

If MM opts to exchange its Morgenesis units for shares of our common stock, we could potentially issue up to 5,106,596 shares of our common stock to MM, which may result in significant dilution to our existing stockholders.

The LLC Agreement provides that MM is entitled, at any time, to convert its units in Morgenesis for our common stock (such exchange option being the "Stock Exchange Option"). Under the Stock Exchange Option, MM is entitled, at any time prior to July 1, 2025, to exchange its units in Morgenesis for our common stock (the "MM Exchange Right"). The amount of shares of common stock to be received by MM upon exercise of the MM Exchange Right shall be equal to (i) the fair market value of MM's units to be exchanged, as determined by a nationally recognized independent accounting firm in the United States with experience in performing valuation services selected by MM and us, divided by (ii) the average closing price per share of our common stock during the 30-day period ending on the date on which MM provides an exchange notice to us (the "Exchange Price"); provided, that in no event shall (A) the Exchange Price be less than a price per share that would result in us having an enterprise value of less than $200,000,000 and (B) the maximum number of shares of our common stock to be issued pursuant to the MM Exchange Right exceed 5,106,596 shares of our common stock. If MM opts to exchange its Morgenesis units for shares of our common stock, we could potentially issue up to 5,106,596 shares of our common stock to MM. The common stock issuable to MM upon exchange of the Morgenesis units for our common stock could have a depressive effect on the market price of our common stock by increasing the number of shares of common stock outstanding and the proportionate voting power of the existing stockholders may be significantly diluted.

Risks Related to our Common Stock

If we issue additional shares in the future, it will result in the dilution of our existing stockholders.

Our articles of incorporation authorizes the issuance of up to 145,833,334 shares of our common stock with a par value of $0.0001 per share. Our Board of Directors may choose to issue some or all of such shares to acquire one or more companies or products and to fund our overhead and general operating requirements. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our company.

Our stock price and trading volume may be volatile, which could result in losses for our stockholders.

The equity trading markets have recently experienced high volatility resulting in highly variable and unpredictable pricing of equity securities. If the turmoil in the equity trading markets continues, the market for our common stock could change in ways that may not be related to our business, our industry or our operating performance and financial condition. In addition, the trading volume in our common stock may fluctuate and cause significant price variations to occur. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any;
- announcements relating to our business;
- conditions generally affecting the biotechnology industry;
- the success of our operating strategy; and
- the operating and stock performance of other comparable companies.

Many of these factors are beyond our control, and we cannot predict their potential effects on the price of our common stock. In addition, the stock market is subject to extreme price and volume fluctuations. During the 52 weeks ended December 31, 2022, our stock price has fluctuated from a low of $1.23 to a high of $3.74. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

No assurance can be provided that a purchaser of our common stock will be able to resell their shares of common stock at or above the price that they acquired those shares. We can provide no assurances that the market price of common stock will increase or that the market price of common stock will not fluctuate or decline significantly.

We do not intend to pay dividends on any investment in the shares of stock of our company.

We have never paid any cash dividends, and currently do not intend to pay any dividends for the foreseeable future. The Board of Directors has not directed the payment of any dividends and does not anticipate paying dividends on the shares for the foreseeable future and intends to retain any future earnings to the extent necessary to develop and expand our business. Payment of cash dividends, if any, will depend, among other factors, on our earnings, capital requirements, and the general operating and financial condition, and will be subject to legal limitations on the payment of dividends out of paid-in capital. Because we do not intend to declare dividends, any gain on an investment in our company will need to come through an increase in the stock's price. This may never happen, and investors may lose all of their investment in our company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We do not own any real property. A description of the leased premises we utilize in several of our facilities is as follows:

Entity	Property Description
Orgenesis Inc.	●Our principal office is located at 20271 Goldenrod Lane, Germantown, MD 20876.
Orgenesis Maryland LLC.	●FastForward laboratory and office located at 1812 Ashland Ave, Baltimore, Maryland 21205.
Orgenesis Korea Co. Ltd	●Operational production laboratory and office area located at Gwanggyo business centre 156, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea.
Orgenesis Ltd.	●Laboratory and office located in Nes Ziona, Israel
Koligo Therapeutics Inc.	●Production facility and development labs in New Albany, Indiana.
Tissue Genesis International LLC	●Production facility and development labs in Leander, Texas
Orgenesis Biotech Israel Ltd.	●Laboratories and offices located in the Bar Lev Industrial Park M.P. MISGAV, Israel.
Mida Biotech BV	●Laboratories and offices located in Leiden, The Netherlands
Orgenesis Belgium and Orgenesis Services SRL	●Laboratories and offices located near Namur, at Novalis Science Park, Belgium
Theracell Laboratories	●Laboratory and offices located Koropi, Greece

We believe that our facilities are generally in good condition and suitable to carry on our business. We also believe that, if required, suitable alternative or additional space will be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On January 18, 2022, a complaint (the "Complaint") was filed in the Tel Aviv District Court (the "Court") against the Company, the Israeli Subsidiary, Orgenesis Ltd., Prof. Sarah Ferber, Vered Caplan and Dr. Efrat Assa Kunik (collectively, the "defendants") by plaintiffs the State of Israel, as the owner of Chaim Sheba Medical Center at Tel Hashomer ("Sheba"), and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (collectively, the "plaintiffs"). In the Complaint, the plaintiffs are seeking that the Court issue a declaratory remedy whereby the defendants are required to pay royalties to the plaintiffs at the rate of 7% of the sales and 24% of any and all revenues in consideration for sublicenses related to any product, service or process that contains know-how and technology of Sheba and any and all know-how and technology either developed or supervised by Prof. Ferber in the field of cell therapy, including in the category of the point-of-care platform and any and all services and products in relation to the defendants' CDMO activity. In addition, the plaintiffs seek that the defendants provide financial statements and pay NIS 10 million to the plaintiffs due to the royalty provisions of the license agreement, dated February 2, 2012, between the Israeli Subsidiary and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (the "License Agreement"). The Complaint alleges that the Company and the Israeli Subsidiary used know-how and technology of Sheba and know-how and technology either developed or supervised by Prof. Ferber while employed by Sheba in the field of cell therapy, including in the category of the point-of-care platform and the services and products in relation to the defendants' CDMO activity and are entitled to the payment of certain royalties pursuant to the terms of the License Agreement. The defendants have filed their statements of defense responding to this Complaint. The Company believes that the allegations in this Complaint are without merit and intends to vigorously defend itself against the claims. Since a material loss is not considered probable, no provision was made in the financial statements.

Except as described above, we are not involved in any pending material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Since March 13, 2018, our common stock has been listed for trading on the Nasdaq Capital Market ("Nasdaq CM") under the symbol "ORGS."

As of March 22, 2023, there were 305 holders of record of our common stock, and the last reported sale price of our common stock on the NasdaqCM on March 22, 2023 was $1.43. A significant number of shares of our common stock are held in either nominee name or street name brokerage accounts, and consequently, we are unable to determine the total number of beneficial owners of our common stock.

Dividend Policy

To date, we have paid no dividends on our common stock and do not expect to pay cash dividends in the foreseeable future. We plan to retain all earnings to provide funds for the operations of our company. In the future, our Board of Directors will decide whether to declare and pay dividends based upon our earnings, financial condition, capital requirements, and other factors that our Board of Directors may consider relevant. We are not under any contractual restriction as to present or future ability to pay dividends.

Unregistered Sales of Equity Securities

As previously disclosed in a Current Report on Form 8-K, on October 23, 2023, the Company and Ricky Neumann that were parties to the Securities Purchase Agreement, dated as of March 30, 2022 (the "SPA") and the Registration Rights Agreement, dated as of March 30, 2022 (the "RRA"), entered into an Amendment, Consent and Waiver Agreement (the "RRA Amendment"). Pursuant to the RRA Amendment, the Company and Neumann agreed that Neumann shall (i) consent and agree to an extension of the date for filing the Registration Statement to register the Registrable Securities (as defined in the RRA) to April 3, 2023 and the effective date of such Registration Statement as provided for in the RRA Amendment; and (ii) waive any potential damages or claims under the RRA with respect to the Company's obligations under the RRA or SPA and release the Company therefrom. In consideration for such consent, agreement, waiver and release, the Company agreed to issue an additional warrant to purchase 174,460 shares of Common Stock to Neumann (the "Neumann Additional PIPE Warrant") and such Neumann Additional PIPE Warrant shall have an exercise price of $2.50 per share of Common Stock, be exercisable beginning six months and one day after the Effective Date and end 36 months after the Effective Date and be in the same form as the original Warrants issued pursuant to the SPA. In connection with such RRA Amendment, an aggregate of 41,042 additional Warrants identical to the Neumann Additional PIPE Warrant were issued to the other investors under the SPA, who also agreed to become parties to the RRA Amendment. Such additional Warrants and the shares of Common Stock issuable upon exercise of such Warrants have not been registered under the Securities Act and shall be exempt from registration under Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

Issuer Purchases of Equity Securities

On May 14, 2020, our Board of Directors approved the stock repurchase plan (the "Stock Repurchase Plan") pursuant to which we may, from time to time, purchase up to $10 million of our outstanding shares of common stock. The shares may be repurchased from time to time in privately negotiated transactions or the open market, including pursuant to Rule 10b5-1 trading plans, and in accordance with applicable regulations of the SEC. The timing and exact amount of any repurchases will depend on various factors including, general and business market conditions, corporate and regulatory requirements, share price, alternative investment opportunities and other factors. The Repurchase Plan commenced on May 29, 2020 and does not obligate us to acquire any specific number of shares in any period, and may be expanded, extended, modified, suspended or discontinued by the Board of Directors at any time.

There were no repurchases to the Stock Repurchase Plan during the year ended December 31, 2022.

ITEM 6. [RESERVED]

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the years ended December 31, 2022 and December 31, 2021 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2022, as compared to the year ended December 31, 2021.

This discussion should be read in conjunction with our consolidated financial statements for the years ended December 31, 2022 and December 31, 2021 and related notes included elsewhere in this Annual Report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains numerous forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

Corporate Overview

We are a global biotech company working to unlock the potential of CGTs in an affordable and accessible format. CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products, or ATMPs. We are mostly focused on autologous therapies that can be manufactured under processes and systems that are developed for each therapy using a closed and automated approach that is validated for compliant production near the patient for treatment of the patient at the point of care, or POCare. This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

To achieve these goals, we have developed a collaborative worldwide network of research institutes and hospitals who are engaged in the POCare model, or our POCare Network, and a pipeline of licensed POCare advanced therapies that can be

processed and produced under such closed and automated processes and systems, or POCare Therapies. We are developing our pipeline of advanced therapies and with the goal of entering into out-licensing agreements for these therapies.

Following the Metalmark Investment in November 2022, we separated our operations into two operating segments namely 1) Morgenesis and 2) Therapies. Prior to that, we conducted all of our operations as one single segment. The Morgenesis operations includes mainly POCare Services, and include the results of the subsidiaries transferred to Morgenesis. The Therapies segment includes our therapeutic development operations. The segment information presented in note 5 of item 8 reflects the results of the subsidiaries that were transferred to Morgenesis.

Morgenesis segment (mainly POCare Services)

The POCare Services that we and our affiliated entities perform include:

- Process development of therapies, process adaptation, and optimization inside the OMPULs, or "OMPULization";
- Adaptation of automation and closed systems to serviced therapies;
- Incorporation of the serviced therapies compliant with GMP in the OMPULs that we designed and built;
- Tech transfers and training of local teams for the serviced therapies at the POCare Centers;
- Processing and supply of the therapies and required supplies under GMP conditions within our POCare Network, including required quality control testing; and
- Contract Research Organization services for clinical trials.

The POCare Services are performed in decentralized hubs that provide harmonized and standardized services to customers, or POCare Centers. We are working to expand the number and scope of our POCare Centers. We believe that this provides an efficient and scalable pathway for CGT therapies to reach patients rapidly at lowered costs. Our POCare Services are designed to allow rapid capacity expansion while integrating new technologies to bring together patients, doctors and industry partners with a goal of achieving standardized, regulated clinical development and production of therapies.

Therapies segment (POCare Therapies)

While the biotech industry struggles to determine the best way to lower cost of goods and enable CGTs to scale, the scientific community continues to advance and push the development of such therapies to new heights. Clinicians and researchers are excited by all the new tools (new generations of industrial viruses, big data analysis for genetic and molecular data) and technologies (CRISPR, mRNA, etc.) available (often at a low cost) to perform advanced research in small labs. Most new therapies arise from academic institutes or small spinouts from such institutes. Though such research efforts may manage to progress into a clinical stage, utilizing lab based or hospital-based production solutions they lack the resources to continue the development of such drugs to market approval.

Historically, drug/therapeutic development has required investments of hundreds of millions of dollars to be successful. One significant cause for the high cost is that each therapy often requires unique production facilities and technologies that must be subcontracted or built. Further the cost of production during the clinical stage is extremely expensive, and the cost of the clinical trial itself is very high. Given these financial restraints, researchers and institutes hope to out- license their therapeutic products to large biotech companies or spin-out new companies and raise large fundraising rounds. However, in many cases they lack the resources and the capability to de-risk their therapeutic candidates enough to be attractive for such fundings or partnership.

Our POCare Network is an alternative to the traditional pathway of drug development. Orgenesis works closely with many such institutes and is in close contact with researchers in the field. The partnerships with leading hospitals and research institutes gives us a deep insight as to the developments in the field, as well as the market potential, the regulatory landscape and optimal clinical pathway to get these products to market.

The ability to produce these products at low cost, allows for an expedited development process and the partnership with hospitals around the globe enables joint grants and lower cost of clinical development. The POCare Therapies division reviews many therapies available for out licensing and select the ones which they believe have the highest market potential, can benefit the most from a point of care approach and have the highest chance of clinical success. It assesses such issues by utilizing its global POCare Network and its internal knowhow accumulated over a decade of involvement in the field.

The goal of this in-licensing is to quickly adapt such therapies to a point-of- care approach through regional partnerships, and to out-license the products for market approval in preferred geographical regions. This approach lowers overall development cost, through minimizing pre-clinical development costs incurred by us, and through receiving of the additional funding from grants and/or payments by regional partners.

Significant Developments During Fiscal 2022

Financing Activities

Equity

From March to June 2022, we sold to certain investors pursuant to a Securities Purchase Agreement, dated as of March 30, 2022, in a private placement, an aggregate of 724,999 shares of our Common Stock at a purchase price of $3.00 per share and warrants to purchase up to an aggregate of 146,959 shares of Common Stock at an exercise price of $4.50 per share. The warrants were not exercisable until after six months and expire three years from the date of issuance. We received gross proceeds of $2,175,000 before deducting related offering expenses through the final closing on June 30, 2022.

Convertible Loan Agreements

During April and May 2022, we entered into three convertible loan agreements (the “Convertible Loan Agreements”) with three non-U.S. investors (the “Lenders”), pursuant to which the Lenders loaned us an aggregate of $9.15 million (the “Loan Amount”). Interest is calculated at 6% per annum (based on a 365-day year) and is payable, along with the principal, during or before the third quarter of 2023. At any time prior to or on the maturity date, the Lenders may provide us with written notice to convert all or part of the loans into shares of our Common Stock at a conversion price equal to $4.50 per share (subject to adjustment for certain capital events, such as stock splits) (the “Conversion Price”). In connection with such loans, we issued to the Lenders warrants representing the right to purchase an aggregate of 408,335 shares of our Common Stock (which is 25% of the shares of our Common Stock into which the loans are initially convertible at the Conversion Price), at an exercise price per share of $4.50 per share. Such warrants are exercisable at any time beginning six months and one day after the closing date and ending 36 months after such closing date.

During October 2022, we entered into convertible loan extension agreements (the “Convertible Loan Extension Agreements”) with two of the Lenders, which amended their respective Convertible Loan Agreements in an aggregate $8,000,000 principal Loan Amount as follows: (i) the interest rate increased from 6% to 10% per annum from the loan receipt date on the unconverted and then outstanding loan amount; (ii) the maturity date was extended to repayment to the first quarter of 2024; (iii) we agreed to issue a warrant to the Lender for the right to purchase an aggregate of 1,777,777 shares of Common Stock, at an exercise price per share of $2.50 per share, which is exercisable at any time beginning from April 2023 and ending October 2025; and (iv) the Conversion Price was amended to a price per share of $2.50 per share instead of $4.50 per share.

In addition, we repaid four loans in the principal amount of $2.3 million.

Metalmark Investment in Morgenesis LLC

In November 2022, we and MM OS Holdings, L.P. (“MM”), an affiliate of Metalmark Capital Partners (“Metalmark”), entered into a series of definitive agreements intended to finance, strengthen and expand our POCare Services business.

Pursuant to a unit purchase agreement (the "UPA"), MM purchased 3,019,651 Class A Preferred Units of Morgenesis (the "Class A Units"), which represented 22.31% of the outstanding equity interests of Morgenesis following the initial closing, for a purchase price of $30.2 million, comprised of (i) $20 million of cash consideration and (ii) the conversion of $10.2 million of MM's then-outstanding senior secured convertible loans previously entered into with MM (collectively, the "Consideration"). Under certain conditions related to Morgenesis' performance among others, MM has agreed to make future payments of up to $20 million in cash for additional Class A (or Class B) Units, and/or make a one-time cash payment of $10 million to Orgenesis (the "Earnout Payment").

Until the consummation of a Company IPO or Change of Control of Morgenesis (in each case, as defined in the LLC Agreement), MM may, in its sole discretion, elect to invest up to an additional $60 million in Morgenesis (any such investment, an "Optional Investment") in exchange for certain Class C Preferred Units of Morgenesis (the "Class C Units" and, together with the Class A Units and the Class B Units, the "Preferred Units").

The proceeds of the investment will generally be used to fund the activities of Morgenesis and its consolidated subsidiaries.

In connection with the entry into of the UPA, we, Morgenesis and MM entered into the Second Amended and Restated Limited Liability Company Agreement (the "LLC Agreement") providing for certain restrictions on the disposition of Morgenesis securities, the provisions of certain options and rights with respect to the management and operations of Morgenesis, a right for MM to exchange any units of Morgenesis for shares of Orgenesis common stock and certain other rights and obligations. In addition, MM was provided certain protective rights in Morgenesis.

Purchase of Mida Biotech BV

During February 2022, pursuant to the joint venture agreement between ourselves and Mida Biotech BV "Mida"), we purchased all the issued shares in Mida for consideration of $100 thousand. In lieu of cash, the consideration was paid via the issuance of shares of our Common Stock to Mida's shareholders.

License, Collaboration and Joint Venture Agreements

License and Research Agreement with Yeda Research and Development Company Limited

During January 2022, we and Yeda Research and Development Company Limited ("Yeda"), an Israeli company, entered into a license and research agreement. Pursuant to the agreement, Yeda granted us an exclusive, worldwide royalty bearing license to creating licensed information and the licensed patents, for the development, manufacture, use, offer for sale, sale and import of products in the field of tumor-infiltrating lymphocytes (TIL) and Chimeric antigen receptor (CAR) T cell immunotherapy platforms (excluding CAR-Cytokine Induced Killer cell immunotherapy.

In addition, during 2022, we continued the development of license agreements previously entered into, as described more fully in notes 11 and 12 to our consolidated financial statements included in Item 8 of this annual report on Form 10-K.

Results of Operations

Comparison of the Year Ended December 31, 2022 to the Year Ended December 31, 2021.

Our financial results for the year ended December 31, 2022 are summarized as follows in comparison to the year ended December 31, 2021:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenues	$ 34,741	$ 31,646
Revenues from related party	1,284	3,856
Total revenues	36,025	35,502
Cost of revenues, development services and research and development expenses	27,066	36,644
Amortization of intangible assets	911	948
Selling, general and administrative expenses	15,589	14,710
Impairment expenses	1,061	-
Operating loss	8,602	16,800
Other income	(173)	(2,278)
Loss from extinguishment in connection with convertible loan (see note 7 a of Item 8)	52	1,865
Financial expense, net	1,971	1,292
Share in income of associated company	1,508	272
Loss before income taxes	11,960	17,951
Tax expense	209	108
Net loss	$ 12,169	$ 18,059

Revenues

The following table shows our revenues by major revenue streams:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenue stream:		
POCare development services	$ 14,894	$ 32,192
Cell process development services and hospital services	11,212	3,310
POCare cell processing	9,919	-
Total	$ 36,025	$ 35,502

Our revenues for the year ended December 31, 2022 were $36,025 thousand, as compared to $35,502 thousand for the year ended December 31, 2021, representing an increase of 1%.The change in revenues for the year ended December 31, 2022 compared to the year ended December 31, 2021 was attributable to the following:

- A decline in POCare development services as a result of our having completed the majority of performance obligations under the POCare development services contracts in 2021. The next stage in our revenue model, following the completion of POCare development services is to enter into cell processing agreements with the relevant customers.
- An increase in cell process development services and hospital services as a result of our having signed new process development services agreements with third party customers who retain the ownership of the intellectual property created through the process.
- During the year ended December 31, 2022 we signed cell processing agreements with customers. In most cases, the cell processing agreements represent a new stage in our revenue model, following the completion of POCare development services contracts.

A breakdown of the revenues per customer that constituted at least 10% of revenues is as follows:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenue earned:		

Customer A (Greece)	$	8,936	$	4,693
Customer B (United States)		8,316		6,491
Customer C (United Arab Emirates)		5,271		6,969
Customer D (Korea)		3,873		7,703

Cost of revenues, development services and research and development expenses

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Salaries and related expenses	$ 11,206	$ 10,977
Stock-based compensation	616	729
Subcontracting, professional and consulting services	5,655	12,796
Lab expenses	2,685	3,513
Depreciation expenses, net	1,017	874
Other research and development expenses	6,010	7,755
Less – grant	(123)	-
Total	$ 27,066	$ 36,644

Cost of revenues, development services and research and development for the year ended December 31, 2022 were $27,066 thousand, as compared to $36,644 thousand for the year ended December 31, 2021, representing a decrease of 26%. In previous years, we made significant investments in research and development services including in the development of several types of OMPULs, the development of automated processing units and processes, owned and licensed advanced therapies to enable commercial production, and additional work that addresses POCare needs. While we continue to invest in these activities, the majority of development work on our OMPULs has been completed thus allowing us to deploy OMPULS in various worldwide locations. As a result of the reduction in development and research and development services expenses, subcontracting, professional and consulting services, lab expenses and other research and development expenses declined by 40%.

Selling, General and Administrative Expenses

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Salaries and related expenses	$ 4,008	$ 6,277
Stock-based compensation	362	945
Accounting and legal fees	5,527	3,293
Professional fees	3,080	1,107
Rent and related expenses	199	249
Business development	474	577
Depreciation expenses, net	50	42
Other general and administrative expenses	1,889	2,220
Total	$ 15,589	$ 14,710

Selling, general and administrative expenses for the year ended December 31, 2022 were $15,589 thousand, as compared to $14,710 thousand for the year ended December 31, 2021, representing an increase of 6%.The increase for the year ended December 31, 2022 is primarily attributable to an increase in accounting and legal fees and professional services as a result of additional investment activities, particularly the Metalmark Investment, in 2022 compared to 2021, offset by a decline in salaries and related expenses. In 2021 a discretionary bonus was granted to our Chief Executive Officer, Vered Caplan, in the amount of $3.6 million. In 2022 no such bonus award was granted.

Impairment Expenses

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Impairment expenses	$ 1,061	$ -

Impairment expenses for the year ended December 31, 2022 were $1,061 thousand, as compared to $0 for the year ended December 31, 2021. These were attributable to the write-off of customer relationships and IPR&D intangible assets purchased in previous years.

Financial Expenses, net

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Interest expense on convertible loans and loans	1,824	943
Foreign exchange loss, net	145	574
Other income	2	(225)
Total	$ 1,971	$ 1,292

Financial expenses, net for the year ended December 31, 2022 were $1,971 thousand, as compared to $1,292 thousand for the year ended December 31, 2021, representing an increase of 53%. The increase was mainly attributable to increased interest and related expenses on new and existing convertible loans.

Tax expense

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Tax expense	$ 209	$ 108
Total	$ 209	$ 108

Tax expense, net for the year ended December 31, 2022 were $209 thousand, as compared to $108 thousand for the year ended December 31, 2021, representing an increase of 94%. The increase is mainly attributable to increased tax liabilities in the U.S. Effective for years beginning after December 31, 2021, Internal Revenue Code Section 174 changed the tax treatment of research and experimentation (R&E) expenditures. While companies have historically deducted such costs for federal income tax purposes, these new rules require capitalization and prescribe cost recovery over a period of five years for research and development paid or incurred in the United States and 15 years for R&E paid or incurred outside of the United States.

Working Capital

	December 31,	
	2022	2021
	(in thousands)	
Current assets	$ 46,318	$ 25,758
Current liabilities	$ 15,910	$ 15,365
Working capital	$ 30,408	$ 10,393

Current assets increased by $20,560 thousand between December 31, 2021 and December 31, 2022, which was primarily attributable to an increase in accounts receivable as a result of increased POCare revenues.

Current liabilities increased by $545 thousand between December 31, 2021 and December 31, 2022, which was primarily attributable to the following: (i) an increase in accounts payable and accrued expenses as a result of expenses incurred towards the end of 2022 not yet paid for, offset by a reduction in current maturities of convertible loans.

Liquidity and Capital Resources

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Net loss	$ (12,169)	$ (18,059)
Net cash used in operating activities	(24,924)	(26,866)
Net cash used in investing activities	(14,133)	(12,384)
Net cash provided by (used in) financing activities	39,578	(106)
Net change in cash and cash equivalents and restricted cash	$ 521	$ (39,356)

During year ended December 31, 2022, we funded our operations from operations as well as from proceeds raised from equity and debt offerings.

Net cash used in operating activities for the year ended December 31, 2022 was approximately $24,924 thousand, as compared to net cash used in operating activities of approximately $26,866 thousand for the year ended December 31, 2021. The decline was mainly as a result of

- a loss of $12,169 thousand for the year ended December 31, 2022 compared to a loss of $18,059 thousand for the year ended December 31, 2021;
- a decline of $763 thousand in stock-based compensation mainly as a result of a reduced share price;
- an increase of $1,236 thousand in our share of losses in our associated companies (see note 13);
- impairment expenses of $1,061 thousand as a result of the write off of certain intangible assets;
- an increase of $881 thousand in interest expenses accrued on convertible loans as a result of increased interest rates and new loan agreements entered into;
- an increase in accounts receivable of $20,938 thousand as a result of an increase in POCare revenue;
- a decline of $1,284 thousand in accounts payable and accrued expenses a result of reduced expenditures.

Net cash used in investing activities for the year ended December 31, 2022 was approximately $14,133 thousand, as compared to net cash used in investing activities of approximately $12,384 thousand for the year ended December 31, 2021. The increase was mainly as a result of additional loans granted to associated companies in the amount of $4,131 thousand and additional purchases of property, plants and equipment of $12,416 thousand used in our POCare facilities.

Net cash provided by financing activities for the year ended December 31, 2022 was approximately $39,578 thousand, as compared to net cash used in financing activities of approximately $106 thousand for the year ended December 31, 2021. The increase was mainly attributable to:

- proceeds raised from equity investments in the amount of $2,181 thousand;
- proceeds raised from loans in the amount of $19,150 thousand, offset by loan repayments in the amount of $2,300 thousand;
- proceeds in the amount of $20,000 thousand from the Metal Mark investment.

Liquidity and Capital Resources Outlook

Through December 31, 2022, we had an accumulated deficit of $121,261 thousand as of December 31, 2022 and negative operating cashflows of $24,924 thousand in the year ended December 31, 2022. Our activities have been funded by generating revenue, through offerings of our securities, and through the raising of loan finance. There is no assurance that our business will generate sustainable positive cash flows to fund its business.

If there are further increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, we will need to use mitigating actions such as to seek additional financing, refinance or amend the terms of existing convertible loans or postpone expenses that are not based on firm commitments. In addition, in order to fund our operations until such time that we can generate sustainable positive cash flows, we will need to raise additional funds. For the year ended December 31, 2022 and as of the date of this report, we assessed our financial condition and concluded that based on our current and projected cash resources and commitments, as well as other factors mentioned above, there is a substantial doubt about our ability to continue as a going concern. We are planning to raise additional capital to continue our operations and to repay our outstanding loans when they become due, as well as to explore additional avenues to increase revenues and reduce expenditures. There can be no assurance that we will be able to raise additional capital on acceptable terms, or at all.

Subsequent to the year end, we and investors representing $12,250 thousand of the convertible loans outstanding at December 31, 2022 agreed to extend the maturity of the loans to January 31, 2026, increase the annual interest rate to 10% effective February 1, 2023, increase the expiry date of related warrants to January 31, 2026, and change the loan conversion price to $2.50. We also entered into new convertible loan agreements pursuant to which the lenders loaned the Company $5,000 thousand. Interest on such convertible loans is calculated at 8% per annum. The loan amount and all accrued but unpaid interest thereon shall either (i) be repaid in cash or (ii) convert into shares of common stock at a conversion price of $2.464 per share on the maturity date (January 10, 2026). At any time prior to the maturity date, the outstanding amount may be converted into shares of common stock at the conversion price. We used part of the loan proceeds to repay an existing loan in the principal amount of $3,000 thousand. Finally, on February 23, 2023, we entered into a securities purchase agreement with certain institutional and accredited investors relating to the issuance and sale of 1,947,368 shares of common stock and warrants to purchase up to 973,684 shares of common stock at a purchase price of $1.90 per share of common Stock and accompanying warrants in a registered direct offering. The warrants also have an alternate cashless exercise option (beginning on or after the earlier of (a) the thirty-day anniversary of the date of the purchase agreement and (b) the date on which the aggregate composite trading volume of our common stock exceeds 13,600,000 shares), to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of our common stock that would be issuable upon a cash exercise and (y) 1.0. The offering closed on February 27, 2023 and we received approximately $3.7 million, before deducting the placement agent’s cash fee equal to 7% of the proceeds and offering expenses. We intend to use the net proceeds from the offering and convertible loans raised for working capital and general corporate purposes, including our therapy related activities.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in the notes to our financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2022. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Income Taxes

Deferred income tax assets and liabilities are computed for differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

In addition, our management performs an evaluation of all uncertain income tax positions taken or expected to be taken in the course of preparing our income tax returns to determine whether the income tax positions meet a “more likely than not” standard of being sustained under examination by the applicable taxing authorities. This evaluation is required to be performed for all open tax years, as defined by the various statutes of limitations, for federal and state purposes.

Revenue from Contracts with Customers

Our agreements are primarily service contracts that range in duration. We recognize revenue when control of these services is transferred to the customer for an amount, referred to as the transaction price, which reflects the consideration to which we are expected to be entitled in exchange for those goods or services.

A contract with a customer exists only when:

- the parties to the contract have approved it and are committed to perform their respective obligations;
- we can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations");
- we can determine the transaction price for the goods or services to be transferred; and
- the contract has commercial substance, and it is probable that we will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Nature of Revenue Streams

We have three main revenue streams, which are POCare development services, cell process development services, including hospital supplies, and POCare cell processing.

POCare Development Services

Revenue recognized under contracts for POCare development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages are not interrelated or the customer is able to complete the services performed.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices.

We recognize revenue when, or as, it satisfies a performance obligation. At contract inception, we determine whether the services are transferred over time or at a point in time. Performance obligations that have no alternative use and that we have the right to payment for performance completed to date, at all times during the contract term, are recognized over time. All other Performance obligations are recognized as revenues by us at point of time (upon completion).

Significant Judgement and Estimates

Significant judgment is required to identifying the distinct performance obligations and estimating the standalone selling price of each distinct performance obligation and identifying which performance obligations create assets with alternative use to us, which results in revenue recognized upon completion, and which performance obligations are transferred to the customer over time.

Cell Process Development Services

Revenue recognized under contracts for cell process development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages and milestones are not interrelated or the customer is able to complete the services performed independently or by using our competitors. In other contracts when the above circumstances are not met, the promises are not considered distinct, and the contract represents one performance obligation. All performance obligations are satisfied over time, as there is no alternative use to the services it performs, since, in nature, those services are unique to the customer, which retain the ownership of the intellectual property created through the process.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices. For these contracts, the standalone selling prices are based on our normal pricing practices when sold separately with consideration of market conditions and other factors, including customer demographics and geographic location.

We measure the revenue to be recognized over time on a contract-by-contract basis, determining the use of either a cost-based input method or output method, depending on whichever best depicts the transfer of control over the life of the performance obligation.

Included in Cell Process Development Services is hospital supplies revenue which is derived principally from the sale or lease of products and the performance of services to hospitals or other medical providers. Revenue is earned and recognized when product and services are received by the customer.

Revenue from POCare Cell processing

Revenues from POCare Cell processing represent performance obligations which are recognized either over, or at a point of time. The progress towards completion will continue to be measured on an output measure based on direct measurement of the value transferred to the customer (units produced).

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the “Index to Financial Statements” on page F-1 contained in this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act and regulations promulgated thereunder) as of December 31, 2022, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

Management’s Report on Internal Control over Financial Reporting

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this evaluation, our management used the criteria set forth in the Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022 based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm on internal control over financial reporting because we are a smaller reporting company and non-accelerated filer.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our each of our current Directors and Executive Officers as of March 22, 2023.

Name	Age	Position
Vered Caplan	54	Chief Executive Officer and Chairperson of the Board of Directors
Neil Reithinger	53	Chief Financial Officer, Secretary and Treasurer
Efrat Assa Kunik	48	Chief Development Officer
David Sidransky (1) (2) (4)	62	Director
Guy Yachin (1) (2) (3) (4)	55	Director
Yaron Adler (2) (3)	52	Director
Ashish Nanda (3)	57	Director
Mario Philips (1)	53	Director

(1) A member on the audit committee.
(2) A member on the compensation committee.
(3) A member on the nominating and corporate governance committee.
(4) A member of the research and development committee.

Our Executive Officers

Vered Caplan – Chief Executive Officer and Chairperson of the Board of Directors

Ms. Caplan has served as our CEO and Chairperson of the Board of Directors since August 14, 2014, prior to which she served as Interim President and CEO commencing on December 23, 2013. She joined our Board of Directors in February 2012. She has 26 years of industry experience, previously holding positions as CEO of Kamedis Ltd. from 2009 to 2014, CEO of GammaCan International Inc. from 2004 to 2007. She also served as a director of the following companies: Opticul Ltd., Inmotion Ltd., Nehora Photonics Ltd., Ocure Ltd., Eve Medical Ltd., and Biotech Investment Corp. Ms. Caplan holds a M.Sc. in biomedical engineering from Tel Aviv University specializing in signal processing; management for engineers from Tel Aviv University specializing in business development; and a B.Sc. in mechanical engineering from the Technion– Israel Institute of Technology specialized in software and cad systems.

Neil Reithinger – Chief Financial Officer, Secretary and Treasurer

Mr. Reithinger was appointed Chief Financial Officer, Secretary and Treasurer on August 1, 2014. Mr. Reithinger is the Founder and President of Eventus Advisory Group, LLC, a private, CFO-services firm incorporated in Delaware, which specializes in capital advisory and SEC compliance for publicly-traded and emerging growth companies. He is also the President of Eventus Consulting, P.C. Prior to forming Eventus, Mr. Reithinger was Chief Operating Officer & CFO from March 2009 to December 2009 of New Leaf Brands, Inc., a branded beverage company, CEO of Nutritional Specialties, Inc. from April 2007 to October 2009, a nationally distributed nutritional supplement company that was acquired by Nutraceutical International, Inc., Chairman, CEO, President and director of Baywood International, Inc. from January 1998 to March 2009, a publicly-traded nutraceutical company and Controller of Baywood International, Inc. from December 1994 to January 1998. Mr. Reithinger earned a B.S. in Accounting from the University of Arizona and is a Certified Public Accountant. He is a Member of the American Institute of Certified Public Accountants and the Arizona Society of Certified Public Accountants.

Efrat Assa-Kunik – Chief Development Officer

Dr. Assa-Kunik was appointed as our Chief Development Officer in December 2021. Dr. Assa-Kunik joined the Company in September 2016 as Head of Pre-Clinical Development. In August 2017, she was appointed General Manager of the Israeli subsidiary. Dr Assa-Kunik earned her PhD at the Weizmann Institute of Science in the fields of genetics and developmental biology and a Masters from the Ben-Gurion University in immunology and cancer research. Additionally, Dr Assa-Kunik was a postdoctoral fellow at the Weizmann Institute in the department of neural biology. After completing her postdoc, Dr. Assa-Kunik joined BioGenCell as a Senior Scientist. In 2012, she joined Pharmaseed as the director of the Business Development Unit, VP business development and manager of the business development activity in USA.

Our Directors

Dr. David Sidransky – Director

Dr. Sidransky has served as a director since his appointment on July 18, 2013. Dr. Sidransky is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine's Department of Otolaryngology and Professor of Oncology, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at the John Hopkins University School of Medicine. Dr. Sidransky is one of the most highly cited researchers in clinical and medical journals in the world in the field of oncology during the past decade, with over 600 peer reviewed publications. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents. Dr. Sidransky has served as Vice Chairman of the board of directors, and was, until the merger with Eli Lilly, a director of ImClone Systems, Inc., a global biopharmaceutical company committed to advancing oncology care. He is currently on the board of Directors of Ascentage Pharma, Galmed and Champions Oncology. and chairs the board of directors of Advaxis and Ayala. Dr. Sidransky served as Director from 2005 until 2008 of the American Association for Cancer Research (AACR). He was the chairperson of AACR International Conferences during the years 2006 and 2007 on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Personalized Treatment. Dr. Sidransky is the recipient of a number of awards and honors, including the 1997 Sarstedt International Prize from the German Society of Clinical Chemistry, the 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians, and the 2004 Richard and Hinda Rosenthal Award from the American Association of Cancer Research. Dr. Sidransky received his BS in Chemistry from Brandies University and his medical degree from Baylor College of medicine where he also completed his residency in internal medicine. His specialty in Medical Oncology was completed at Johns Hopkins University and Hospital.

We believe Dr. Sidransky is qualified to serve on our Board of Directors because of his education, medical background, experience within the life science industry and his business acumen in the public markets.

Guy Yachin – Director

Mr. Yachin has served as a director since his appointment on April 2, 2012. Mr. Yachin serves, since November 2020, as the executive chairman of Xerient Pharma which develops a drug for the treatment of abdominal cancers. He served as the President and CEO of Serpin Pharma, a clinical stage Virginia-based company focused on the development of anti-inflammatory drugs, from April 2013 until October 2020. Prior to that, Mr. Yachin was the CEO of NasVax Ltd., a company focused on the development of improved immunotherapeutics and vaccines. Prior to joining NasVax, Mr. Yachin served as CEO of MultiGene Vascular Systems Ltd (a.k.a. Vessl), a cell therapy company focused on blood vessels disorders, leading the company through clinical studies in the U.S. and Israel, financial rounds, and a keystone strategic agreement with Teva Pharmaceuticals Industries Ltd. He was CEO and founder of Chiasma Inc., a biotechnology company focused on the oral delivery of macromolecule drugs, where he built the company's presence in Israel and the U.S., concluded numerous financial rounds, and guided the company's strategy and operation for over six years. Earlier, he was CEO of Naiot Technological Center Ltd., and provided seed funding and guidance to more than a dozen biomedical startups such as Remon Medical Technologies Ltd., Enzymotec Ltd. and NanoPass Technologies Ltd. He holds a BSc. in Industrial Engineering and Management and an MBA from the Technion – Israel Institute of Technology.

We believe Mr. Yachin is qualified to serve on our Board of Directors because of his education, experience within the life science industry and his business acumen in the public markets.

Yaron Adler – Director

Mr. Adler has served as a director since his appointment on April 17, 2012. Mr. Adler is the co-founder of a startup incubator, We Group Ltd. In 1999, Mr. Adler co-founded IncrediMail Ltd. and served as its CEO until 2008 and President until 2009. After IncrediMail, Mr. Adler consulted Israeli startup companies regarding Internet products, services and technologies. Mr. Adler served as a product manager from 1997 to 1999, and as a software engineer from 1994 to 1997, at Tecnomatix Technologies Ltd., a software company that develops and markets production engineering solutions to complex automated manufacturing lines that fill the gap between product design and production, and which was acquired by UGS Corp. in April 2005. In 1993, Mr. Adler held a software engineer position at Intel Israel Ltd. He has a B.A. in computer sciences and economics from Tel Aviv University.

We believe Mr. Adler is qualified to serve on our Board of Directors because of his education, success with early-stage enterprises and his business acumen in the public markets.

Ashish Nanda – Director

Mr. Nanda has served as a director since his appointment on February 22, 2017. Since 1998, Mr. Nanda has been the Managing Director of Innovations Group, one of the largest outsourcing companies in the financial sector that employs close to 14,000 people working across various financial sectors. Since 1992, Mr. Nanda has served as the Managing Partner of Capstone Insurance Brokers LLC and, since 2009, has served as Managing Partner of Dive Tech Marine Engineering Services L.L.C. From 1991 to 1994, Mr. Nanda held the position of Asst. Manager Corporate Banking at Emirates Banking Group where he was involved in establishing relationships with business houses owned by UAE nationals and expatriates in order to set up banking limits and also where he managed portfolios of USD $26 billion. Mr. Nanda holds a Chartered Accountancy from the Institute of Chartered Accountants from India.

We believe that Mr. Nanda is qualified to serve on our Board of Directors because of his business experience and strategic understanding of advancing the valuation of companies in emerging industries.

There are no family relationships between any of the above executive officers or directors or any other person nominated or chosen to become an executive officer or a director. Pursuant to an agreement entered into between us and Image Securities fzc. ("Image"), for so long as Image's ownership of our company is 10% or greater, it was granted the right to nominate a director to our Board of Directors. Mr. Nanda was nominated for a directorship at the 2017 annual meeting in compliance with our contractual undertakings.

Mario Philips – Director

Mr. Philips has served as a director since his appointment on January 9, 2020. Since November 2020, Mr. Philips has been Chief Executive Officer of Polyplus, a leading Biotech supplier of transfection reagents for cell & gene therapy as well as the research life sciences market. He is also chairmen of the Board of PLL Therapeutics, a drug company based in France that has developed a diagnostic platform technology for neurodegenerative diseases in combination with a therapy to cure neurodegenerative diseases such as ALS and Parkinson's.

Prior to that, Mr. Philips acted as VP/GM for Danaher Pall Biotech business with full P&L responsibility for a $1.3 billion business unit. Mr. Philips joined Pall in February 2014, as part of the Pall acquisition of ATMI Life Sciences, and was appointed to Vice President and General Manager to lead the Single-Use Technologies BU. In this role he was responsible for leading and executing an aggressive investment and growth strategy.

Mr. Philips joined ATMI in 1999 with ATMI's acquisition of MST Analytics, Inc., serving as European Sales Manager for ATMI Analytical Systems. In 2004, he was appointed to General Manager of ATMI Packaging, a role he held through 2010 when he was promoted to the position of Senior Vice President and General Manager, ATMI Life Sciences. In that role, he was responsible for developing and executing all business strategies, including the introduction of new products and service solutions for the Life Sciences industry. A strong leading innovative IP portfolio was created, Pall acquired the business in 2014.

Mr. Philips also held in the past several board member positions in the life sciences industry with Clean Biologics, Austar Life Sciences (China), Disposable Lab (France) and Artelis (Belgium).

We believe that Mr. Philips is qualified to serve on our Board of Directors because of his business experience and strategic understanding of advancing the valuation of companies in emerging industries.

Board of Directors

Our Board of Directors currently consists of six (6) members. All directors hold office until the next annual meeting of stockholders. At each annual meeting of stockholders, the successors to directors whose terms then expire are elected to serve from the time of election and qualification until the next annual meeting following election.

Management has been delegated the responsibility for meeting defined corporate objectives, implementing approved strategic and operating plans, carrying on our business in the ordinary course, managing cash flow, evaluating new business opportunities, recruiting staff and complying with applicable regulatory requirements. The Board of Directors exercises its supervision over management by reviewing and approving long-term strategic, business and capital plans, material contracts and business transactions, and all debt and equity financing transactions and stock issuances.

Director Independence

Our Board of Directors is comprised of a majority of independent directors. In determining director independence, we use the definition of independence in Rule 5605(a)(2) of the listing standards of The Nasdaq Stock Market.

The Board has concluded that each of Dr. Sidransky, and Messrs. Yachin, Adler, Philips and Nanda is "independent" based on the listing standards of the Nasdaq Stock Market, having concluded that any relationship between such director and our company, in its opinion, does not interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Board Committees

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, with each comprised of independent directors in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. The members of the Audit Committee are Dr. Sidransky and Messrs. Yachin and Philips. The members of the Compensation Committee are Dr. Sidransky and Messrs. Adler and Yachin. The members of the Nominating and Corporate Governance Committee are Messrs. Nanda, Adler and Yachin. The members of the Research and Development Committee are Mr. Yachin and Dr. Sidransky. We have also established a Research and Development Committee.

Each committee operates under a written charter that has been approved by our Board of Directors. Copies of our committee charters are available on the investor relations section of our website, which is located at http://www.orgenesis.com.

Audit Committee

The Audit Committee (a) assists the Board of Directors in fulfilling its oversight of: (i) the quality and integrity of our financial statements; (ii) our compliance with legal and regulatory requirements relating to our financial statements and related disclosures; (iii) the qualifications and independence of our independent auditors; and (iv) the performance of our independent auditors; and (b) prepares any reports that the rules of the SEC require be included in our proxy statement for our annual meeting.

The Audit Committee held 5 meetings in 2022. In addition, the Audit Committee reviewed and approved various corporate items by way of written consent during the year 2022. The Board has determined that each member of the Audit Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. In addition, the Board has determined that Dr. Sidransky is an “audit committee financial expert” within the meaning of Item 407(d)(5) of Regulation S-K and has designated him to fill that role. See “Directors, Executive Officers and Corporate Governance – Directors” above for descriptions of the relevant education and experience of each member of the Audit Committee.

At no time since the commencement of our most recently completed fiscal year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

The Audit Committee is responsible for the oversight of our financial reporting process on behalf of the Board of Directors and such other matters as specified in the Audit Committee’s charter or as directed by the Board of Directors. Our Audit Committee is directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged by us for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us (or to nominate the independent registered public accounting firm for stockholder approval), and each such registered public accounting firm must report directly to the Audit Committee. Our Audit Committee must approve in advance all audit, review and attest services and all non-audit services (including, in each case, the engagement and terms thereof) to be performed by our independent auditors, in accordance with applicable laws, rules and regulations.

Compensation Committee

The Compensation Committee (i) assists the Board of Directors in discharging its responsibilities with respect to compensation of our executive officers and directors, (ii) evaluates the performance of our executive officers, and (iii) administers our stock and incentive compensation plans and recommends changes in such plans to the Board as needed.

The Compensation Committee held 2 meetings in 2022. In addition, the Compensation Committee reviewed and approved various corporate items by way of written consent during the year ended December 31, 2022. The Board of Directors has determined that each member of the Compensation Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee assists the Board in (i) identifying qualified individuals to become directors, (ii) determining the composition of the Board and its committees, (iii) developing succession plans for executive officers, (iv) monitoring a process to assess Board effectiveness, and (v) developing and implementing our corporate governance procedures and policies.

The Nominating and Corporate Governance Committee held 3 meetings in 2022. In addition, the Nominating and Corporate Governance Committee reviewed and approved various corporate items by way of written consent during the year ended December 31, 2022. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

Research and Development Committee

The Research and Development Committee assists the Board in fulfilling the Board's responsibilities to oversee our research and development programs, and strategies.

The Research and Development Committee was established in January 2021. The Research and Development Committee held 2 meeting in 2022.

DELINQUENT SECTION 16(a) REPORTS

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our officers and directors and persons who beneficially own more than ten percent (10%) of the Common Stock outstanding to file initial statements of beneficial ownership of Common Stock (Form 3) and statements of changes in beneficial ownership of Common Stock (Forms 4 or 5) with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all such forms they file.

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis, except that one report on Form 4 was filed late by David Sidransky, one report on Form 4 was filed late by Yaron Adler, one report on Form 4 was filed late by Mario Philips, one report on Form 4 was filed late by Guy Yachin, and one report on Form 4 was filed late by Ashish Nanda.

Corporate Code of Conduct and Ethics

Our Board of Directors has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Copies of our corporate code of conduct and ethics are available, without charge, upon request in writing to Orgenesis Inc., 20271 Goldenrod Lane, Germantown, MD, 20876, Attn: Secretary and are posted on the investor relations section of our website, which is located at www.orgenesis.com. The inclusion of our website address in this Annual Report on Form 10-K does not include or incorporate by reference the information on our website into this Annual Report on Form 10-K. We also intend to disclose any amendments to the Corporate Code of Conduct and Ethics, or any waivers of its requirements, on our website.

ITEM 11. EXECUTIVE COMPENSATION

The following table shows the total compensation paid or accrued during the years ended December 31, 2022 and 2021 to our Chief Executive Officer, Chief Financial Officer and Chief Development Officer. As of December 31, 2022, there were no other executive officers who earned more than $100,000 during the year ended December 31, 2022 and were serving as executive officers as of such date (the "named executive officers").

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) [1]	Non-Equity Incentive Plan Compensa-tion ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensa-tion ($) [2]	Total ($)
Vered Caplan CEO(3)	2022	243,868	-	-	107,941	-	-	92,100	443,909
	2021	264,483	3,600,000	-	-	-	-	112,345	3,976,828
Neil Reithinger CFO, Treasurer & Secretary	2022	126,005	-	-	19,048	-	-	-	145,053
	2021	239,670	-	-	-	-	-	-	239,670
Efrat Assa-Kunik, *Chief Development Officer*	2022	162,316	-	-	19,048	-	-	44,467	225,831
	2021	169,533	-	-	-	-	-	46,387	215,919

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for us that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 15 to this Annual Report on Form 10-K for the year ended December 31, 2022. No executive officers received options awards in the year ended December 31, 2022. See below for a summary of options awarded in previous years.

(2) For 2022 and 2021, represents the compensation as described under the caption “All Other Compensation” below.

All Other Compensation

The following table provides information regarding each component of compensation for the years ended December 31, 2022 and 2021 included in the All Other Compensation column in the Summary Compensation Table above. Represents amounts paid in New Israeli Shekels (NIS) or Swiss Franks and converted at average exchange rates for the year.

Name	Year	Automobile and Communication Related Expenses $	Social Benefits $ (1)	Total $
Vered Caplan	2022	2,536	89,564	92,100
	2021	-	112,345	112,345
Efrat Assa Kunik	2022	436	44,031	44,467
	2021	924	45,462	46,387

(1) These are comprised of contributions by us to savings, health, severance, pension, disability and insurance plans generally provided in Israel and Switzerland, including health, education, managerial insurance funds, and redeemed vacation pay. This amount represents Israeli and Swiss severance fund payments, managerial insurance funds, disability insurance, supplemental education fund contribution and social securities. See discussion below under “Narrative Disclosure to Summary Compensation Table – Vered Caplan.”

Outstanding Equity Awards at December 31, 2022

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of December 31, 2022.

Name	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Vered Caplan	22-Aug-14[(1)]	230,189	-	0.0012	22-Aug-24
	09-Dec-16[(1)]	166,667	-	4.80	09-Dec-26
	06-Jun-17[(1)]	83,334	-	7.20	06-Jun-27
	28-Jun-18[(1)]	250,001	-	8.36	28-Jun-28
	22-Oct-18[(1)]	85,000	-	5.99	22-Oct-28
	19-Mar-20[(1)]	85,000	-	2.99	18-Mar-30
	14-Jun-22[(2)]	21,250	63,750	2.00	13-Jun-32
Neil Reithinger	09-Dec-16[(1)]	83,334	-	4.80	09-Dec-26
	08-Mar-19[(1)]	25,000	-	5.07	08-Mar-29
	19-Mar-20[(1)]	15,000	-	2.99	18-Mar-30
	14-Jun-22[(2)]	3,750	11,250	2.00	13-Jun-32
Efrat Assa Kunik	09-Dec-16[(1)]	16,667	-	4.8	09-Dec-26
	22-Oct-18[(1)]	15,000	-	5.99	22-Oct-28
	19-Mar-20[(1)]	15,000	-	2.99	18-Mar-30
	14-Jun-22[(2)]	3,750	11,250	2.00	13-Jun-32

(1) The options were fully vested as of December 31, 2022.
(2) The options vest on a quarterly basis over a period of two years from the date of grant.

Option Exercises and Stock Vested in 2022

The following table shows information regarding exercises of options to purchase our common stock and vesting of stock awards held by each executive officer named in the Summary Compensation Table during the year ended December 31, 2022.

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($) (1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
(a)	(b)	(c)	(d)	(e)
Vered Caplan	278,191	875,745	-	-

(1) Amounts shown in this column do not necessarily represent actual value realized from the sale of the shares acquired upon exercise of options because in many cases the shares are not sold on exercise but continue to be held by the executive officer exercising the option. The amounts shown represent the difference between the option exercise price and the market price on the date of exercise, which is the amount that would have been realized if the shares had been sold immediately upon exercise.

Narrative Disclosure to Summary Compensation Table and Employment Agreements

Vered Caplan

On August 14, 2014, our Board of Directors confirmed that Ms. Vered Caplan, who had served as our President and Chief Executive Officer on an interim basis since December 23, 2013, was appointed as our President and Chief Executive Officer.

On March 30, 2017, we and Ms. Caplan entered into an employment agreement replacing a previous employment agreement dated August 22, 2014 (the "Amended Caplan Employment Agreement"). Under the Amended Caplan Employment Agreement, which took effect April 1, 2017, Ms. Caplan's annual salary continued at $160,000 per annum, subject to adjustment to $250,000 per annum upon the listing of the Company's securities on an Exchange. On May 10, 2017, we and Ms. Caplan further amended the Amended Caplan Employment Agreement pursuant to which Ms. Caplan became entitled to a grant under the 2017 of options (the "Initial Option") to purchase 83,334 shares of the Company's common stock at a per share exercise price equal to the Fair Market Value (as defined in our 2017 Equity Incentive Plan (the "2017 Plan")) of the Company's common stock on the date of grant. The amendment further provided that beginning in fiscal 2018, subject to approval by the compensation committee, Ms. Caplan became entitled to an additional option (the "Additional Option"; together with the Initial Option, the "Options") under the 2017 Plan for up to 250,000 shares of common stock of the Company to be awarded in such amounts per fiscal year as shall be consistent with the Plan, in each case at a per share exercise price equal to the Fair Market Value (as defined in the Plan) of the Company's common stock on the date of grant. In 2018, following the listing of the Company's securities on Nasdaq, Ms. Caplan's annual salary was raised to $250,000.

For additional information regarding Ms. Caplan's stock options awards, see the Outstanding Equity Awards table above.

On November 19, 2020, we and Ms. Caplan entered into an executive directorship agreement, effective as of October 1, 2020 (the "Executive Directorship Agreement"), that supersedes and replaces the Amended Caplan Employment Agreement (the "Prior Agreement"). Pursuant to the Executive Directorship Agreement, Ms. Caplan will continue to serve the Company as its Chairperson of the Board of Directors (the "Board") and shall receive in consideration for her serving as Chairperson of the Board an annual regular Board fee in the amount of $75,000 payable by the Company in equal quarterly installments in advance. In addition, Ms. Caplan may be eligible for non-recurring special Board fees as reviewed and approved by the Compensation Committee of the Board (the "Compensation Committee") and then reviewed and ratified by the Board. In addition, Ms. Caplan may be granted option awards from time to time at the discretion of the Compensation Committee.

Ms. Caplan's position as Chairperson of the Board under the Executive Directorship Agreement may be terminated for any reason by either Ms. Caplan or the Company upon 90 days prior written notice (the "Notice Period"), provided that the Company may terminate such appointment as Chairperson at any time during the Notice Period subject to certain conditions. Such termination as Chairperson of the Board will be deemed a termination even if Ms. Caplan remains as a regular director of the Board. Upon termination by the Company of Ms. Caplan's employment other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations (as defined therein) she shall be entitled to receive a lump sum payment equal to the sum of (i) the annual regular Board fee (the "Board Fee") and (ii) the greater of actual or target annual performance bonus to which she may have been entitled to as of the termination date (in each case, less all customary and required taxes and related deductions).

Ms. Caplan's position under the Executive Directorship Agreement may be terminated in the event of a Change of Control (as defined therein) by the Company other than for cause or by Ms. Caplan for any reason whatsoever. In the event of a Change of Control and if, within one year following such Change of Control, employment under the Executive Directorship Agreement is terminated by the Company other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations, she shall be entitled to receive a lump sum payment equal to one and a half times the sum of (i) the Board Fee and (ii) the target annual performance remuneration to which she may have been entitled as of the termination date (in each case, less all customary and required taxes and related deductions).

In addition, on November 19, 2020, Orgenesis Services Sàrl, a Swiss corporation and wholly-owned, direct subsidiary of the Company ("Orgenesis Services"), and Ms. Caplan entered into a personal employment agreement (the "Swiss Employment Agreement" and together with the Executive Directorship Agreement, the "Agreements"), pursuant to which Ms. Caplan will serve as Chief Executive Officer, President and Chairperson of the Board of Directors of Orgenesis Services and will be a material provider of services to the Company pursuant to a services agreement between the Company and Orgenesis Services. The Swiss Employment Agreement provides that Ms. Caplan is entitled to a monthly base salary of CHF 13,345.05 (equivalent to $14,583 based on the current exchange rate at signing), and an annual representation fee of CHF 24,000 (equivalent to $26,226 based on the current exchange rate at signing), payable in monthly installments of CHF 2,000. Ms. Caplan is eligible to receive a bonus at the absolute discretion of Orgenesis Services and its compensation committee. Ms. Caplan may also be granted option awards from time to time, as per the recommendation of the compensation committee of Orgenesis Services as reviewed and approved by the Compensation Committee. Under the Swiss Employment Agreement, Ms. Caplan is entitled to be paid annual vacation days, monthly travel allowance, sick leave, expenses reimbursement and a mobile phone. The Swiss Employment Agreement has an effective date as of October 1, 2020.

Employment under the Swiss Employment Agreement may be terminated for any reason by Ms. Caplan or by Orgenesis Services other than for just cause (as defined therein) upon six months prior written notice or by Orgenesis Services other than for just cause in the event of a Change of Control (as defined therein) of the Company upon at least 12 months prior written notice. Upon termination by Orgenesis Services of Ms. Caplan's employment without just cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations (as defined therein), she shall be entitled to receive a lump sum payment equal to the sum of (i) her Base Salary (as defined therein) at the rate in effect as of the termination date and (ii) the greater of actual or target annual performance bonus to which she may have been entitled to for the year in which employment terminates (in each case, less all customary and required taxes and employment-related deductions). In the event of a Change of Control and if, within one year following such Change of Control, employment is terminated by Orgenesis Services other than for cause or by Ms. Caplan for any reason whatsoever, in addition to any Accrued Obligations she shall be entitled to receive a lump sum payment equal to one and a half times the sum of (i) her Base Salary and (ii) the target annual performance bonus to which she may have been entitled to for the year in which employment terminates (in each case, less all customary and required taxes and employment-related deductions).

The Swiss Employment Agreement provides for customary protections of Orgenesis' confidential information and intellectual property.

Ms. Caplan received an aggregate salary and board fee of $264,483 during 2021. On November 19, 2020, the Compensation Committee approved a special remuneration of $400,000 to Ms. Caplan for her outstanding service in the business development of the Company and its affiliates. The payment of such remuneration was made at the time of entry into the Agreements. On July 28, 2021, the Compensation Committee approved a discretionary bonus to Ms. Caplan in the amount of $3.6 million pursuant to the discretionary bonus provisions of the Personal Employment Agreement between Ms. Caplan and Orgenesis Services Sàrl. The bonus was paid during September 2021.

Ms. Caplan received an aggregate salary and board fee of $243,868 during 2022. As of December 31, 2022, the $75 thousand chairperson fee for 2022 was unpaid, but accrued, per agreement by Ms. Caplan. In addition, in 2022 Ms. Caplan was awarded options to purchase 85,000 shares of common stock.

Neil Reithinger

Mr. Reithinger was appointed Chief Financial Officer, Treasurer and Secretary on August 1, 2014. Mr. Reithinger's employment agreement stipulates a monthly salary of $1,500; payment of an annual bonus as determined by the Company in its sole discretion, participation in the Company's pension plan; grant of stock options as determined by the Company; and reimbursement of expenses. In addition, on August 1, 2014, the Company entered into a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, of which Mr. Reithinger is the sole shareholder ("Eventus"), pursuant to which Eventus has agreed to provide financial consulting services to the Company. In consideration for Eventus' services, the Company agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement was for a period of one year from August 1, 2014 and automatically renews for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Mr. Reithinger. On December 16, 2020, the Compensation Committee of the Board of Directors of the Company, approved a special one-time bonus of $200,000 that was paid prior to December 31, 2020. As of December 31, 2022, Eventus was owed $23 thousand for accrued and unpaid services under the financial consulting agreement. In addition, in 2022 Mr. Reithinger was awarded options to purchase 15,000 shares of common stock

Efrat Assa-Kunik

Ms. Assa-Kunik was appointed Chief Development Officer in December 2021. According to the terms of Ms. Assa-Kunik's Employment Agreement Ms. Assa Kunik is entitled to a monthly salary of 45 thousand New Israeli Shekels, customary contributions to a pension and training fund, participation in cellphone expenses, and annual leave of 24 days. In 2022 Ms. Assa-Kunik was awarded options to purchase 15,000 shares of common stock.

Potential Payments upon Change of Control or Termination following a Change of Control

Our employment agreements with our named executive officers provide incremental compensation in the event of termination, as described herein. Generally, we currently do not provide any severance specifically upon a change in control nor do we provide for accelerated vesting upon change in control. Termination of employment also impacts outstanding stock options.

Due to the factors that may affect the amount of any benefits provided upon the events described below, any actual amounts paid or payable may be different than those shown in this table. Factors that could affect these amounts include the basis for the termination, the date the termination event occurs, the base salary of an executive on the date of termination of employment and the price of our common stock when the termination event occurs.

The following table sets forth the compensation that would have been received by each of our executive officers had they been terminated as of December 31, 2022.

Name	Salary Continuation
Vered Caplan	$ *

(*) Termination by Company without cause: $250,000
Termination without cause following a change in control: $375,000

Director Compensation

The following table sets forth for each non-employee director that served as a director during the year ended December 31, 2022:

Year Ended December 31, 2022

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) [1]	Non-equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Guy Yachin	100,000	-	23,161 [2]	-	-	-	123,161
Yaron Adler	60,000	-	17,725 [3]	-	-	-	77,725
Dr. David Sidransky	105,000	-	24,165 [4]	-	-	-	129,165
Ashish Nanda	65,000	-	18,729 [5]	-	-	-	83,729
Mario Philips	50,000	-	16,248 [6]	-	-	-	66,248

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for us that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our common stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 15 (Stock Based Compensation) to our financial statements, which are included in this Annual Report on Form 10-K.

(2) In respect of 19,600 options which will vest on December 23, 2023.

(3) In respect of 15,000 options which will vest on December 23, 2023.

(4) In respect of 20,450 options which will vest on December 23, 2023.

(5) In respect of 15,850 options which will vest on December 23, 2023.

(6) In respect of 13,750 options which will vest on December 23, 2023.

All directors receive reimbursement for reasonable out of pocket expenses in attending Board of Directors meetings and for participating in our business.

Compensation Policy for Non-Employee Directors.

In January 2021, the Board of Directors adopted an updated compensation policy for non-employee directors which replaced the previous non-employee director compensation terms, and which became effective January 2021. Under the policy, each director is to receive an annual cash compensation of $40,000 and the Chairman or lead director is paid an additional $20,000 per annum. Each committee member will be paid an additional $10,000 per annum and the committee chairman of the Audit and Research and Development committees is to receive $20,000 per annum while the chairman of the other committees is to receive $15,000 per annum. Cash compensation will be made on a quarterly basis.

All newly appointed directors also receive options to purchase up to 6,250 shares of our common stock. All directors are entitled to an annual bonus of options for 12,500 shares and each committee member is entitled to a further option to purchase up to 1,250 shares of common stock and each committee chairperson to options for an additional 2,100 shares of common stock. In addition, the Chairman and Vice Chairman shall be granted an option to purchase 4,200 shares of our common stock. In all cases, the options are granted at a per share exercise price equal to the closing price of our publicly traded stock on the date of grant and the vesting schedule is determined by the compensation committee at the time of grant.

Compensation Committee Interlocks and Insider Participation

None of our executive officers has served as a member of the Board of Directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our Board of Directors or Compensation Committee during the year ended December 31, 2022.

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 March 22, 2023 for (a) the named executive officers, (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 22, 2023 pursuant to the exercise of options or warrants to be outstanding 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 27,493,123 shares of common stock outstanding on March 22, 2023.

Security Ownership of Greater than 5% Beneficial Owners

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership [1]	Percent[1]
Yehuda Nir c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	8,718,861[2]	24.08%

Security Ownership of Directors and Executive Officers

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership [1]	Percent[1]
Vered Caplan c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	1,210,257[3]	4.26%
Neil Reithinger 14201 N. Hayden Road, Suite A-1 Scottsdale, AZ 85260	128,959[4]	<1%
Efrat Assa Kunik c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	52,292[5]	<1%
Guy Yachin c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	131,267[6]	<1%
Dr. David Sidransky c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	153,851[7]	<1%
Yaron Adler c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	188,721[8]	<1%
Ashish Nanda c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	82,550[9]	<1%
Mario Philips c/o Orgenesis Inc. 20271 Goldenrod Lane Germantown, MD 20876	46,250[10]	<1%

Directors & Executive Officers as a Group (8 persons)	1,994,147	7.25%

Notes:

(1) Percentage of ownership is based on 27,493,123 shares of our common stock outstanding as of March 22, 2023. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants or convertible debt currently exercisable, or convertible or exercisable or convertible within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such options, warrants or convertible debt but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(2) Consists of (i) 10,016 shares of common stock, (ii) 453,294 shares of common stock issuable upon exercise of outstanding warrants at a price of $6.24 per share, exercisable until January 31, 2026, (iii) 277,778 shares of common stock issuable upon exercise of outstanding warrants at a price of $4.50 per share, exercisable until January 31, 2026, (iv) 1,111,111 shares of common stock issuable upon exercise of outstanding warrants at a price of $2.50 per share, exercisable until January 31, 2026, and (v) 6,866,662 shares of common stock issuable upon conversion of convertible debt at a conversion price of $2.50 per share.

(3) Consists of (i) 278,191 shares of common stock, (ii) 230,189 shares of common stock issuable upon exercise of outstanding options at a price of $0.0012 per share, (iii) 166,667 shares of our common stock issuable upon exercise of outstanding options at a price of $4.80 per share, (iv) 83,334 shares of our common stock issuable upon exercise of outstanding options at a price of $7.20 per share, (v) 250,001 shares of our common stock issuable upon exercise of outstanding options at a price of $8.36 per share, (vi) 85,000 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (vii) 85,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share and (viii) 31,875 shares of our common stock issuable upon exercise of outstanding options at a price of $2.00 per share. Does not include option for 53,125 shares of common stock with an exercise price of $2.00 per share that are exercisable quarterly after March 31, 2023.

(4) Consists of (i) 83,334 shares of our common stock issuable upon exercise of outstanding options at a price of $4.80 per share, (ii) 25,000 shares of our common stock issuable upon exercise of outstanding options at a price of $5.07 per share, (iii) 15,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share and (iv) 5,625 shares of our common stock issuable upon exercise of outstanding options at a price of $2.00 per share. Does not include option for 9,375 shares of common stock with an exercise price of $2.00 per share that are exercisable quarterly after March 31, 2023.

(5) Consists of (i) 16,667 shares of our common stock issuable upon exercise of outstanding options at a price of $4.8 per share, (ii) 15,000 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (iii) 15,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share and (iv) 5,625 shares of our common stock issuable upon exercise of outstanding options at a price of $2 per share. Does not include option for 9,375 shares of common stock with an exercise price of $2 per share that are exercisable quarterly after March 31, 2023.

(6) Consists of (i) 41,667 shares of our common stock issuable upon exercise of outstanding options at a price of $4.80 per share, (ii) 28,750 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (iii) 25,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share, (iv) 16,250 shares of our common stock issuable upon exercise of outstanding options at a price of $4.60 per share, (v) 19,600 shares of our common stock issuable upon exercise of outstanding options at a price of $2.89 per share. Does not include option for 19,600 shares of common stock with an exercise price of $1.86 per share that are exercisable on December 23, 2023.

(7) Consists of (i) 20,834 shares of our common stock issuable upon exercise of outstanding options at a price of $9.00 per share, (ii) 41,667 shares of our common stock issuable upon exercise of outstanding options at a price of $4.80 per share, (iii) 29,200 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (iv) 25,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share, (v) 16,700 shares of our common stock issuable upon exercise of outstanding options at a price of $4.60 per share and (vi) 20,450 shares of our common stock issuable upon exercise of outstanding options at a price of $2.89 per share. Does not include option for 20,450 shares of common stock with an exercise price of $1.86 per share that are exercisable on December 23, 2023.

(8) Consists of (i) 63,304 shares of our common stock, (ii) 41,667 shares of our common stock issuable upon exercise of outstanding options at a price of $4.80 per share, (iii) 28,750 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (iv) 25,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share, (v) 15,000 shares of our common stock issuable upon exercise of outstanding options at a price of $4.60 per share and (vi) 15,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.89 per share. Does not include option for 15,000 shares of common stock with an exercise price of $1.86 per share that are exercisable on December 23, 2023.

(9) Consists of (i) 27,100 shares of our common stock issuable upon exercise of outstanding options at a price of $5.99 per share, (ii) 25,000 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share, (iii) 14,600 shares of our common stock issuable upon exercise of outstanding options at a price of $4.60 per share and (iv) 15,850 shares of our common stock issuable upon exercise of outstanding options at a price of $2.89 per share. Does not include option for 15,850 shares of common stock with an exercise price of $1.86 per share that are exercisable on December 23, 2023.

(10) Consists of (i) 6,250 shares of our common stock issuable upon exercise of outstanding options at a price of $4.70 per share, (ii) 12,500 shares of our common stock issuable upon exercise of outstanding options at a price of $2.99 per share, (iii) 13,750 shares of our common stock issuable upon exercise of outstanding options at a price of $4.60 per share and (iv) 13,750 shares of our common stock issuable upon exercise of outstanding options at a price of $2.89 per share. Does not include option for 13,750 shares of common stock with an exercise price of $1.86 per share that are exercisable on December 23, 2023.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2022:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1]	2,825,860	$ 4.17	1,174,140
Equity compensation plans not approved by security holders	726,780	$ 4.68	-
Total	3,552,640	$ 4.27	1,552,834

(1) Consists of the 2017 Equity Incentive Plan and the Global Share Incentive Plan (2012). For a short description of those plans, see Note 15 to our 2022 Consolidated Financial Statements included in this Annual Report on Form 10-K for the year ended December 31, 2022.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

Except as set out below, as of December 31, 2022, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest:

- any director or executive officer of our company;
- any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock;
- any promoters and control persons; and
- any member of the immediate family (including spouse, parents, children, siblings and in laws) of any of the foregoing persons.

Pursuant to a financial consulting agreement with Eventus Consulting, P.C., an Arizona professional corporation, of which Mr. Reithinger is the sole shareholder (“Eventus”), dated as of August 1, 2014, Mr. Reithinger received $108 thousand during the year ended December 31, 2022 and $240 thousand during the year ended December 31, 2021 for financial consulting services. Such amounts are included in Mr. Reithinger’s executive compensation presented in the Summary Compensation Table in Item 11 of this Annual Report on Form 10-K. Eventus has agreed to provide financial consulting services to the Company and in consideration for Eventus’ services, the Company agreed to pay Eventus according to its standard hourly rate structure. The term of the consulting agreement was for a period of one year from August 1, 2014 and automatically renews for additional one-year periods upon the expiration of the term unless otherwise terminated. Eventus is owned and controlled by Mr. Reithinger

Pursuant to our Audit Committee charter adopted in March 2017, the Audit Committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us have or will have a direct or indirect material interest.

Named Executive Officers and Current Directors

For information regarding compensation for our named executive officers and current directors, see "Executive Compensation."

Director Independence

See "Directors, Executive Officers and Corporate Governance – Director Independence" and "Directors, Executive Officers and Corporate Governance – Board Committees" in Item 10 above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our Board of Directors has appointed Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited ("PwC") as our independent registered public accounting firm for the years ended December 31, 2022 and 2021. The following table sets forth the fees billed to us for professional services rendered by PwC for the years ended December 31, 2022 and December 31, 2021:

	Years Ended December 31,	
Services:	**2022**	**2021**
Audit Fees (1)	$ 288,705	$ 228,188
Audit-Related Fees (2)	6,405	16,634
Tax Fees (3)	-	29,863
Total fees	$ 295,110	$ 274,685

(1) Audit fees consisted of audit work performed in the preparation of financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as statutory audits.

(2) Audit related fees consisted principally of audits of employee benefit plans and special procedures related to regulatory filings in 2022.

(3) The tax fees were paid for reviewing various tax related matters.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. ***Audit*** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. ***Other Fees*** are those associated with services not captured in the other categories. We generally do not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted, and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a)

c. Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

d. Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

e. Exhibits required by Regulation S-K

No.	Description
3.1	Articles of Incorporation, as amended (incorporated by reference to an exhibit to our registration statement on Form S-8, filed on August 7, 2020)
3.2	Amended and Restated Bylaws of the Company, as amended dated December 14, 2022 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 19, 2022)
4.1	Description of Securities (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2020)
4.2	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on January 22, 2020)
4.3	Form of Stock Option Agreement (incorporated by reference to an exhibit to our registration statement on Form S-8, filed on August 7, 2020)
4.4	Form of Warrant, dated as of September 13, 2021, issued in connection with Convertible Note Extension Agreements (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
4.5	Form of Warrant, dated as of September 13, 2021, issued in connection with Convertible Note Extension Agreements (incorporated by reference to an exhibit to our quarterly report filed on Form 10-Q, filed November 4, 2021)

4.6	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 5, 2022)
4.7	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on April 25, 2022)
4.8	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 17, 2022)
4.9	Form of Warrant (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 23, 2022)
4.10	Form of Nir Additional Warrant, dated as of October 23, 2022 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 27, 2022)
4.11	Form of Neumann Additional Warrant, dated as of October 23, 2022 (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 27, 2022)
10.1	Financial Consulting Agreement, dated August 1, 2014, with Eventus Consulting, P.C. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)
10.2	Personal Employment Agreement, dated August 1, 2014, by and between Orgenesis Inc. and Neil Reithinger (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 5, 2014)
10.3	2017 Equity Incentive Plan (incorporated by reference to an exhibit to our definitive proxy statement on Schedule 14A, filed on March 30, 2017)
10.4	Collaboration and License Agreement, dated as of June 8, 2018, between Orgenesis Inc. and Mircod Limited (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on October 12, 2018)
10.5	Controlled Equity Offering Sales Agreement, dated December 20, 2018, between Orgenesis Inc. and Cantor Fitzgerald & Co. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on December 20, 2018)
10.6	Joint Venture Agreement between the Company and First Choice International Company, Inc. dated March 12, 2019 (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on May 8, 2019)
10.7	Convertible Loan Agreement between Orgenesis Maryland Inc. and Yosef Ram dated April 12, 2019 (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on May 8, 2019)
10.8	Convertible Loan Agreement, dated April 10, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.9	Form of Subscription Agreement, dated May 17, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.10	Form of Subscription Agreement, dated May 30, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on form 10-Q, filed on November 7, 2019)
10.11	Form of Subscription Agreement, dated June 6, 2019, by and between the Company and Investor (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 7, 2019)
10.12	Transfer Agreement, dated as of August 7, 2019 by and among Masthercell Global, Orgenesis Inc. and GPP-II Masthercell, LLC (incorporated by reference to our current report on Form 8-K, filed on August 13, 2019)
10.13	Executive Directorship Agreement between the Company and Vered Caplan dated November 19, 2020 (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2021)
10.14	Swiss Employment Agreement between the Company and Vered Caplan dated November 19, 2020 (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 9, 2021)
10.15	Convertible Loan Agreement, dated as of August 24, 2021, between the Company and Image Securities FCZ (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)

10.16	Convertible Credit Line and Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yosef Dotan (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.17	Convertible Credit Line Extension Agreement, dated as of September 13, 2021, between the Company and Aharon Lukach (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.18	Unsecured Convertible Note Extension Agreement, dated as of September 13, 2021, between the Company and Yehuda Nir (incorporated by reference to an exhibit to our quarterly report on Form 10-Q, filed on November 4, 2021)
10.19	Employment Agreement, dated as of December 16, 2021, between the Company and Efrat Assa Kunik (incorporated by reference to an exhibit to our annual report on Form 10-K filed on March 30, 2022)
10.20	Securities Purchase Agreement, dated March 30, 2022, by and among the Company and certain investors (incorporated by reference to our current report on Form 8-K, filed on April 5, 2022)
10.21	Registration Rights Agreement, dated March 30, 2022, by and among the Company and certain investors (incorporated by reference to our current report on Form 8-K, filed on April 5, 2022)
10.22	Convertible Loan Agreement, dated April 21, 2022, by and among the Company and Yehuda Nir (incorporated by reference to our current report on Form 8-K, filed on April 25, 2022)
10.23	Amendment to Convertible Loan Agreement, dated May 16, 2022, by and among the Company and Yehuda Nir (incorporated by reference to our current report on Form 8-K, filed on May 16, 2022)
10.24	Convertible Loan Agreement, dated May 17, 2022, by and among the Company and Southern Israel Bridging Fund Two, LP (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 17, 2022)
10.25	Convertible Loan Agreement, dated May 19, 2022, by and among the Company and Ricky Neumann (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 23, 2022)
10.26	Convertible Note Extension Agreement, dated July 15, 2022, by and among the Company and J. Ezra Merkin (incorporated by reference to an exhibit to our current report on Form 8-K, filed on July 20, 2022)
10.27	Senior Secured Convertible Loan Agreement, dated August 15, 2022, by and among Morgenesis, Orgenesis, and the Lender (incorporated by reference to an exhibit to our current report on Form 8-K, filed on August 17, 2022)
10.28	Convertible Loan Extension Agreement, dated as of October 23, 2022, by and between the Company and Yehuda Nir (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 27, 2022)
10.29	Convertible Loan Extension Agreement, dated as of October 23, 2022, by and between the Company and Ricky Neumann (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 27, 2022)
10.30	Amendment, Consent and Waiver Agreement, dated as of October 23, 2022, by and between the Company and Ricky Neumann (incorporated by reference to an exhibit to our current report on Form 8-K, filed on October 27, 2022)
10.31	Unit Purchase Agreement dated as of November 4, 2022 by and among Orgenesis Inc., Morgenesis LLC and MM OS Holdings, L.P. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 7, 2022)
10.32	Form of Second Amended and Restated Limited Liability Company Agreement of Morgenesis LLC (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 7, 2022)
10.33	Services Agreement, dated as of November 4, 2022, by and between Morgenesis LLC and Orgenesis Inc. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 7, 2022)
10.34	Advisory Services and Monitoring Agreement dated as of November 4, 2022 by and between Morgenesis LLC and Metalmark Management II LLC. (incorporated by reference to an exhibit to our current report on Form 8-K, filed on November 7, 2022)
10.35	Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)
10.36	Appendix – Israeli Taxpayers Global Share Incentive Plan (2012) (incorporated by reference to an exhibit to our current report on Form 8-K, filed on May 31, 2012)
21.1*	List of Subsidiaries of Orgenesis Inc.
23.1*	Consent of independent registered public accounting firm
31.1*	Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1**	Certification Statement of the Chief Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2**	Certification Statement of the Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

*Filed herewith
**Furnished herewith

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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.

ORGENESIS INC.

By: */s/ Vered Caplan*
Vered Caplan
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: March 22, 2023

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)
Date: March 22, 2023

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

By: */s/ Vered Caplan*
Vered Caplan
Chief Executive Officer and Chairperson of the Board of Directors (Principal Executive Officer)
Date: March 22, 2023

By: */s/ Neil Reithinger*
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
Date: March 22, 2023

By: */s/ Guy Yachin*
Guy Yachin
Director
Date: March 22, 2023

By: */s/ David Sidransky*
David Sidransky
Director
Date: March 22, 2023

By: */s/ Yaron Adler*
Yaron Adler
Director
Date: March 22, 2023

By: */s/ Ashish Nanda*
Ashish Nanda
Director
Date: March 22, 2023

By: */s/ Mario Philips*
Mario Philips
Director
Date: March 22, 2023

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGENESIS INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2022

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and shareholders of Orgenesis Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orgenesis Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of comprehensive loss (income), change in equity and cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has suffered recurring losses from operations and has incurred cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Goodwill Impairment Assessment

As described in Note 2 and 8 to the consolidated financial statements, the Company's consolidated goodwill balance was $8 million at December 31, 2022. In the fourth quarter of 2022, following the separation of the Company's business into two operating segments, the Company reallocated goodwill to its newly reorganized reporting units (Morgenesis and Therapies) using a relative fair value approach. As a result, the goodwill associated with Morgenesis and Therapies reporting units were $7 million and $1 million, respectively. Based on this reallocation, the Company performed an impairment analysis for these two reporting units on the date of change. Fair value is estimated by management using a discounted cash flow model. Management's cash flow projections for the reporting units included significant judgments and assumptions relating to revenue growth rates, projected operating income and the discount rate.

The principal considerations for our determination that performing procedures relating to the goodwill impairment assessment is a critical audit matter are there was significant judgment by management when determining the fair value measurement of the reporting units; This in turn led to high degree of auditor judgment, subjectivity and effort in performing procedures and evaluate management's cash flow projections and significant assumptions including revenue growth rates, projected operating income and discount rate. In addition, the audit effort involved the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing management's process for developing the fair value estimate; evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy and relevance of underlying data used in the model; and evaluating the significant assumptions used by management, including the discount rate, revenue growth rates, and projected operating income. Evaluating management's assumptions related to revenue growth rates and projected operating income involved evaluating whether the assumptions used by management were reasonable considering (i) the current performance of the reporting units (ii) the consistency with external market and industry data, and (iii) whether these assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in the evaluation of Company's discounted cash flow model and certain significant assumptions, including the discount rate.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited
Tel Aviv, Israel

March 22, 2023

We have served as the Company's auditor since 2012.

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,311	$ 5,473
Restricted cash	1,058	501
Accounts receivable, net *	36,183	15,245
Prepaid expenses and other receivables	958	1,188
Convertible loan to related parties	2,688	3,064
Grants receivable	-	169
Inventory	120	118
Total current assets	46,318	25,758
NON CURRENT ASSETS:		
Deposits	$ 331	$ 363
Investments and loans to associates	135	584
Loans receivable	-	821
Property, plants and equipment, net	22,834	10,271
Intangible assets, net	9,694	11,821
Operating lease right-of-use assets	2,304	1,015
Goodwill	8,187	8,403
Deferred tax	103	-
Other assets	1,022	805
Total non-current assets	44,610	34,083
TOTAL ASSETS	$ 90,928	$ 59,841

* Including related party in the amount of $1,972 thousand as of December 31, 2021.

ORGENESIS INC.
CONSOLIDATED BALANCE SHEETS
(U.S. Dollars, in thousands, except share and per share amounts)

	December 31,	
	2022	2021
Liabilities and equity		
CURRENT LIABILITIES:		
Accounts payable	$ 4,429	$ 5,238
Accrued expenses and other payables	2,578	485
Income tax payable	289	54
Employees and related payables	1,860	1,907
Advance payments on account of grant	1,578	1,238
Contract liabilities	70	59
Current maturities of finance leases	60	18
Current maturities of operating leases	542	481
Short-term and current maturities of convertible loans	4,504	5,885
TOTAL CURRENT LIABILITIES	15,910	15,365
LONG-TERM LIABILITIES:		
Non-current operating leases	$ 1,728	$ 561
Convertible loans	13,343	4,854
Retirement benefits obligation	163	101
Long-term debt and finance leases	95	41
Advance payments on account of grant	144	-
Other long-term liabilities	271	288
TOTAL LONG-TERM LIABILITIES	15,744	5,845
TOTAL LIABILITIES	31,654	21,210
REDEEMABLE NON-CONTROLLING INTEREST	30,203	-
EQUITY:		
Common stock of $0.0001 par value: Authorized at December 31, 2022 and December 31, 2021: 145,833,334 shares; Issued at December 31, 2022 and December 31, 2021: 25,832,322 and 24,567,366 shares, respectively; Outstanding at December 31, 2022 and December 31, 2021: 25,545,755 and 24,280,799 shares, respectively.	3	3
Additional paid-in capital	150,355	145,916
Accumulated other comprehensive income (loss)	(270)	207
Treasury stock 286,567 shares as of December 31, 2022 and December 31, 2021	(1,266)	(1,266)
Accumulated deficit	(121,261)	(106,372)
Equity attributable to Orgenesis Inc.	27,561	38,488
Non-controlling interests	1,510	143
TOTAL EQUITY	29,071	38,631
TOTAL LIABILITIES, REDEEMABLE NON-CONTROLLING INTEREST AND EQUITY	$ 90,928	$ 59,841

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (INCOME)
(U.S. Dollars, in thousands, except share and per share amounts)

	Years Ended December 31,	
	2022	**2021**
Revenues	$ 34,741	$ 31,646
Revenues from related party	1,284	3,856
Total revenues	36,025	35,502
Cost of revenues, development services and research and development expenses	27,066	36,644
Amortization of intangible assets	911	948
Selling, general and administrative expenses	15,589	14,710
Impairment expenses of intangible assets	1,061	-
Operating loss	8,602	16,800
Other income, net	(173)	(2,278)
Loss from extinguishment in connection with convertible loan	52	1,865
Financial expenses, net	1,971	1,292
Share in net loss of associated companies	1,508	272
Loss before income taxes	11,960	17,951
Tax expense	209	108
Net loss	$ 12,169	$ 18,059
Net income (loss) attributable to non-controlling interests	2,720	(6)
Net loss attributable to Orgenesis Inc.	$ 14,889	$ 18,053
Loss per share:		
Basic and diluted	$ 0.59	$ 0.74
Weighted average number of shares used in computation of Basic and Diluted loss per share:		
Basic and diluted	25,096,284	24,273,658
Comprehensive loss:		
Net loss	$ 12,169	$ 18,059
Other Comprehensive loss – Translation adjustment	477	541
Comprehensive loss	$ 12,646	$ 18,600
Comprehensive income (loss) attributed to non-controlling interests	2,720	(6)
Comprehensive loss attributed to Orgenesis Inc.	$ 15,366	$ 18,594

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. Dollars, in thousands, except share amounts)

	Common Stock								
	Number	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Treasury Shares	Accumulated Deficit	Equity Attributable to Orgenesis Inc.	Non-Controlling Interest	Par Value
Balance at January 1, 2021	24,167,784	$ 3	$ 140,397	$ 748	$ (250)	$ (88,319)	$ 52,579	$ 149	$ 52,728
Changes during the Year ended December 31, 2021:									
Stock-based compensation to employees and directors	-	-	1,349	-	-	-	1,349	-	1,349
Stock-based compensation to service providers	25,000	*	396	-	-	-	396	-	396
Exercise of options	13,750	*	64	-	-	-	64	-	64
Extinguishment in connection with convertible loan restructuring	-	-	1,848	-	-	-	1,848	-	1,848
Issuance of Shares due to exercise of warrants	305,523	*	1,862	-	-	-	1,862	-	1,862
Repurchase of treasury stock	(231,258)	-	-	-	(1,016)	-	(1,016)	-	(1,016)
Comprehensive loss for the period	-	-	-	(541)	-	(18,053)	(18,594)	(6)	(18,600)
Balance at December 31, 2021	24,280,799	$ 3	$ 145,916	$ 207	$ (1,266)	$ (106,372)	$ 38,488	$ 143	$ 38,631

*Represents an amount lower than $1 thousand

The accompanying notes are an integral part of these consolidated financial statement

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. Dollars, in thousands, except share amounts)

	Common Stock			Accumulated Other			Equity Attributable		
	Number	Par Value	Additional Paid-in Capital	Comprehensive Income (loss)	Treasury Shares	Accumulated Deficit	to Orgenesis Inc.	Non-Controlling Interest	Par Value
Balance at January 1, 2022	24,280,799	$ 3	$ 145,916	$ 207	$ (1,266)	$ (106,372)	$ 38,488	$ 143	$ 38,631
Changes during the Year ended December 31, 2022:									
Stock-based compensation to employees and directors	-	-	916	-	-	-	916	-	916
Stock-based compensation to service providers	-	-	66	-	-	-	66	-	66
Exercise of options	510,017	*	6	-	-	-	6	-	6
Issuance and modification of warrants with respect to convertible loans			950				950		950
Extinguishment in connection with convertible loan restructuring	-	-	226	-	-	-	226	-	226
Issuance of Shares	724,999	*	2,175	-	-	-	2,175	-	2,175
Issuance of shares related to acquisition of Mida	29,940	*	100	-	-	-	100	-	100
Non-Controlling Interest arising from a business combination	-	-	-	-	-	-	-	(1,353)	(1,353)
Comprehensive income (loss) for the period	-	-	-	(477)	-	(14,889)	(15,366)	2,720	(12,646)
Balance at December 31, 2022	25,545,755	3	150,355	(270)	(1,266)	(121,261)	27,561	1,510	29,071

*Represents an amount lower than $1 thousand

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

ORGENESIS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS(*)
(U.S. Dollars, in thousands)

	Years Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,169)	$ (18,059)
Adjustments required to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	982	1,745
Capital loss (gain), net	(170)	25
Share in loss of associated company	1,508	272
Depreciation and amortization expenses	1,978	1,864
Impairment expenses of intangible assets	1,061	-
Effect of exchange differences on inter-company balances	502	341
Net changes in operating leases	(61)	(4)
Interest expense accrued on loans and convertible loans	1,372	482
Loss from extinguishment in connection with convertible loan restructuring	52	1,865
Changes in operating assets and liabilities:		
Increase in accounts receivable	(21,051)	(12,178)
Decrease (increase) in inventory	(7)	55
Decrease (increase) in other assets	26	(18)
Decrease (increase) in prepaid expenses, other accounts receivable	391	(173)
Decrease in accounts payable	(1,321)	(3,755)
Increase (decrease) in accrued expenses and other payable	1,570	(248)
Increase (decrease) in employee and related payables	(216)	487
Decrease in contract liabilities	10	-
Change in advance payments and receivables on account of grant, net	722	433
Change in deferred taxes, net	(103)	-
Net cash used in operating activities	$ (24,924)	$ (26,866)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in convertible loan to related party partners	-	(3,000)
Repayment of convertible loan to related party partners	538	-
Increase in loan to associate entities	(4,131)	(430)
Loan granted	-	(818)
Repayment of loan granted	782	-
Sale of property, plants and equipment	246	-
Purchase of property, plants and equipment	(12,416)	(7,866)
Investment in associated company	-	(242)
Cash acquired from acquisition of Mida (see note 4)	702	-
Increase in cash from business combinations of TLABS and Orgenesis Austria (see note 13a)	160	-
Investment in long-term deposits	(14)	(28)
Net cash used in investing activities	$ (14,133)	$ (12,384)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of treasury stock	-	(1,016)
Proceeds from issuance of shares	2,181	1,926
Proceeds from issuance of convertible loans	19,150	-
Proceeds from transaction with redeemable non-controlling interest that do not acquire control of a subsidiary	20,000	-
Repayment of convertible loans and convertible bonds	(2,300)	(1,000)
Repayment of short and long-term debt	(46)	(16)
Grant received in respect of third party	1,396	-
Transfer of the grant received to third party	(803)	-
Net cash provided (used in) by financing activities	$ 39,578	$ (106)
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	521	(39,356)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (126)	$ (238)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	$ 5,974	$ 45,568

CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 6,369	$ 5,974
SUPPLEMENTAL NON-CASH FINANCING AND INVESTING ACTIVITIES		
Recognition of finance lease liability and right-of-use assets	$ 136	$ -
Recognition of operating lease liability and right-of-use assets	$ 432	$ -
Increase (decrease) in accounts payable related to purchase of property, plant and equipment	$ (383)	$ 331
Loan conversion for Redeemable non-controlling interest (See note 3)	$ 10,203	$ -
Issuance of common stocks in connection with the acquisition of Mida (see note 4)	$ 100	$ -
Extinguishment in connection with convertible loan restructuring	226	$ 1,848
CASH PAID DURING THE YEAR FOR:		
Interest	$ 458	$ 443

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

NOTE 1 – DESCRIPTION OF BUSINESS

a. General

Orgenesis Inc. is a global biotech company working to unlock the potential of CGTs in an affordable and accessible format. CGTs can be centered on autologous (using the patient's own cells) or allogenic (using master banked donor cells) and are part of a class of medicines referred to as advanced therapy medicinal products, or ATMPs. The Company is mostly focused on autologous therapies that can be manufactured under processes and systems that are developed for each therapy using a closed and automated approach that is validated for compliant production near the patient for treatment of the patient at the point of care, or POCare. This approach has the potential to overcome the limitations of traditional commercial manufacturing methods that do not translate well to commercial production of advanced therapies due to their cost prohibitive nature and complex logistics to deliver such treatments to patients (ultimately limiting the number of patients that can have access to, or can afford, these therapies).

To achieve these goals, the Company has developed a collaborative worldwide network of research institutes and hospitals who are engaged in the POCare model, or the Company's POCare Network, and a pipeline of licensed POCare advanced therapies that can be processed and produced under such closed and automated processes and systems, or POCare Therapies. The Company is developing its pipeline of advanced therapies and with the goal of entering into out-licensing agreements for them. The Company's cellular therapies, though defined as drug products, conceptually differ from other drug modalities in that they are based on reprogramming of cells sourced from the patient or from a donor. In most cases, they are individually produced per patient in a highly sterile and controlled environment, and their efficacy is optimized when administered a short time following production as fresh product.

To advance the execution of the Company's goal of bringing such therapies to market, the Company has designed and built the Company's POCare Platform - a scalable infrastructure of technology and services that ensures a central quality system, replicability and standardization of infrastructure and equipment, and centralized monitoring and data management. The platform is constructed on POCare Centers that serve as hubs that implement locally the Company's POCare quality system, Good Manufacturing Practices, training procedures, quality control testing, incoming supply of materials and oversee the actual production in the Orgenesis Mobile Processing Units & Labs, or OMPULs. During the year ended December 31, 2022 the Company streamlined its POCare platform with the incorporation of a new subsidiary, Morgenesis, which became responsible for certain POC operations. This platform is utilized by other parties, such as biotech companies and hospitals for the supply of their products. Morgenesis services include adapting the process to the platform and supplying the products, or POCare Services. These are services for third party companies and for CGT's that are not necessarily based on the Company's POCare Therapies.

POCare Services

The POCare Services that the Company and its affiliated entities perform include:

- Process development of therapies, process adaptation, and optimization inside the OMPULs, or "OMPULization";
- Adaptation of automation and closed systems to serviced therapies;
- Incorporation of the serviced therapies compliant with GMP in the OMPULs that the Company designs and built;
- Tech transfers and training of local teams for the serviced therapies at the POCare Centers;
- Processing and supply of the therapies and required supplies under GMP conditions within the Company's POCare Network, including required quality control testing; and
- Contract Research Organization services for clinical trials.

The POCare Services are performed in decentralized hubs that provide harmonized and standardized services to customers, or POCare Centers. The Company is working to expand the number and scope of the Company's POCare Centers with the intention of providing an efficient and scalable pathway for CGT therapies to reach patients rapidly at lowered costs. Our POCare Services are designed to allow rapid capacity expansion while integrating new technologies to bring together patients, doctors and industry partners with a goal of achieving standardized, regulated clinical development and production of therapies.

POCare Services Operations via Subsidiaries

The Company currently conducts its core business operations itself and through Morgenesis and its subsidiaries which are all wholly owned except as otherwise stated below (collectively, the "Subsidiaries"). The following is a description of the Company's Subsidiaries:

Morgenesis LLC

In August 2022, the Company formed Morgenesis LLC, a subsidiary to hold substantially all the assets of the Company's POCare Services. The Company formed Morgenesis to streamline all existing POCare Service business units into one unified entity, bringing together a full-service range of solutions for therapeutic developers for point of care treatments. The newly formalized service offering provides solutions from initial process development, regulatory strategy and implementation, "OMPULization" which includes cGMP process development, closing/automating the process, and with the end goal of optimizing full cGMP processing and supply of therapeutic product to patients at the point of care. The Company currently owns 76.9% of Morgenesis.

During November 2022, the Company and MM OS Holdings, L.P. ("MM"), an affiliate of Metalmark Capital Partners ("Metalmark"), entered into a series of definitive agreements intended to finance, strengthen and expand the Company's POCare Services business (the "Metalmark Investment"). Pursuant to a unit purchase agreement (the "UPA"), MM purchased 3,019,651 Class A Preferred Units of Morgenesis (the "Class A Units"), which represents 22.31% of the outstanding equity interests of Morgenesis following the initial closing, for a purchase price of $30.2 million, comprised of (i) $20 million of cash consideration and (ii) the conversion of $10.2 million of MM's then-outstanding senior secured convertible loans previously entered into with MM. Under certain conditions related to Morgenesis' performance among others, MM has agreed to make future payments of up to $20 million in cash for additional Class A (or Class B) Units, and/or make a one-time cash payment of $10 million to Orgenesis (the "Earnout Payment"). In connection with the entry into of the UPA, the Company, Morgenesis and MM entered into the Second Amended and Restated Limited Liability Company Agreement (the "LLC Agreement") providing for certain restrictions on the disposition of Morgenesis securities, the provisions of certain options and rights with respect to the management and operations of Morgenesis, a right for MM to exchange any units of Morgenesis for shares of Orgenesis common stock and certain other rights and obligations. In addition, MM was provided certain protective rights in Morgenesis. (See note 3)

The Company transferred the following subsidiaries to Morgenesis:

- Orgenesis Maryland LLC, which is the center of POCare Services activity in North America and is currently focused on setting up and providing POCare Services and cell-processing services to the POCare Network.
- Tissue Genesis International LLC, which was formed in Texas in 2022, is currently focused on development of the Company's technologies and therapies.
- Orgenesis Services SRL, which was incorporated in 2022 and is currently focused on expanding the Company's POCare Network in Belgium.
- Orgenesis Germany GmbH, which is currently focused on providing CRO services to the POCare Network.
- Orgenesis Korea Co. Ltd., which is a provider of cell-processing and pre-clinical services in Korea. The Company owns 94.12% of the Korean Subsidiary.
- Orgenesis Biotech Israel Ltd., which is a provider of process development and cell-processing services in Israel.

POCare Therapies

The Company's POCare Network is an alternative to the traditional pathway of drug development. The Company collaborates with academic institutions and entities that have been spun out from such institutions. The Company is in close contact with researchers who are experts in the field of the drug and also partners with leading hospitals and research institutes. Based on such collaborations, the Company enters into in-licensing agreements with relevant institutions for promising therapies with the aim of adapting them to a point-of-care setting through regional or strategic biological partnerships. It then is able to out-license its own therapeutic developments, as well as those therapies developed from in-licensing agreements, to out-licensing partners at preferred geographical regions.

This approach lowers overall development costs through minimizing pre-clinical development costs incurred by the Company, and through receiving of the additional funding from grants and/or payments by regional partners.

The Company's therapies development subsidiaries are:

- Koligo Therapeutics, Inc., a Kentucky corporation, which is a regenerative medicine company, specializing in developing personalized cell therapies. It is currently focused on commercializing its metabolic pipeline via the POCare Network throughout the United States and in international markets.

- Orgenesis CA, Inc. a Delaware corporation, which is currently focused on development of technologies and therapies in California.

- Orgenesis Belgium SRL which is currently focused on product development. Since its incorporation, the subsidiary been awarded grants in excess of 18 million Euro from the Walloon region for several projects (DGO6 grants).

- Orgenesis Switzerland Sarl, which is currently focused on providing group management services.

- MIDA Biotech BV, which was acquired in 2022 and is currently focused on research and development activities, was granted a 4 million Euro grant under the European Innovation Council Pathfinder Challenge Program which supports cutting-edge science and technology. The grant is for technologies enabling the production of autologous induced pluripotent stem cells (iPSCs) using microfluidic technologies and artificial intelligence (AI).

- Orgenesis Italy SRL which was incorporated in 2022 and is currently focused on R&D activities.

- Orgenesis Ltd., an Israeli subsidiary which is focused on R&D and a provider of R&D management services for out licenced products. Israel as a hub for biotech research and pioneers in this field

- Orgenesis Australia PTY LTD, which was incorporated in 2022 and is currently focused on the development of the Company's technologies and therapies.

b. Liquidity

Through December 31, 2022, the Company had an accumulated deficit of $121 million as of December 31, 2022 and negative operating cashflows of $24.9 million in the year ended December 31, 2022. The Company's activities have been funded by generating revenue, offerings of the Company's securities and raising of loans. There is no assurance that the Company's business will generate sustainable positive cash flows to fund its business.

If there are further increases in operating costs for facilities expansion, research and development, commercial and clinical activity or decreases in revenues from customers, the Company will need to use mitigating actions such as to seek additional financing or postpone expenses that are not based on firm commitments. In addition, in order to fund the Company's operations until such time that the Company can generate sustainable positive cash flows, the Company may need to raise additional funds.

Current and projected cash resources and commitments, as well as other factors mentioned above, raise a substantial doubt about the Company's ability to continue as a going concern to meet the Company's current operations for the next 12 months. Management plans include raising additional capital to fund its operations, as well as exploring additional avenues to increase revenue and reduce capital expenditures. If the Company is unable to raise sufficient additional capital or meet revenue targets, it may have to curtail certain activities.

The estimation and execution uncertainty regarding the Company's future cash flows and management's judgments and assumptions in estimating these cash flows is a significant estimate. Those assumptions include reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

a. Use of Estimates in the Preparation of Financial Statements

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity, the amount of revenues and expenses and determining whether an acquisition is a business combination or a purchase of asset. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. The Company examined the impact of COVID-19 on the Company's financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

b. Business Combination

The Company allocates the fair value of consideration transferred in a business combination to the assets acquired, liabilities assumed, and non-controlling interests in the acquired business based on their fair values at the acquisition date. All assets and liabilities are recognized in fair value. The purchase price allocation process requires management to make significant estimates and assumptions, especially at the acquisition date with respect to intangible assets. Direct transaction costs associated with the business combination are expensed as incurred. The excess of the fair value of the consideration transferred plus the fair value of any non-controlling interest in the acquiree over the fair value of the assets acquired, liabilities assumed in the acquired business is recorded as goodwill. The allocation of the consideration transferred in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date. The cumulative impact of revisions during the measurement period is recognized in the reporting period in which the revisions are identified. The Company includes the results of operations of the business that it has acquired in its consolidated results prospectively from the date of acquisition.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquire is re-measured to fair value at the acquisition date; any gains or losses arising from such re-measurement are recognized in profit or loss.

c. Cash Equivalents

The Company considers cash equivalents to be all short-term, highly liquid investments, which include money market instruments, that are not restricted as to withdrawal or use, and short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

d. Cost of revenues, development services and research and development expenses

Cost of revenues, development services and research and development expenses include costs directly attributable to the conduct of research and development activities, including the cost of salaries, stock-based compensation expenses, payroll taxes and other employees' benefits, lab expenses, consumable equipment, courier fees, travel expenses, professional fees and consulting fees. All costs associated with research and developments are expensed as incurred. Participation from government departments and from research foundations for development of approved projects is recognized as a reduction of expense as the related costs are incurred. Research and development in-process acquired as part of an asset purchase, which has not reached technological feasibility and has no alternative future use, is expensed as incurred.

e. Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its Subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

f. Non-Marketable Equity Investments

The Company's investments in certain non-marketable equity securities in which it has the ability to exercise significant influence, but it does not control through variable interests or voting interests. These are accounted for under the equity method of accounting and presented as Investment in associates, net, in the Company's consolidated balance sheets. Under the equity method, the Company recognizes its proportionate share of the comprehensive income or loss of the investee. The Company's share of income and losses from equity method investments is included in share in losses of associated company.

The Company reviews its investments accounted for under the equity method for possible impairment, which generally involves an analysis of the facts and changes in circumstances influencing the investments.

For other investments, the Company applies the measurement alternative upon the adoption of ASU 2016-01 and elected to record equity investments without readily determinable fair values at cost, less impairment, adjusted for subsequent observable price changes. In this measurement alternative method, changes in the carrying value of the equity investments are reflected in current earnings. Changes in the carrying value of the equity investment are required to be made whenever there are observable price changes in orderly transactions for the identical or similar investment of the same issuer.

g. Fair value measurement

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below: Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs. Level 2: Observable inputs that are based on inputs not quoted on active markets, but corroborated by market data. Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

h. Functional Currency

The currency of the primary economic environment in which the operations of the Company and part of its Subsidiaries are conducted is the U.S. dollar ("$" or "dollar"). The functional currency of the Belgian Subsidiaries is the Euro ("€" or "Euro"). The functional currency of Orgenesis Korea is the Won ("KRW"). Most of the Company's expenses are incurred in dollars, and the source of the Company's financing has been provided in dollars. Thus, the functional currency of the Company and its other subsidiaries is the dollar. Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for nonmonetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions – exchange rates at transaction dates or average rates and (2) for other items (derived from nonmonetary balance sheet items such as depreciation) – historical exchange rates. The resulting transaction gains or losses are recorded as financial income or expenses. The financial statements of the Belgian Subsidiaries and Orgenesis Korea are included in the consolidated financial statements, translated into U.S. dollars. Assets and liabilities are translated at year-end exchange rates, while revenues and expenses are translated at yearly average exchange rates during the year. Differences resulting from translation of assets and liabilities are presented as other comprehensive income.

i. Inventory

The Company’s inventory consists of raw material for use for the services provided. The Company periodically evaluates the quantities on hand. Cost of the raw materials is determined using the weighted average cost method. The inventory is recorded at the lower of cost or net realizable value.

j. Property, plants and Equipment

Property, plants and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the related assets.

Annual rates of depreciation are presented in the table below:

	Weighted Average Useful Life (Years)
Production facility	3 – 10
Laboratory equipment	1 – 10
Office equipment and computers	3 – 17

k. Intangible assets

Intangible assets and their useful lives are as follows:

	Useful Life (Years)	Amortization Recorded at Comprehensive Loss Line Item
Customer Relationships	10	Amortization of intangible assets
Know-How	12	Amortization of intangible assets
Technology	15	Amortization of intangible assets
In-process research and development	Indefinite	

Intangible assets are recorded at acquisition less accumulated amortization and impairment. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated. The Company capitalizes IPR&D projects acquired as part of a business combination. On successful completion of each project, IPR&D assets are reclassified to developed technology and amortized over their estimated useful lives.

l. Goodwill

Goodwill represents the excess of consideration transferred over the value assigned to the net tangible and identifiable intangible assets of businesses acquired. Goodwill is allocated to reporting units expected to benefit from the business combination. Goodwill is not amortized but rather tested for impairment at least annually in the fourth quarter, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Following the Metalmark Investment, the Company conducted an analysis of its operations, which led to changes in the Company's identified reporting units, operating and reporting segments. As a result of the analysis, two operating units were identified: Morgenesis and Therapies. As a result, the Company reallocated its goodwill to the adjusted reporting units using a relative fair value allocation. Goodwill impairment is recognized when the quantitative assessment results in the carrying value exceeding the fair value, in which case an impairment charge is recorded to the extent the carrying value exceeds the fair value.

There were no impairment charges to goodwill during the periods presented.

m. Impairment of Long-lived Assets

The Company reviews its property, plants and equipment, intangible assets subject to amortization and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset class may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted cash flows. For indefinite life intangible assets, the Company performs an impairment test annually in the fourth quarter and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. The Company determines the fair value of the asset based on discounted cash flows and records an impairment loss if its book value exceeds fair value.

Impairment charges to customer relationships and IPR&D during the year ended December 31, 2022 were $1,061.

n. Income Taxes

1) With respect to deferred taxes, income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

2) The Company follows a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained on examination. If this threshold is met, the second step is to measure the tax position as the largest amount that is greater than 50% likely of being realized upon ultimate settlement.

3) Taxes that would apply in the event of disposal of investment in Subsidiaries and associated companies have not been taken into account in computing the deferred income taxes, as it is the Company's intention to hold these investments and not realize them.

o. Stock-based Compensation

The Company recognizes stock-based compensation for the estimated fair value of share-based awards. The Company measures compensation expense for share-based awards based on estimated fair values on the date of grant using the Black-Scholes option-pricing model. This option pricing model requires estimates as to the option's expected term and the price volatility of the underlying stock. The Company amortizes the value of share-based awards to expense over the vesting period on a straight-line basis.

p. Redeemable Non-controlling Interest

Non-controlling interests with embedded redemption features, whose settlement is not at the Company's discretion, are considered redeemable non-controlling interest. Redeemable non-controlling interests are considered to be temporary equity and are therefore presented as a mezzanine section between liabilities and equity on the Company's consolidated balance sheets. Redeemable non-controlling interests are measured at the greater of the initial carrying amount adjusted for the non-controlling interest's share of comprehensive income or loss or its redemption value. Subsequent adjustment of the amount presented in temporary equity is required only if the Company's management estimates that it is probable that the instrument will become redeemable. Adjustments of redeemable non-controlling interest to its redemption value are recorded through additional paid-in capital.

q. Loss per Share of Common Stock

Basic net loss (income) per share is computed by dividing the net loss (income) for the period by the weighted average number of shares of common stock outstanding for each period. Diluted net loss (income) per share is based upon the weighted average number of common shares and of common shares equivalents outstanding when dilutive. Common share equivalents include: (i) outstanding stock options and warrants which are included under the treasury share method when dilutive, and (ii) common shares to be issued under the assumed conversion of the Company's outstanding convertible loans and debt, which are included under the if-converted method when dilutive (See Note 14).

r. Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of principally cash and cash equivalents, bank deposits and certain receivables. The Company held these instruments with highly rated financial institutions and the Company has not experienced any significant credit losses in these accounts and does not believe the Company is exposed to any significant credit risk on these instruments apart of accounts receivable. The Company performs ongoing credit evaluations of its customers for the purpose of determining the appropriate allowance for doubtful accounts. As of December 31, 2022, the Company does not have credit losses with respect to these accounts and does not believe it is exposed to significant credit risk on these instruments.

Bad debt allowance is created when objective evidence exists of inability to collect all sums owed it under the original terms of the debit balances. Material customer difficulties, the probability of their going bankrupt or undergoing economic reorganization and insolvency, material delays in payments and other objective considerations by management that indicate expected risk of payment are all considered indicative of reduced debtor balance value.

s. Treasury shares

The Company repurchases its common stock from time to time on the open market and holds such shares as treasury stock. The Company presents the cost to repurchase treasury stock as a reduction of shareholders' equity. The Company did not reissue nor cancel treasury shares during the year ended December 31, 2022 and December 31, 2021.

t. Other Comprehensive Loss

Other comprehensive loss represents adjustments of foreign currency translation.

u. Revenue from Contracts with Customers

The Company's agreements are primarily service and processing contracts, the performance obligations of which range in duration from a few months to one year. The Company recognizes revenue when control of the services is transferred to the customer for an amount, referred to as the transaction price, which reflects the consideration to which the Company is expected to be entitled in exchange for those goods or services.

The Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between the time of transfer of the promised goods or services to the customer and the time the customer pays for these goods or services to be generally one year or less. The Company's credit terms to customers are in average between thirty and one hundred and fifty days.

Nature of Revenue Streams

The Company has three main revenue streams, which are POCare development services, cell process development services, including hospital supplies, and POCare cell processing.

POCare Development Services

Revenue recognized under contracts for POCare development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages are not interrelated or the customer is able to complete the services performed.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices.

The Company recognizes revenue when, or as, it satisfies a performance obligation. At contract inception, the Company determines whether the services are transferred over time or at a point in time. Performance obligations that have no alternative use and that the Company has the right to payment for performance completed to date, at all times during the contract term, are recognized over time. All other performance obligations are recognized as revenues by the Company at a point of time (upon completion). Revenues from support services provided to the Company's customers are recognized as and when the services are provided, because the customer simultaneously receives and consumes the benefits provided.

Significant Judgement and Estimates

Significant judgment is required to identifying the distinct performance obligations and estimating the standalone selling price of each distinct performance obligation and identifying which performance obligations create assets with alternative use to the Company, which results in revenue recognized upon completion, and which performance obligations are transferred to the customer over time.

Cell Process Development Services

Revenue recognized under contracts for cell process development services may, in some contracts, represent multiple performance obligations (where promises to the customers are distinct) in circumstances in which the work packages and milestones are not interrelated or the customer is able to complete the services performed independently or by using competitors of the Company. In other contracts when the above circumstances are not met, the promises are not considered distinct, and the contract represents one performance obligation. All performance obligations are satisfied over time, as there is no alternative use to the services it performs, since, in nature, those services are unique to the customer, which retain the ownership of the intellectual property created through the process.

For arrangements that include multiple performance obligations, the transaction price is allocated to the identified performance obligations based on their relative standalone selling prices. For these contracts, the standalone selling prices are based on the Company's normal pricing practices when sold separately with consideration of market conditions and other factors, including customer demographics and geographic location.

The Company measures the revenue to be recognized over time on a contract-by-contract basis, determining the use of either a cost-based input method or output method, depending on whichever best depicts the transfer of control over the life of the performance obligation.

Included in cell process development services is hospital supplies revenue, which is derived principally from the performance of services to hospitals or other medical providers. Revenue is earned and recognized when product and services are received by the customer.

POCare Cell Processing

Revenues from POCare Cell processing represent performance obligations which are recognized either over, or at a point of time. The progress towards completion is measured on an output measure based on direct measurement of the value transferred to the customer (units produced).

Change Orders

Changes in the scope of work are common and can result in a change in transaction price, equipment used and payment terms. Change orders are evaluated on a contract-by-contract basis to determine if they should be accounted for as a new contract or as part of the existing contract. Generally, services from change orders are not distinct from the original performance obligation. As a result, the effect that the contract modification has on the contract revenue, and measure of progress, is recognized as an adjustment to revenue when they occur.

v. Leases

The Company determines if an arrangement is a lease at inception. Lease classification is governed by five criteria in ASC 842-10-25-2. If any of these five criteria is met, The Company classifies the lease as a finance lease; otherwise, the Company classifies the lease as an operating lease. When determining lease classification, the Company's approach in assessing two of the mentioned criteria is: (i) generally 75% or more of the remaining economic life of the underlying asset is a major part of the remaining economic life of that underlying asset; and (ii) generally 90% or more of the fair value of the underlying asset comprises substantially all of the fair value of the underlying asset.

Operating leases are included in operating lease right-of-use (“ROU”) assets and operating lease liabilities in the consolidated balance sheet.

Finance leases are included in property, plants and equipment, net and finance lease liabilities in the consolidated balance sheet.

ROU assets represent Orgenesis’ right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments.

The standard also provides practical expedients for an entity’s ongoing accounting. The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means that for those leases, the Company does not recognize ROU assets or lease liabilities but recognizes lease expenses over the lease term on a straight-line basis.

Lease terms will include options to extend or terminate the lease when it is reasonably certain that Orgenesis will exercise or not exercise the option to renew or terminate the lease.

w. Segment reporting

Since the Metalmark Investment, the Company’s business includes two reporting segments: Morgenesis and Therapies. See note 5.

x. Recently adopted accounting pronouncements

In the first quarter of 2022, the Company early adopted Accounting Standards Update (“ASU”) ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40) (“ASU 2020-06”). The update simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and limiting the number of embedded conversion features separately recognized from the primary contract. The guidance also includes targeted improvements to the disclosures for convertible instruments and earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 in the first quarter of 2022 using the modified retrospective method which resulted with no material effect.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815- 40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (“ASU 2021-04”). The guidance is effective for the Company from January 1, 2022. The Company adopted ASU 2021-24 in the first quarter of 2022 which resulted in no material effect.

In November 2021, the FASB issued ASU 2021-10 “Government Assistance (Topic 832),” which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity’s financial statements. The Company applied the guidance prospectively to all in-scope transactions beginning fiscal year 2022. The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements

y. Recently issued accounting pronouncements, not yet adopted

In June 2016, the FASB issued ASU 2016-13 “Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments.” This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for Smaller Reporting Companies (SRCs, as defined by the SEC) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The Company will apply the guidance prospectively to transactions occurring on or after January 2023.

In October 2021, the FASB issued ASU 2021-08 “Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers”, which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, Revenue from Contracts with Customers. The guidance will result in the acquirer recognizing contract assets and contract liabilities at the same amounts recorded by the acquiree. The guidance should be applied prospectively to acquisitions occurring on or after the effective date. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. The Company plans to adopt the new accounting standard effective January 1, 2023 and will apply the guidance prospectively to all business combinations with an acquisition date occurring on or after January 2023.

NOTE 3 – REDEEMABLE NON-CONTROLLING INTEREST

Metalmarket Investment in Morgenesis LLC

On November 4, 2022, the Company and MM OS Holdings, L.P. (“MM”), an affiliate of Metalmark Capital Partners (“Metalmark”), entered into a series of definitive agreements (“MM agreement”) intended to finance, strengthen and expand the Company’s POCare Services business (the “Metalmark Investment”).

Pursuant to the Unit Purchase Agreement (the “UPA”), MM agreed to purchase 3,019,651 Class A Preferred Units of Morgenesis (the “Class A Units”), which represents 22.31% of the outstanding equity interests of Morgenesis following the initial closing, for a purchase price of $30,196 thousand, comprised of (i) $20,000 thousand of cash consideration and (ii) the conversion of $10,200 thousand of MM’s then-outstanding senior secured convertible loans previously entered into with MM pursuant to that certain Senior Secured Convertible Loan Agreement, dated as of August 15, 2022, between MM, Morgenesis and the Company. The investment was made at a pre-money valuation of $125,000,000, subject to customary adjustments for debt and accounts receivable and an adjustment related to a certain intercompany loan and closed on November 14, 2022. Following the initial closing, the Company held 77.69% of the issued and outstanding equity interests of Morgenesis.

If (a) Morgenesis and its subsidiaries generate Net Revenue (as defined in the UPA) equal to or greater than $30,000,000 during the twelve month period ending December 31, 2022 (the “First Milestone”) and/or equal to or greater than $50,000,000 during the twelve month period ending December 31 2023 (the “Second Milestone”), and (b) the Company’s shareholders approve the LLC Agreement Terms (as defined below under “Principal Terms of the LLC Agreement”) on the earlier of (x) the date that is seven (7) months following the initial closing date and (y) the date of the Company’s 2023 annual meeting of its shareholders (such stockholder approval hereafter being the “Orgenesis Stockholder Approval” and such Orgenesis Stockholder Approval deadline hereafter being the “Stockholder Approval Deadline”), in accordance with applicable law and in a manner that will ensure that MM is able to exercise its rights under the LLC Agreement (as defined below) without any further action or approval by MM, then MM will pay up to $10,000,000 in cash in exchange for 1,000,000 additional Class A Units if the First Milestone is achieved and $10,000,000 in cash in exchange for 1,000,000 Class B Units Preferred Units of Morgenesis (the “Class B Units”) if the Second Milestone is achieved. Notwithstanding the foregoing, if the First Milestone is not achieved, but Morgenesis and its subsidiaries generate Net Revenue equal or greater to $13,000,000 for the three months ending March 31, 2023, then MM shall make the first $10,000,000 future investment for 1,000,000 Class A Units described above. In the event that the Company fails to obtain Orgenesis Stockholder Approval by the Stockholder Approval Deadline, the Company will not be entitled to receive (but MM may, in its sole discretion, elect to make) the first $10,000,000 future investment or the second future $10,000,000 investment.

At any time until the consummation of a Company IPO or Change of Control (in each case, as defined in the LLC Agreement), MM may, in its sole discretion, elect to invest up to an additional $60,000,000 in Morgenesis (any such investment, an "Optional Investment") in exchange for certain Class C Preferred Units of Morgenesis (the "Class C Units" and, together with the Class A Units and the Class B Units, the "Preferred Units"). $10,000,000 of such Optional Investment shall be to purchase Class C-1 Preferred Units based on an enterprise value of $125,000,000, with such enterprise value adjusted by any net debt as of such time; $25,000,000 of Optional Investment shall be to purchase Class C-2 Preferred Units based on an enterprise value of $156,250,000, with such enterprise value adjusted by any net debt as of such time; and $25,000,000 of Optional Investment shall be to purchase Class C-3 Preferred Units based on an enterprise value of $250,000,000, with such enterprise value adjusted by any net debt as of such time.

The proceeds of the investment will generally be used to fund the activities of Morgenesis and its consolidated subsidiaries. In addition, if, during the twelve month period ending on December 31, 2023, Morgenesis and its subsidiaries generate (i) Net Revenue (as defined in the UPA) equal to or greater than $70,000,000, (ii) Gross Profit (as defined in the UPA) equal to or greater than $35,000,000 and (iii) EBITDA (as defined in the UPA) equal to or greater than $10,000,000, then MM shall make (or cause to be made) a one-time cash payment of $10,000,000 to the Company upon such payment becoming final and binding pursuant to the UPA (the "Earnout Payment").

In connection with the entry into the UPA, each of the Company, Morgenesis and MM entered into the Second Amended and Restated Limited Liability Company Agreement (the "LLC Agreement") providing for certain restrictions on the disposition of Morgenesis securities, the provisions of certain options and rights with respect to the management and operations of Morgenesis, a right for MM to exchange any units of Morgenesis for shares of the Company's common stock and certain other rights and obligations.

In connection with the entry into the UPA, each of the Company, Morgenesis and MM entered into a services agreement (the "Services Agreement") under which the Company will provide certain operational services to Morgenesis for an initial term of three years. Also, in connection with the entry into the UPA, each of Morgenesis and Metalmark Management II LLC, an affiliate of Metalmark ("MM Management"), entered into an advisory services and monitoring agreement (the "Monitoring Agreement") under which MM Management will provide certain analytical and financial and business monitoring services to Morgenesis. Under the Monitoring Agreement, MM Management will be paid a quarterly cash fee equal to 0.25% of the total amount invested by MM in Morgenesis as of the date of any payment and will be entitled to the reimbursement of certain expenses.

The Preferred Units have voting rights, may be converted into ordinary shares, and are prioritized over ordinary shares in case of dividend or redemption. The Company considers the provisions of Accounting Standards Codification Distinguishing Liabilities from Equity ("ASC 480") in order to determine whether the Preferred Units should be classified as a liability. If the instrument is not within the scope of ASC 480, the Company further analyzes the instrument's characteristics in order to determine whether it should be classified within temporary equity (mezzanine) or within permanent equity in accordance with the provisions of ASC 480-10-S99. The preferred units are not mandatorily or currently redeemable. However, they include a liquidation or deemed liquidation event that would constitute a redemption event that is outside of the Company's control. As such, all redeemable preferred units have been presented outside of permanent equity as a redeemable non-controlling interest.

The Company further analyzed and concluded that the future Preferred Units investments are considered embedded in the initial Preferred Units that were issued and are considered clearly and closely related to the host instrument and therefore should not be bifurcated.

NOTE 4 – ACQUISITIONS

Purchase of Mida Biotech BV

During February 2022, pursuant to the joint venture agreement between the Company and Mida Biotech BV, the Company purchased all the issued shares of Mida for a consideration of $100 thousand. In lieu of cash, the consideration was paid via 29,940 Company shares of Common Stock issued to Mida Biotech BV's shareholders.

Theracell Laboratories

See note 13a.

NOTE 5 – SEGMENT INFORMATION

Following the Metalmark Investment, the Company separated its operations into two operating segments: Morgenesis operations and therapies. Prior to that, the Company conducted all its operations as one segment. The Morgenesis operations includes mainly POCare Services, while the therapies segment includes the Company's therapeutic development operations.

Because the Company conducted all its operations as one segment prior to the Metalmark Investment, the above changes were reflected through retroactive revision of prior period segment information based on the subsidiaries that were transferred to Morgenesis. Certain activities of these subsidiaries have changed after they were transferred to Morgenesis operations segment.

The Company's Chief Executive Officer ("CEO"), who is the chief operating decision maker ("CODM"), reviews financial information prepared on a consolidated basis, accompanied by disaggregated information about revenues and contributed profit by the two identified reportable segments, namely Morgenesis and Therapies, to make decisions about resources to be allocated to the segments and assess their performance.

The Company does not review assets by segment. Therefore, the measure of assets has not been disclosed for each segment.

Segment data for the year ended December 31, 2022 is as follows:

	Morgenesis	Therapies	Eliminations	Consolidated
	(in thousands)			
Revenues	$ 33,884	$ 6,432	$ (5,575)	$ 34,741
Revenues from related party	1,284	-	-	1,284
Total revenues	35,168	6,432	(5,575)	36,025
Cost of revenues, development services and research and development expenses*	(17,373)	(13,350)	4,675	(26,048)
Operating expenses*	(7,762)	(8,678)	900	(15,540)
Other income, net	168	5	-	173
Depreciation and amortization	(1,006)	(972)	-	(1,978)
Impairment expenses	(420)	(641)	-	(1,061)
Loss from extinguishment in connection with convertible loan	-	(52)	-	(52)
Financial Expenses, net	(1,748)	(223)	-	(1,971)
Share in net income of associated companies	(1,352)	(156)	-	(1,508)
Income (loss) before income taxes	$ 5,675	$ (17,635)	$ -	$ (11,960)

*Excluding Depreciation, amortization and impairment expenses

Reconciliation of segment performance to loss for the year ended December 31, 2021:

	Morgenesis	Therapies	Eliminations	Consolidated
	(in thousands)			
Revenues	$ 31,211	$ 11,925	$ (11,490)	$ 31,646
Revenues from related party	3,856	-	-	3,856
Total revenues	35,067	11,925	(11,490)	35,502
Cost of revenues, development services and research and development expenses*	(21,096)	(24,000)	9,327	(35,769)
Operating expenses*	(3,545)	(13,287)	2,163	(14,669)
Other income, net	24	2,254	-	2,278
Depreciation and amortization	(1,020)	(844)	-	(1,864)
Loss from extinguishment in connection with convertible loan	-	(1,865)	-	(1,865)
Financial Expenses, net	(2,508)	1,216	-	(1,292)
Share in net income of associated companies	(15)	(257)	-	(272)
Income (loss) before income taxes	$ 6,907	$ (24,858)	$ -	$ (17,951)

*Excluding Depreciation, amortization and impairment expenses

NOTE 6 – EQUITY

a. Financings

In March 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement) with certain investors (collectively, the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a private placement (the "Offering"), an aggregate of 4,933,333 shares of the Company's Common Stock at a purchase price of $3.00 per share and warrants to purchase up to an aggregate of 1,000,000 shares of Common Stock at an exercise price of $4.50 per share. The warrants are not exercisable until after six months and expire three years from the date of issuance. The Company received proceeds of $2.175 million. The Company does not expect to receive the remaining $12.625 million from the defaulting investors. The Company issued an aggregate of 724,999 shares of Common Stock and warrants to purchase 146,959 shares of Common Stock pursuant to the Purchase Agreement. In connection with the Purchase Agreement, the Company and the Investors entered into a Registration Rights Agreement (the "Registration Rights Agreement"), pursuant to which the Company has agreed to register the resale of the Shares and Underlying Shares on a registration statement on Form S-3 (the "Registration Statement") to be filed with the United States Securities and Exchange Commission (the "SEC") by April 3, 2023.

b. Purchase of Mida Biotech BV

In connection with the acquisition of Mida, the Company issued 29,940 Common Stock to Mida's shareholders (See Note 4).

c. Warrants

A summary of the Company's warrants granted to investors and as finder's fees as of December 31, 2022, and December 31, 2021 and changes for the periods then ended is presented below:

	December 31,			
	2022		2021	
	Number of Warrants	Weighted Average Exercise Price $	Number of Warrants	Weighted Average Exercise Price $
Warrants outstanding at the beginning of the period	3,042,521	6.09	7,070,241	6.20
Changes during the period:				
Issued	2,978,575	3.16	926,413	6.24
Exercised	-	-	(319,811)	6.19
Expired	(639,636)	6.58	(4,634,323)	6.29
Warrants outstanding and exercisable at end of the period*	5,381,460	4.41	3,042,521	6.09

Amendment, Consent and Waiver Agreement

In October and November 2022, the Company and certain investors that were parties to the Securities Purchase Agreement of March 2022 (the "SPA") and the Registration Rights Agreement of March, 2022 (the "RRA") (see note 5(a)), entered into an Amendment, Consent and Waiver Agreement (the "RRA Amendment"). Pursuant to the RRA Amendment, the Company and the investors agreed to an extension of the date for filing the Registration Statement to register the Registrable Securities (as defined in the RRA) to April 3, 2023 and the effective date of such Registration Statement as provided for in the RRA Amendment; and (to) waive any potential damages or claims under the RRA with respect to the Company's obligations under the RRA or SPA and release the Company therefrom. In consideration for such consent, agreement, waiver and release, the Company agreed to issue additional warrants to purchase an aggregate of 215,502 shares of Common Stock to the investors (the "Additional PIPE Warrants") and such Additional PIPE Warrants shall have an exercise price of $2.50 per share of Common Stock, be exercisable beginning six months and one day after the applicable effective date and ending 36 months after the applicable effective date and be in the same form as the original Warrants issued pursuant to the SPA.

As of December 31, 2022 and December 31, 2021, there are no warrants that are subject to exercise price adjustments.

d. Treasury shares

During the year ended December 31, 2021, the Company repurchased its shares under a stock repurchase plan (the "Stock Repurchase Plan"). The following table summarizes the share repurchase activity pursuant to the Stock Repurchase Plan during the year ended December 31, 2021.

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs
January 2021	2,306	$ 4.45	$ 10,255
April 2021	8,850	4.49	39,730
May 2021	195,625	4.34	848,234
November 2021	24,477	4.32	105,806
	231,258	$ 4.34	$ 1,004,025

e. Controlled Equity Offering Sales Agreement

In December 2018, the Company entered into a Controlled Equity Offering Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of its common stock having an aggregate offering price of up to $25.0 million. The Company will pay Cantor a commission rate equal to 3.0% of the aggregate gross proceeds from each sale. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company's Shelf Registration Statement on Form S-3 (Registration No. 333-223777) that was declared effective by the Securities and Exchange Commission on March 28, 2018, or the Shelf Registration Statement, and a prospectus supplement and accompanying base prospectus that the Company filed with the Securities and Exchange Commission on December 20, 2018. The Company has not yet sold any shares of its common stock pursuant to the Sales Agreement.

NOTE 7 – PROPERTY, PLANTS AND EQUIPMENT

The following table represents the components of property, plants and equipment:

	December 31,	
	2022	2021
	(in thousands)	
Cost:		
Production facility	$ 3,944	$ 4,040
Office furniture and computers	589	555
Lab equipment	4,811	2,435
Advance payment	17,442	6,181
Subtotal	26,786	13,211
Less – accumulated depreciation	(3,952)	(2,940)
Total	$ 22,834	$ 10,271

Depreciation expense for the years ended December 31, 2022 and December 31, 2021 were $1,067 thousand and $916 thousand, respectively.

Property, plants and equipment, net by geographical location were as follows:

	December 31,	
	2022	2021
	(in thousands)	
Belgium	$ 1,095	$ 1,149
Greece	858	-
Netherlands	380	-
Korea	466	694
Israel	2,284	2,602
U.S.	17,751	5,826
Total	$ 22,834	$ 10,271

NOTE 8 – INTANGIBLE ASSETS AND GOODWILL

Changes in the carrying amount of the Company's goodwill for the years ended December 31, 2022 and 2021 are as follows:

	(in thousands)
Goodwill as of December 31, 2020	$ 8,745
Translation differences	(342)
Goodwill as of December 31, 2021	$ 8,403
Translation differences	(216)
Goodwill as of December 31, 2022	$ 8,187

Goodwill impairment assessment for the year ended December 31, 2022

In the fourth quarter of 2022, following the separation of the Company's business into two operating segments, the Company reallocated goodwill to its newly reorganized reporting units (Morgenesis and Therapies) using a relative fair value approach. As a result, the carrying amount of goodwill assigned to the Morgenesis segment reporting unit was $7 million and $1 million was assigned to the Therapies segment. The Company performed an impairment analysis for these two reporting units. Based on the Company's assessment as of date of the change in the reporting units, it was concluded that the fair value of each of the Morgenesis and Therapies reporting units exceeded its carrying amount and therefore no goodwill impairment was required.

In evaluating the fair value of reporting units under the income approach, the Company used a discounted cash flow model. Key assumptions used to determine the estimated fair value included: (a) internal cash flows forecasts for 5 years following the assessment date, including expected revenue growth, costs to produce, operating profit margins and estimated capital needs; (b) an estimated terminal value using a terminal year long-term future growth determined based on the growth prospects of the reporting units; and (c) a discount rate which reflects the weighted average cost of capital adjusted for the relevant risk associated with the Company's reporting unit operations and the uncertainty inherent in the Company's internally developed forecasts.

Actual results may differ from those assumed in the Company's valuation method. It is reasonably possible that the Company's assumptions described above could change in future periods. If any of these were to vary materially from the Company's plans, it may record impairment of goodwill allocated to any of these reporting units in the future.

Other Intangible Assets

Other intangible assets consisted of the following:

	December 31,	
	2022	2021
	(in thousands)	
Gross Carrying Amount:		
Know How	$ 2,735	$ 2,904
Customer relationships	345	811
Kyslecel Technology	9,340	9,340
IPR&D	-	641
Subtotal	12,420	13,696

Less – Accumulated amortization	(2,726)	(1,875)
Net carrying amount of other intangible assets	$ 9,694	$ 11,821

Intangible assets amortization expenses were approximately $911 thousand and $948 thousand for the years ended December 31, 2022 and December 31, 2021, respectively.

Following an annual impairment check, the Company determined that certain IPR&D and customer relationships intangible assets were no longer relevant. Therefore the Company wrote off IPR&D intangible assets in the amount of $641 thousand and customer relationship intangible assets in the amount of $420 thousand in the year ended December 31, 2022.

Estimated aggregate amortization expenses for the five succeeding years ending on December 31st are as follows:

	2023	2024 to 2027
	(in thousands)	
Amortization expenses	$ 840	$ 3,362

NOTE 9 – CONVERTIBLE LOANS

a. Long-Term Convertible Loans

Long-term convertible loans outstanding as of December 31, 2022 and December 31, 2021 are as follows:

Convertible Loans Outstanding as of December 31, 2022

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	NOTE	BCF
(in thousands)			(Years)			
$ 750	2018	2%	5	7.00	(1)+(5)	-
6,600	2019	6%-8%	3-5	7.00	(2)+(5)	-
100	2020	8%	3	7.00	(3)	-
9,150	2022	6%-10%	1-2	2.5-4.5	(4,5+6)	-
$ 16,600						

During January 2023 the Company and investors representing $12,250 of the convertible loans outstanding at December 31, 2022 agreed to extend the maturity of the loans to January 31, 2026, increase the annual interest rate to 10% effective February 1, 2023, increase the expiry date of related warrants to January 31, 2026, and change the loan conversion price to $2.50.

Convertible Loans Outstanding as of December 31, 2021

$ 750	*2018	2%	5	7.00	(1)+(5)	39
8,750	*2019	6%-8%	3-5	7.00	(2)+(5)	-
250	*2020	8%	3	7.00	(3)	-
$ 9,750						

*Extended

Convertible Loans repaid during the year ended December 31, 2022

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
150	2019	8%	2.5	$ 7	-
50	2019	6%	3	7	-
150	2020	8%	2.5	7	-
1,950	2019	6%-8%	3	4.5-7	-
2,300					

Convertible Loans repaid during the year ended December 31, 2021

Principal Amount	Issuance Year	Interest Rate	Maturity Period	Exercise Price	BCF
750	2019	8%	3	$ 7	31
250	2018	2%	2	7	-
1,000					

Apart from the items mentioned below there were no repayments of convertible loans during the years ended December 31, 2022 and December 31, 2021. In addition, except for the Metalmark Morgenesis loan conversion mentioned below there were no other conversions during the years ended December 31, 2022 and December 31, 2021.

(1)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 115,918 shares and 115,918 three-year warrants to purchase up to an additional 115,918 shares of the Company's common stock at a per share exercise price of $7. As of December 31, 2022, the loans are presented in current maturities of convertible notes in the balance sheet.

(2)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 1,069,602 shares and 1,011,781 three-year warrants to purchase up to an additional 1,011,781 shares of the Company's common stock at a per share exercise price of $7. As of December 31, 2022, $1,600 thousands of the principal amount is included in current maturities of convertible loans in the balance sheet and the remainder in long-term convertible loans. See also note 9(b).

(3)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 17,711 shares at a per share exercise price of $7. As of December 31, 2022, all the principal amount is included in short-term convertible loans in the balance sheet. See also note 9(b).

(4)The holders, at their option, may convert the outstanding principal amount and accrued interest under this note into a total of 3,678,575 shares at a per share exercise price of between $2.5 $4.5. As of December 31, 2022, all the principal amount is included in short-term convertible loans in the balance sheet. See also note 9(a)6.

(5)During the year ended December 31, 2021, the Company and certain convertible loan holders (including certain credit line investors, see note 9 (b)) agreed to extend the maturity date on loans due during the fourth quarter of 2021 to June 30, 2023. The loan repayment extension included the loan holders' right to request that the Company repay them on November 21, 2022 (the "Early Redemption Option"). In consideration for the extension, including for the credit line investors, warrants to purchase 926,413 shares of common stock of the Company were issued to the loan holders at an exercise price of $6.24 per share. During March 2022 the loan holders waived the early redemption option. Based on the analysis, the Company concluded that the change in terms should be accounted for as a modification.

The Company concluded that the change in the terms (including for the credit line investors extension) does not constitute a troubled debt restructuring. The Company therefore applied the guidance in ASC 470-50, Modifications and Extinguishments. The accounting treatment is determined by whether terms of the new debt and original debt are substantially different. The new debt and the old debt are considered "substantially different" pursuant to ASC 470-50 when the change in the fair value of the embedded conversion option is at least 10% of the carrying amount of the original debt instrument immediately before the modification or exchange or the value of the cash flows under the terms of the new debt instrument is at least 10% different from the present value of the remaining cash flows under the terms of the original instrument (including the incremental fair value resulting from issuing new warrants held by the lender). If the original and new debt instruments are substantially different, the original debt is derecognized and the new debt should be initially recorded at fair value, with the difference recognized as an extinguishment gain or loss. Based on the analysis, the Company concluded that the change in terms should be accounted for as an extinguishment. The extinguishment resulted in a loss of $1,865 thousand recorded in the 12 months ended December 31, 2021. The Company concluded that, since the warrants cannot be exercised prior to the expiry date of the Early Redemption Option, the warrants are considered embedded in the convertible loan and not freestanding instruments. It also concluded that the prepayment option and the embedded warrants should not be bifurcated from the debt host. In accordance with ASC 470-20-25-13, if a convertible debt instrument is issued at a substantial premium, there is a presumption that such premium represents paid-in capital. Since the fair value of the new convertible loan instrument issued as part of the change in terms are higher than the par value of the loan and the premium is substantial, the Company allocated the premium to paid in capital and the reminder to the convertible loan.

The fair value of the conversion feature was estimated using the binomial model. The total fair value of the new instruments is $4.4M (including the credit line agreements).

Following are the main estimates and assumptions that were used for the valuation of the new instruments as of the valuation date:

Parameter	8% Note	2% Note	Warrants
Notional (USD)	1,500,000	750,000	926,413
Accrued Coupon (USD)	224,603	41,945	-
Coupon Rate	8.00%	2.00%	-
Conversion Ratio (USD)	7.00	7.00	-
Exercise Price (USD)	-	-	6.24
Stock Price (USD)	5.02	5.02	5.02
Expected Term (years)	1.79	1.79	1.79
Risk Free Rate	0.20%	0.20%	0.20%
Volatility	72.84%	72.84%	72.84%
Yield	7.87%	7.84%	-

(6) During April and May 2022, the Company entered into three convertible loan agreements (the "Convertible Loan Agreements") with three non-U.S. investors (the "Lenders"), pursuant to which the Lenders loaned the Company an aggregate of $9.15 million (the "Loan Amount"). Interest is calculated at 6% per annum (based on a 365-day year) and is payable, along with the principal, during or before the third quarter of 2023. At any time prior to or on the maturity date, the Lenders may provide the Company with written notice to convert all or part of the loans into shares of Common Stock at a conversion price equal to $4.50 per share (subject to adjustment for certain capital events, such as stock splits) (the "Conversion Price"). In connection with such loans, we issued to the Lenders warrants representing the right to purchase an aggregate of 408,335 shares of Common Stock (which is 25% of the shares of the Company's Common Stock into which the loans are initially convertible at the Conversion Price), at an exercise price per share of $4.50 per share. Such warrants are exercisable at any time beginning six months and one day after the closing date and ending 36 months after such closing date.

On October 23, 2022, the Company entered into a Convertible Loan Extension Agreement with one of the Lenders, which amended the respective Lender's Convertible Loan Agreement for the $5,000,000 principal Loan Amount as follows: (i) the interest rate increased from 6% to 10% per annum as of April 21, 2022 on the unconverted and then outstanding loan amount; (ii) the maturity date was extended to January 20, 2024; (iii) the Company agreed to issue a warrant to the Lender for the right to purchase 1,111,111 shares of Common Stock, at an exercise price per share of $2.50 per share, which is exercisable at any time beginning April 23, 2023 and ending October 23, 2025; and (iv) the Conversion Price was amended to a price per share of $2.50 per share instead of $4.50 per share. Based on the analysis, the Company concluded that the change in terms should be accounted for as a modification.

In addition, on October 23, 2022, the Company entered into a Convertible Loan Extension Agreement with one of the Lenders, which amended the respective Lender's Convertible Loan Agreement for the $3,000,000 principal Loan Amount as follows: (i) the interest rate increased from 6% to 10% per annum as of May 19, 2022 on the unconverted and then outstanding loan amount; (ii) the maturity date was extended to February 19, 2024; (iii) the Company agreed to issue a warrant to the Lender for the right to purchase 666,666 shares of Common Stock, at an exercise price per share of $2.50 per share, which is exercisable at any time beginning April 23, 2023 and ending October 23, 2025; (iv) the prepayment terms were amended to allow the outstanding Loan Amount to be prepaid by the Company at the Lender's option following any financings by the parent Company, and in the event that any of the Company's subsidiaries raises financing, the Company will make reasonable commercial efforts to ensure the funds are received in order to repay the loan amount; and (v) the Conversion Price was amended to a price per share of $2.50 per share instead of $4.50 per share. Based on the analysis, the Company concluded that the change in terms should be accounted for as an extinguishment. The extinguishment resulted in a loss of $459 thousand. In accordance with ASC 470-20-25-13, if a convertible debt instrument is issued at a substantial premium, there is a presumption that such premium represents paid-in capital. Since the fair value of the new convertible loan instrument issued as part of the change in terms are higher than the par value of the loan and the premium is substantial, the Company allocated the premium to paid in capital and the reminder to the convertible loan. During January 2023, following the receipt of a loan financing (see note 21), the Company refunded the entire principal and accrued interest to the Lender).

b. Private Placements

During May 2019, the Company entered into a private placement subscription agreement with an investor for $5 million. The lender shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of (1) shares of common stock of the Company at a conversion price per share equal to $7.00 and (2) warrants to purchase an equal number of additional shares of the Company's common stock at a price of $7.00 per share.

In June 2019, the Company entered into private placement subscription agreements with lenders for an aggregate unsecured convertible note in the aggregate principal amount of $2 million. During the year ended December 31, 2022, the Company repaid the lenders the debt in full.

During 2019, the Company entered into a Private Placement Subscription Agreement and Convertible Credit Line Agreement (collectively, the "Credit Line Agreements") with certain non-U.S. investors (the "Lenders"), pursuant to which the Lenders furnished to the Company access to an aggregate $5.0 million credit line (collectively, the "Credit Line"). Pursuant to the terms of the Credit Line Agreements and the Notes, the total loan amount, and all accrued but unpaid interest thereon, became due and payable on the second anniversary of the Effective Date (the "Maturity Date"). The Maturity Date may be extended by each Lender in its sole discretion and shall be in writing signed by the Company and the Lender. Interest on any amount that has been drawn down under the Credit Line accrues at a per annum rate of eight percent (8%). At any time prior to or on the Maturity Date, by providing written notice to the Company, each of the Lenders is entitled to convert its respective drawdown amounts and all accrued interest, into shares of the Company's common stock, par value $0.0001 per share (the "Common Stock"), at a conversion price equal to $7.00 per share.

During the years ended December 2020, December 2021, and December 2022 the Company repaid principal amounts of $1,400 thousand, $750 thousand and $150 thousand respectively and a total interest amount of $31 thousand, $124 thousand and $29 thousand respectively to certain of the credit line investors.

In 2019, the Company entered into private placement subscription agreements with investors for an aggregate amount of $250 thousand. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into units of 1 share of common stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted the investors 183,481 warrants to purchase an equal number of additional shares of Common Stock at a price of $7.00 per share. The fair value of the warrants was $124 thousand using the fair value of the shares on the grant date. During the year ended December 31, 2021, the Company and the investors agreed to extend the maturity of the loans to December 2022. During the year ended December 2022, the Company and certain investors agreed to extend the maturity of the loans to December 2023. Based on the analysis, the Company concluded that the changes in terms should be accounted for as a modification.

During the year ended December 2022, the Company repaid a principal amount of $150 thousand and a total interest amount of $29 thousand to a certain investor.

In 2020, the Company entered into private placement subscription agreements with certain investors for an aggregate amount of $250 thousand of convertible loans. The lenders shall be entitled, at any time prior to or no later than the maturity date, to convert the outstanding amount, into shares of Common Stock of the Company at a conversion price per share equal to $7.00. In addition, the Company granted the investors 151,428 warrants to purchase an equal number of additional shares of Common Stock at a price of $7.00 per share. During 2021, the Company and the investors agreed to extend the maturity of the loans to December 2022. During the year ended December 2022, the Company repaid a principal amount of $150 thousand and a total interest amount of $29 thousand to a certain investor. During 2022, the Company and other investors agreed to extend the maturity of the loans to December 2023 and to extend the warrants maturity date to December 2023 and January 2024. Based on the analysis, the Company concluded that the change in terms should be accounted for as a modification.

c. Unsecured Convertible Notes

On November 2, 2016, the Company entered into unsecured convertible note agreements with accredited or offshore investors for an aggregate amount of NIS 1 million ($280 thousand). The loan bears a monthly interest rate of 2% and mature on May 1, 2017, unless converted earlier. On April 27, 2017 and November 2, 2017, the Company entered into extension agreements through November 2, 2017 and May 2, 2018, respectively.

In March 2018, the investor submitted a notice of its intention to convert into shares of the Company's common stock the principal amount and accrued interest of approximately $383 thousand outstanding. A related party of such investor at the same time, exercised warrants issued in November 2016 to purchase shares of the Company's Common Stock. The exercise price of the warrants and conversion price were fixed at $0.52 per share (pre-reverse stock split implemented by the Company in November 2017). There is a significant disagreement between the Company and these two entities as to the number of shares of Common Stock issuable to these entities, and they contend that the number of shares of Common Stock issuable to them should not consider the reverse stock split. The Company rejects these contentions in their entirety and, based on the advice of specially retained counsel, believes that these claims are without legal merit and not made in good faith. The Company intends to vigorously defend its interests and pursue other avenues of legal address. Through its counsel, the Company has advised these entities that unless they withdraw their request within a specified period, the Company will cancel the above referenced agreements and these parties' right to receive any shares of the Company's Common Stock. In April 2018, the Company withdrew the agreements and deposited the shares in total amount of 107,985 issued under those agreements and the principal amount and accrued interest of the loan in escrow account. The deposit of the principal amount and accrued interest presented as restricted cash in the balance sheet as of December 31, 2022.

d. Senior Secured Convertible Loan Agreement

In August 2022, Morgenesis entered into a senior secured convertible loan agreement (the "Agreement") with MM ("Lender") pursuant to which the Lender agreed to loan Morgenesis $10 million (the "Loan") at an interest rate of 8.0% paid-in-kind interest per annum (the "PIK Interest"), which shall be capitalized, compounded and added to the unpaid outstanding principal balance of the Loan on the applicable quarterly interest payment date and which, along with the principal, was scheduled to mature on March 29, 2023 (the "Maturity Date"). During the fourth quarter of 2022 the Loan was fully converted into preferred units of Morgenesis (see note 3).

NOTE 10 – LEASES

The Company leases research and development facilities, equipment and offices under finance and operating leases. For leases with terms greater than 12 months, the Company record the related asset and obligation at the present value of lease payments over the term. Many of the leases include rental escalation clauses, renewal options and/or termination options that are factored into the determination of lease payments when appropriate.

The Company's leases do not provide a readily determinable implicit rate. Therefore, the Company estimated the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

Manufacturing facilities

The Company leases space for its manufacturing facilities under operating lease agreements. The leasing contracts are for a period of 3 – 10 years.

Research and Development facilities

The Company leases space for its research and development facilities under operating lease agreements. The leasing contracts are for a period of 2 – 5 years.

Offices

The Company leases space for offices under operating leases. The leasing contracts are valid for terms of 5 years.

Lease Position

The table below presents the lease-related assets and liabilities recorded on the balance sheet:

	December 31,	
	2022	2021
Assets		
Operating Leases		
Operating lease right-of-use assets	$ 2,304	$ 1,015
Finance Leases		
Property, plants and equipment, gross	222	91
Accumulated depreciation	(68)	(33)
Property and equipment, net	$ 154	$ 58
Liabilities		
Current liabilities		
Current maturities of operating leases	$ 542	$ 481
Current maturities of long-term finance leases	$ 60	$ 18
Long-term liabilities		
Non-current operating leases	$ 1,728	$ 561
Long-term finance leases	$ 95	$ 41
Weighted Average Remaining Lease Term		
Operating leases	4.7 years	2.3 years
Finance leases	2.4 years	3.2 years
Weighted Average Discount Rate		
Operating leases	8.0%	6.9%
Finance leases	6.4%	2.0%

Lease Costs

The table below presents certain information related to lease costs and finance and operating leases:

	Years ended December 31,	
	2022	2021
Operating lease cost:	$ 546	514
Finance lease cost:		
Amortization of leased assets	43	20
Interest on lease liabilities	7	1
Total finance lease cost	$ 50	21

The table below presents supplemental cash flow information related to lease:

	Years ended December 31,	
	2022	2021
	(in Thousands)	
Cash paid for amounts included in the measurement of leases liabilities:		
Operating leases	$ 559	$ 526
Finance leases	$ 43	$ 20
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 432	$ -
Finance leases	136	-

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the finance lease liabilities and operating lease liabilities recorded on the balance sheet.

	Operating Leases	Finance Leases
Year ended December 31,		
2023	$ 681	$ 69
2024	539	69
2025	367	30
2026	213	-
2027	213	-
Thereafter	960	-
Total minimum lease payments	2,973	168
Less: amount of lease payments representing interest	(703)	(13)
Present value of future minimum lease payments	2,270	155
Less: Current leases obligations	(542)	(60)
Long-term leases obligations	$ 1,728	$ 95

Operating lease right-of-use assets by geographical location were as follows:

	December 31,	
	2022	2021
	(in thousands)	
Greece	$ 1,368	$ -
Korea	218	432
Israel	580	365
U.S.	138	218
Total	$ 2,304	$ 1,015

NOTE 11 – COMMITMENTS AND LICENSE AGREEMENTS

See Note 12 for additional commitments related to Collaborations.

a. Tel Hashomer Medical Research, Infrastructure and Services Ltd ("THM")

On February 2, 2012, the Company's Israeli Subsidiary entered into a licensing agreement with THM. According to the agreement, the Israeli Subsidiary was granted a worldwide, royalty bearing, exclusive license to trans-differentiation of cells to insulin producing cells, including the population of insulin producing cells, methods of making this population, and methods of using this population of cells for cell therapy or diabetes treatment developed by Dr. Sarah Ferber of THM.

As consideration for the license, the Israeli Subsidiary will pay the following to THM:

1) A royalty of 3.5% of net sales;
2) 16% of all sublicensing fees received;
3) An annual license fee of $15 thousand, which commenced on January 1, 2012 and shall be paid once every year thereafter. The annual fee is non-refundable, but it shall be paid each year against the royalty noted above, to the extent that such are payable, during that year; and
4) Milestone payments as follows:

    a. $50 thousand on the date of initiation of Phase I clinical trials in human subjects;
    b. $50 thousand on the date of initiation of Phase II clinical trials in human subjects;
    c. $150 thousand on the date of initiation of Phase III clinical trials in human subjects;
    d. $750 thousand on the date of initiation of issuance of an approval for marketing of the first product by the FDA; and
    e. $2 million when worldwide net sales of Products (as defined in the agreement) have reached the amount of $150 million for the first time, (the "Sales Milestone").

As of December 31, 2022, the Israeli Subsidiary had not reached any of these milestones.

In the event of closing of an acquisition of all of the issued and outstanding share capital of the Israeli Subsidiary and/or consolidation of the Israeli Subsidiary or the Company into or with another corporation ("Exit"), the THM shall be entitled to choose whether to receive from the Israeli Subsidiary a one-time payment based, as applicable, on the value of either 463,651 shares of common stock of the Company at the time of the Exit or the value of 1,000 shares of common stock of the Israeli Subsidiary at the time of the Exit.

b. Department De La Gestion Financiere Direction De L'analyse Financiere ("DGO6")

(1) On November 17, 2014, the Belgian Subsidiary received the formal approval from the DGO6 for a Euro 2 million ($2.4 million) support program for the research and development of a potential cure for Type 1 Diabetes. The financial support was composed of Euro 1.085 million (70% of budgeted costs) grant for the industrial research part of the research program and a further recoverable advance of Euro 930 thousand (60% of budgeted costs) of the experimental development part of the research program. In December 2014, the Belgian Subsidiary received advance payment of Euro 1.209 million under the grant. The grants are subject to certain conditions with respect to the Belgian Subsidiary's work in the Walloon Region. In addition, the DGO6 is also entitled to a royalty upon revenue being generated from any commercial application of the technology. In 2017 the Company received by the DGO6 final approval for Euro 1.8 million costs invested in the project out of which Euro 1.2 million funded by the DGO6. As of December 31, 2022, the Company repaid to the DGO6 a total amount of approximately $167 thousand and amount of $243 thousand was recorded in other payables.

(2) In April 2016, the Belgian Subsidiary received the formal approval from DGO6 for a Euro 1.3 million ($1.5 million) support program for the development of a potential cure for Type 1 Diabetes. The financial support was awarded to the Belgium Subsidiary as a recoverable advance payment at 55% of budgeted costs, or for a total of Euro 717 thousand ($800 thousand). The grant will be paid over the project period. The Belgian Subsidiary received advance payment of Euro 438 thousand ($537 thousand). Up through December 31, 2022, an amount of Euro 438 thousand ($537 thousand) was recorded as deduction of research and development expenses and an amount of Euro 74 thousand was recorded as advance payments on account of grant.

(3) On October 8, 2016, the Belgian Subsidiary received the formal approval from the DGO6 for a Euro 12.3 million ($12.8 million) support program for the GMP production of AIP cells for two clinical trials that will be performed in Germany and Belgium. The project will be conducted during a period of three years commencing January 1, 2017. The financial support is awarded to the Belgium subsidiary at 55% of budgeted costs, a total of Euro 6.8 million ($7 million). The grant will be paid over the project period. On December 19, 2016, the Belgian Subsidiary received a first payment of Euro 1.7 million ($2 million). As of December 31, 2022 the program is pending for extension approval.

In December 2020, the Belgian Subsidiary received the formal approval from DGO6 for a Euro 2.9 million ($3.5 million) support program for research on Dermatitis Treatments and Wound Healing Using Cell Regenerative Technologies. The financial support was awarded to the Belgium Subsidiary as a recoverable advance payment at 60% of budgeted costs, or for a total of Euro 1.7 million ($2.1 million). The grant will be paid over the project period. The Belgian Subsidiary received advance payments of Euro 301 thousand ($366 thousand) in 2020 and of Euro 392 thousand ($445 thousand) in 2021. The research program started in 2021. Up through December 31, 2022, an amount of Euro 247 thousand ($262 thousand) was recorded in research and development expenses.

c. Israel-U.S. Binational Industrial Research and Development Foundation ("BIRD")

On September 9, 2015, the Israeli Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with BIRD and Pall Corporation, a U.S. company. BIRD awarded a conditional grant of up to $400 thousand each (according to terms defined in the agreement), for a joint research and development project for the use of Autologous Insulin Producing (AIP) Cells for the Treatment of Diabetes (the "Project"). Company received a total of $299 thousand under the grant. The project was completed in 2019. The grant is to be repaid at the rate of 5% of gross sales generated from the Project. To date no sales have been generated.

d. Korea-Israel Industrial Research and Development Foundation ("KORIL")

On May 26, 2016, the Israeli Subsidiary and the Korean Subsidiary entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL. KORIL will make a conditional grant of up to $400 thousand to each company (according to terms defined in the agreement), for a joint research and development project for the use of AIP Cells for the Treatment of Diabetes (the "Project"). The Project started on June 1, 2016. The project was completed in 2021. The grant is to be repaid at the yearly rate of 2.5% of gross sales. To date no sales have been generated. As of December 31, 2022, the Israeli Subsidiary and the Korean Subsidiary received $597 thousand under the grant.

e. BIRD Secant

On July 30, 2018, Orgenesis Inc and OBI entered into a collaboration agreement with Secant Group LLC ("Secant"). Under the agreement, Secant will engineer and prototype 3D scaffolds based on novel biomaterials and technologies involving bioresorbable polymer microparticles, while OBI will provide expertise in cell coatings, cell production, process development and support services. Under the agreement, Orgenesis is authorized to utilize the jointly developed technology for its autologous cell therapy platform, including its Autologous Insulin Producing ("AIP") cell technology for patients with Type 1 Diabetes, acute pancreatitis and other insulin deficient diseases. In 2018, OBI entered into a Cooperation and Project Funding Agreement (CPFA) with the BIRD fund, which provided certain grant funding, and Secant.

As of December 31, 2022, OBI had received a total amount of $425 thousand under the grant and the project was completed. The grant is to be repaid at the yearly rate of 5% of gross sales. To date no sales have been generated.

f. BG Negev Technologies and Applications ("BGN").

On August 2, 2018, Company entered into a licensing agreement with BGN. According to the agreement, the Company was granted a worldwide, royalty bearing, exclusive license to develop and commercialize a novel alginate scaffold technology for cell transplantation focused on autoimmune diseases.

On November 25, 2018, the Company entered into a further licensing agreement with BGN. According to the agreement, the U.S. Subsidiary was granted a worldwide, royalty bearing, exclusive license to develop and commercialize technology directed to RAFT modification of polysaccharides and use of a bioreactor for supporting cell constructs.

As of December 31, 2022 no royalty incurring sales were made.

In January 2022, the Company terminated both of the licensing agreements with BGN effective April 26, 2022.

g. Sponsored Research and Exclusive License Agreement with Columbia University

Effective April 2, 2019, the Company and The Trustees of Columbia University in the City of New York, a New York corporation, ("Columbia") entered into a Sponsored Research Agreement (the "SRA") whereby the Company will provide financial support for studying the utility of serological tumor marker for tumor dynamics monitoring.

Effective April 2, 2019, the Company and Columbia entered into an Exclusive License Agreement (the "Columbia License Agreement") whereby Columbia granted to the Company an exclusive license to discover, develop, manufacture, sell, and otherwise distribute certain product in the field of cancer therapy. In consideration of the licenses granted under the Columbia License Agreement, the Company shall pay to Columbia (i) a royalty of 5% of net sales of any product sold which incorporates a licensed Columbia patent and (ii) 2.5% of net sales of other products. In addition, the Company shall pay a flat $100 thousand fee to Columbia upon the achievement of each regulatory milestone. As of December 31, 2022, no royalty incurring sales were made.

h. Regents of the University of California

In December 2019, the Company and the Regents of the University of California ("University") entered into a joint research agreement in the field of therapies and processing technologies according to an agreed upon work plan. According to the agreement, the Company will pay the University royalties of up to 5% (or up to 20% of sub-licensing sales) in the event of sales that includes certain types of University owned IP. As of December 31, 2022, no royalty incurring sales were made.

i. Caerus Therapeutics Inc

In October 2019, the Company and Caerus Therapeutics ("Caerus"), a Virginia company, concluded a license agreement whereby Caerus granted the Company an exclusive license to all Caerus IP relating to Advance Chemeric Antigen Vectors for Targeting Tumors for the development and/or commercialization of certain licensed products. In consideration for the License granted to the Company under this Agreement, the Company shall pay Caerus annual maintenance fees and royalties of sales of up to 5% and up to 18% of sub-license fees. As of December 31, 2022, no royalty incurring sales were made.

j. Tissue Genesis LLC

Included in the Koligo acquisition of 2020 were the assets of Tissue Genesis LLC. The Company is committed to paying the previous owners of Tissue Genesis LLC or their assignees up to $500 thousand upon the achievement of certain performance milestones and earn-out payments on future sales provided that in no event will the aggregate of the earn-out payments exceed $4 million. To date, no performance milestones have been reached.

k. University of Louisville research foundation ("ULRF")

Koligo had exclusively licensed patents and technology from the ULRF related to the revascularization and 3D printing of cell and tissue for transplant ("ULRF licensed products"). The Company is committed to utilizing commercial reasonable efforts to achieving certain milestones regarding the ULRF licensed products. Pursuant to the license, Company will pay ULRF royalties of 3.5% of sales and certain performance milestones. During the year ended December 31, 2021, Company paid $40 thousand under its obligations.

l. Neuro-Immunotherapy Exclusive License Agreement

During the year ended 2021, the Company entered into an exclusive license agreement in the field of neuro-immunotherapy. Pursuant to the agreement, the Company received an exclusive, worldwide, sublicensable, royalty-bearing license of certain technology and patents for the purpose of developing, manufacturing, using, and commercializing the licenced technology. Royalties of between 0.5% and 5% on royalty-bearing sales are payable for up to 15 years from the date of first sale in any country in which licensed products are sold, and sublicense fees are payable at the rate of 12% on sublicense income (but no less than two percent (2.0%) of sublicenses' net sales). Pursuant to the agreement, the Company is required to invest within thirty-six (36) months of the effective date an aggregate amount of at least $2 million in its efforts to develop the licensed technology. In 2023, the Company terminated this license agreement.

m. Savicell

During 2021, the Company and Savicell Ltd ("Savicell") entered into a collaboration agreement (the "Savicell Agreement") to collaborate in the evaluation, continued development, validation, and use of Savicell's platform designed for the early detection and diagnosis of diseases and conditions and for quality control and monitoring purposes, in conjunction with the Company's systems. Pursuant to the Savicell Agreement, the Company will provide to Savicell funding for the performance of certain tasks agreed upon by the parties in a work plan. In consideration for such funding, Savicell will supply the Company with products developed under the Savicell Agreement at preferential rates and grant to the Company a worldwide exclusive licence to sell such products in the Company's point-of-care network of hospitals, clinics and institutions for quality control and monitoring of manufacturing and processing of autologous immune cells manipulated by cell and gene therapies. The Company will be required to pay a 10% royalty for all gross sales of such products developed under the Savicell Agreement. As of December 31, 2022, no royalty incurring sales were made.

n. Stromatis Pharma

During 2021, the Company and Stromatis Pharma Inc. ("Stromatis") entered into a Collaboration and Sublicense Agreement (the "Stromatis Agreement") to collaborate in refining methods for GMP manufacturing of CAR-T/CAR-NK CT109; and the development and validation of the Stromatis technology as it relates to the CAR-T/CAR-NK CT109 antibody up to and inclusive of filing of Investigational New Drug Application relating to Stromatis' CAR-T/CAR-NK CT109 antibody ("Licensed Product"), in accordance with the agreed project plan ("Project"). The Company will fund the Project by providing Stromatis an amount of $1.2 million such funding to be provided based on approved projects. Stromatis will grant the Company certain perpetual, irrevocable royalty free and fully paid-up exclusive rights to manufacture, process and supply the Licensed Product ("Manufacturing Rights") and perpetual, irrevocable, royalty bearing exclusive rights to market and sell and offer for sale the Licensed Product within the Company's point of care network ("Marketing Rights"). As of December 31, 2022, no royalty incurring sales were made.

Stromatis has the option to convert the exclusive Manufacturing Rights to non-exclusive rights subject to repayment by Stromatis of an amount equal to funding provided by the Company and an additional payment by Stromatis of an ongoing revenue share of five percent (5%) of revenues of any kind received by Stromatis or its affiliates from the sale or transfer of Licensed Products or license of rights under the licensed technology in relation to the Licensed Products. The Company shall pay Stromatis in consideration for the Marketing Rights and royalties equal to 12% of net revenues of Licensed Products received by the Company. The Company advanced to Stromatis an initial sum of $500 thousand under the Stromatis Agreement, which was recorded as Cost of revenues, development services and research and development expenses.

o. Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)) ("HMGU")-

During 2021, HMGU granted an exclusive licence under HGMU owned patent rights and non-exclusive license under HGMU know how and licensed materials, to the Company in the field of certain human stem cells. In addition, payments will be due by the Company upon certain milestones. The agreement also includes payment of royalties of between 3% and 4% on net sales of licensed product (with a minimum annual royalty of Euro 200,000, creditable against royalties on net sales incurred during such contract year) and 5% in service revenues and payment of between 10% and 18% on sublicense revenues.

p. License and research agreement with Yeda Research and Development Company Limited

On January 25, 2022, the Company and Yeda Research and Development Company Limited ("Yeda"), an Israeli company, entered into a license and research agreement. Pursuant to the agreement, Yeda granted to the Company an exclusive, worldwide royalty bearing license to certain licensed information and the licensed patents, for the development, manufacture, use, offer for sale, sale and import of products in the field of tumor-infiltrating lymphocytes (TIL) and Chimeric antigen receptor (CAR) T cell immunotherapy platforms (excluding CAR-Cytokine Induced Killer cell immunotherapy). The Company undertook to make commercially reasonable efforts to develop and commercialize products in the field and to achieve certain milestones. In consideration for the grant of the License, the Company shall pay Yeda:

1. A non-refundable annual license fee of $10 thousand;
2. Royalties of up to 2% on net sales of licensed products;
3. 25% of all Other Receipts received in respect of a Sublicense first granted or an assignment of rights made prior to the achievement of the dosing of a first patient in a Phase I Clinical Trial; and (ii) 12.5% of all Other Receipts received in respect of a Sublicense first granted or an assignment of rights made on or after achievement of the dosing of a first patient in a Phase I Clinical Trial
4. Milestone Events payments:

    a. $50 thousand upon the dosing of a first patient in a Phase I Clinical Trial;
    b. $500 thousand upon the receipt of FDA marketing approval in respect of a product;
    c. $350 thousand upon receipt of marketing approval from a non-FDA regulatory agency in a major market territory (namely, a regulatory agency in Europe, Japan, China or Canada);
    d. $250 thousand upon receipt of marketing approval from an additional non-FDA major regulatory agency (namely, a regulatory agency in Europe, Japan, China or Canada);

5. Patent fees already incurred by Yeda in connection with the Licensed Patents and all future costs and fees relating to the filing, prosecution, and maintenance of the Licensed Patents; and
6. Research related expenses based on a budget to be agreed upon.

As of December 31, 2022, the Company recognized $120 thousand as expenses under this contract.

q. European Innovation Council and SMEs Executive Agency ("EISMEA")

During the year ended December 31, 2022, the Dutch Subsidiary, together with a consortium of other entities ("Consortium") and EISMEA entered into a grant funding agreement for the funding of the development of an artificial intelligence guided microfluidic device that standardizes the GMP production of autologous induced pluripotent stem cells (iSPSCs) at greatly reduced costs ("iPSC project"). The total grant amount is Euro 3.999 million of which the Dutch subsidiary is eligible to receive up to Euro 1.179 million. The project started on September 1, 2022 and is expected to end on August 31, 2026. The Dutch subsidiary is the consortium leader for the iPSC project. During the year ended 31 December 2022, the subsidiary received initial working capital in the amount of Euro 1.1920 million of which Euro 1.338 million was received on behalf of the other members of the Consortium and recorded in restricted cash, and Euro 582 thousand for the use of the subsidiary as per the grant agreement. As at December 31, 2022, the restricted cash related to the iPSC project was $609 thousand. During the year ended December 31, 2022, the Company recognized grant income of $73 thousand which was offset against research and development expenses.

NOTE 12 – COLLABORATIONS

a. Adva Biotechnology Ltd.

On January 28, 2018, the Company and Adva Biotechnology Ltd. ("Adva"), entered into a Master Services Agreement ("MSA"), pursuant to which the Company and/or its affiliates provided certain services relating to development of products for Adva.

In consideration for and subject to the fulfillment by the Company of certain funding commitments which were completed in 2019, Adva agreed that upon completion of the development of the products, the Company and/or its affiliates and Adva shall enter into a supply agreement pursuant to which for a period of eight (8) years following execution of such supply agreement, the Company and/or its affiliates (as applicable) is entitled (on a non-exclusive basis) to purchase the products from Adva at a specified discount pricing from their then standard pricing. The Company and/or its affiliates were also granted a non-exclusive worldwide right to distribute such products, directly or indirectly. The MSA shall remain in effect for 10 years unless earlier terminated in accordance with its terms.

b. Johns Hopkins University

During the year ended December 31, 2021, the Company and Johns Hopkins University entered into a sublease and construction agreement for the establishment of a clinical therapeutic development and point of care center in Maryland of approximately 6,830 rentable square feet. Pursuant to the agreement, the Company will pay for certain leasehold improvements in the premises according to plans and specifications to be agreed upon. The Company advanced $1,976 thousand for this purpose. The costs of the leasehold improvements will be offset by up to $5 million pursuant to a grant from the Board of Public Works of the State of Maryland to Johns Hopkins University. The annual base rent is initially $260 thousand per year, increasing to $324 thousand per year over the 10-year initial lease term. The Company has an option to renew the sublease for two additional periods of five years each under the same terms and conditions. The Company is expected to gain occupancy of the premises during the fourth quarter of 2024.

c. Joint Venture Agreements

The Company has entered into joint venture agreements ("JVAs") with its joint venture partners (Company and partner are referred to as "Parties") to facilitate the collaboration in the field of CGT. During 2022, the Company and / or JV partner continued the POCare Network expansion in each of the territories as relevant. The provisos and the table below summarize the major joint venture agreements. CGT and POCare activities covered by the JVAs include the development, marketing, clinical development, and commercialization of the Company's and / or partner's products within defined territories. The extent of the collaboration is set out in each agreement.

Unless otherwise stated in the table below the JVAs include the following provisos ("Provisos"):

1. The incorporation of a joint venture entity ("JVE") in which the Company or an assignee will hold between 49% and 51% of the equity.
2. The JV partner will manage the joint venture activities until the JVE is incorporated.
3. The JVE will be managed by a steering committee consisting of 3 members which will act as the entity's board of directors. The Company or assignee is entitled to appoint 1 member, the partner is entitled to appoint 1 member, and Company or assignee and partner will jointly appoint the third member.
4. The Company has the right to exercise a call option to acquire the JV partner's share in the JVE based on the occurrence of certain events and according to an agreed upon mechanism.
5. The funding of the parties' investment in the joint venture share may be made in the form of cash investment and / or in-kind services. The Company's or its assignee's cash investment may be in the form of additional shares, a convertible loan, and/or procured services.
6. Each of the Parties may agree to provide additional funding to the JVE to cover the operation costs and such additional funding may be in the form of in-kind contributions. The Company's or its assignee's investments may be made in the form of a cash investment for additional shares, a convertible loan, and/or procured services. Procured services refer to certain services that the Company or assignee has engaged the partner or the JVE to provide the Company or assignee with, in support of Company's or its assignee's activity. All results of these procured services shall be owned by Company or its assignee, as relevant.
7. As appropriate, the parties will grant to the JVE an exclusive or nonexclusive, sublicensable, royalty-bearing, right and license to the relevant party's background IP as required solely to manufacture, distribute and market and sell the party's products within the defined territory. Each party shall receive royalties in an amount of ten percent (10%) of the net sales generated by the JVE and/or its sublicensees with respect to the sale of such parties' products.
8. Once the JVE is profitable, under certain circumstances, the Company will be entitled (in addition to any of its rights as the holder of the JVE) to an additional share of fifteen percent (15%) of the JVE's GAAP profit after tax, over and above all rights granted pursuant to Company's participating interest in the JVE.
9. Unless otherwise stated, the relevant JVE had not been incorporated by December 31, 2022.

Name of party (and country of origin)	Territory	Notes
Theracell Advanced Biotechnology SA (Greece) and / or its related parties	European Union, Israel, Australia	(1) (5) & (11)
Broaden Bioscience and Technology Corp (USA)	Certain projects in China and the Middle East	(5) & (11)
Mircod LLC (US)	Russia (No POCare activities have taken place to date)	(2)
Image Securities FZC (UAE)	India and European Union	(3) (5) & (11)
Cure Therapeutics (Korea)	South Korea, Australia and Japan	(5) & (11)
Kidney Cure Ltd (Israel)	N / A	(4)
Educell D.O.O (Slovenia)	Croatia, Serbia and Slovenia	(6)
Med Centre for Gene and Cell Therapy FZ-LLC (UAE)	European Union and United Arab Emirates	(5) & (11)
First Choice International Company, Inc (USA)	Panama and certain other Latin American countries	(7)
SBH Sciences Inc (USA)	N / A	(8)
Revitas SA (Belgium)	N / A	(9)
Deep Med IO Ltd. (UK)	N / A	(10)

(1) The Theracell JVE was incorporated in Greece under the name of Theracell Laboratories Private Company ("Theracell Laboratories"). (See Note 13). In November 2021, the Company loaned approximately $800 thousand to Theracell which was repaid during 2022. The Company also loaned approximately $4,132 thousand as part of its obligations under the JVA to Theracell Laboratories. The 3-year loan bears interest at the annual rate of 8%.

(2) Under the Mircod JVA, provisos 7 and 8 do not apply. According to the Mircod JVA, subject to payment by the Company of the contribution amount, the JVA will grant Company an exclusive, perpetual, irrevocable, royalty free and fully paid up and sublicensable license to use the Project IP for research and development and for the manufacturing, processing, supplying, and use of products based on point of care manufacturing and/or processing of treatments for patients and for use in hospitals, medical centers and academic institution settings solely outside the territory. In order for the Company to fulfil its obligations pursuant to proviso 6, the Parties concluded a convertible loan agreement pursuant to which Company shall lend to Mircod Biotech Inc up to $5 million. Mircod Biotech Inc., performs technological development work ordered by Company. The loan bears simple interest in the amount of 6% annually. During 2021 and 2022, the Company had transferred $1,640 thousand and $435 thousand respectively under the loan agreement. The Company recorded the loan amounts as research and development expenses under ASC 730. As of December 31, 2022, the technological development work had not been completed.

(3) On August 24, 2021, the Company entered into a convertible loan agreement with Image whereby, pursuant to the terms of the Image joint venture agreement, the Company agreed to loan Image up to $5 million. The loan bears interest at the rate of 6%. The Company and Image have agreed to extend the maturity date of the loan to December 31, 2023. As of December 31, 2022, the outstanding balance under the loan agreement was $2.7 million, and this has been reflected as a short-term asset on the Company's balance sheet.

(4) The Kidney Cure JVE was incorporated in Switzerland under the name of Butterfly Biosciences Sarl ("BB") (See Note 13). The Company recorded the expenses paid to BB as research and development expenses under ASC 730. During the year ended December 31, 2022, development activities continued.

(5) During December 2022 the Company and the relevant joint venture partners agreed to replace the relevant JVAs to reflect updated partners' responsibilities and amend certain terms relating to future licence agreements and conversion mechanisms. In addition, it was agreed that Proviso 8 will be removed from these JVAs.

(6) During 2021, the Company and Educell entered into a convertible loan agreement whereby the Company, pursuant to its obligations under the JVA, agreed to loan up to $1.2 million. As of December 31, 2022, the Company had transferred $970 thousand under the loan agreement. The Company recorded the loan amounts as research and development expenses under ASC 730. The loan bears interest at the annual rate of 4.5% and is repayable after 5 years. At Company's election, the loan is convertible into equity of borrower, or JVE entity if incorporated, at a valuation to be determined by an independent third party.

(7) Under the First Choice JVA, each party shall, subject to fulfilment of the party's JVA, grant the Panama JV Entity an exclusive license to certain intellectual property of the part to develop and commercialize such party's products in the defined territory, subject to minimum sales obligations. In consideration of such license, the Panama JV shall pay the relevant party royalties at the rate of 15% of the Panama JVE net sales of such party's products sold in the defined territory. The First Choice JVE will be managed by a steering committee consisting of 5 members which will act as the

entity’s board of directors. Each of the Parties is entitled to appoint 2 members, and Company and partner will jointly appoint the fifth member. Under the First Choice JVA, provisos 5,6,7 and 8 do not apply. There was no material activity under the First Choice JVA during 2022.

(8) Pursuant to the SBH JVA the parties will collaborate in the field of gene and cell therapy development, process and services of bio-exosome therapy products and services in the areas of diabetes, liver cells and skin applications, including wound healing. According to the JVA, the board of directors of the SBH JVE shall be comprised of three directors with one appointed by SBH and two appointed by the Company. Provisos 7 and 8 do not apply to the SBH JVA. There was no material activity under the SBH JVA during 2022.

(9) The Revitas JVE was incorporated in Belgium under the name of RevaCel Srl during 2021 (See Note 13). The Company holds 51% of the share capital of RevaCel and has the right to appoint two members to the RevaCel board of directors. The Company's partner, Revatis SA, (a Belgian entity) holds the remaining 49% and has the right to appoint two members to the Revacel board of directors. The fifth RevaCel board member will be an independent industry expert appointed with the mutual agreement of the Company and Revatis SA. The Company recorded the expenses paid to Revitas and RevaCel under the JVA as research and development expenses under ASC 730. As part of the Company's agreement with Revatis under the Revatis joint venture agreement, the Company agreed to loan Revacel up to 2 million Euro at an annual interest rate of 8%. The loan is repayable in January 2025, and if not repaid, may be converted into shares of Revacel. As of the date of this Annual Report on Form 10-K, the Company had not made any transfers under the Revacel loan and there was no material activity under the SBH JVA during 2022.

(10) In November 2021, Deep Med IO Ltd ("Deep Med") and Company entered into a JVA. The Parties agreed to collaborate in the development and commercialization of an AI-powered system to be used in the manufacturing and/or quality control of CGTs. The Company has the right to finance its activities under the Deep Med JVA by procuring services, advancing funds under a convertible loan agreement, or by an equity investment. The Deep Med convertible loan bears interest at the annual rate of 6% and is repayable after 5 years. The Company has the right to convert its holdings under the loan into shares of Deep Med, or into shares of the Deep Med JV entity once established. Development work under the Deep Med JVA has continued according to the work plan agreed upon between the Company and Deep Med. During twelve months ended December 31, 2022, the Company transferred $1.9 million to Deep Med as part of its commitment under the Deep Med JVA. The Company recorded the amounts paid to Deep Med under the Deep Med JVA as research and development expenses under ASC 730.

(11) In January 2023, the Company assigned certain rights and obligations under the JVAs to Texas Advanced Therapies LLC, a Delaware Limited Liability company ("Texas AT") not related to the Company. Texas AT will receive the Company's option to require the incorporation of the JV Entity, Company's share in the JV Entity if and when the latter are incorporated, an option to invest additional funding in the JV Entity, and board and veto rights on certain critical decisions in the JV Entity. The Company has retained the call option to acquire the JV partner's share in the JVE, to receive a royalty and a right to conclude the Manufacturing and Service Agreement with the JV entity. Proviso 8 has been removed from these JVAs. The Company has no obligation to provide any additional funding to the JV entities.

NOTE 13 – INVESTMENTS AND LOANS TO ASSOCIATES, NET

a. Theracell Laboratories Private Company ("Theracell Laboratories" or "TLABS")

During 2020, the Company and Theracell, pursuant to the Greek JVA (See Note 12) incorporated the Greek JVA entity known as TLABS. The Theracell Project activities are run through TLABS. The Company and Theracell each hold a 50% participating interest in TLABS. Until December 31, 2022, due to the Company's significant influence over the JVE the Company applied the equity method of accounting. On December 31, 2022, the shareholders of Theracell Laboratories agreed to a change in the composition of the board of directors thus giving the Company effective control of Theracell Laboratories. See note 4.

Business combination

The following table summarizes the allocation of purchase price to the fair values of the assets acquired and liabilities assumed as of the transaction date:

	(in thousands)
Total assets:	
Cash and cash equivalents	$ 147
Prepaid expenses and other receivables	133
Orgenesis Accounts Receivable	241
Other long-term assets	281
Property, plants and equipment, net	858
Investments in associates, net	19
Operating lease right-of-use assets	1,368
Advanced payment for Accounts payable	366
Total assets	3,413
Total liabilities:	
Operating leases	1,368
Orgenesis loan	4,567
Other payable	184
Total liabilities	6,119
Total Net Liabilities	$ 2,706
Non-controlling interests (50%)	1,353
Total Net Liabilities (50%)	1,353

b. Butterfly Biosciences Sarl

During 2020, the Company and Kidney Cure (“KC”), pursuant to the Kidney Cure JVA (See Note 11) incorporated the KC JV Entity known as Butterfly Biosciences Sarl (“BB”) in Switzerland. BB will be involved in the (i) implementation of a point-of-care strategy; (ii) assessment of the options for development and manufacture of various cell-based types (including kidney derived cells, MSC cells, exosomes, gene therapies) development; and (iii) development of protocols and tests for kidney therapies. The Company holds a 49% participating interest in BB and Kidney Cure holds the remaining 51%. Due to the Company’s significant influence over the JVE the Company applies the equity method of accounting.

c. RevaCel

During 2021, the Company and Revatis S.A (“Revatis”), pursuant to the Revatis JVA (See Note 11) incorporated the Revatis JV Entity known as RevaCel Srl (“RevaCel”) in Belgium. RevaCel will develop products in the field of muscle-derived mesenchymal stem/progenitor cells. The Company holds a 51% participating interest in RevaCel and Revatis holds the remaining 49% and is entitled to appoint 2 of the 5 members of RevaCel’s board. Due to the Company’s significant influence over the JVE, the Company applies the equity method of accounting and is treated as an associated company. As part of the Revatis JVA, the Company and Revacel, the Company agreed to loan Revacel up to 2 million Euro at an annual interest rate of 8%. The loan is repayable in January 2025, and if not repaid, may be converted into shares of Revacel. As of the date of this annual report on Form 10-k, the Company had not made any transfers under the Revacel loan.

The table below sets forth a summary of the changes in the investments and loans for the years ended December 31, 2022 and December 31, 2021:

	December 31,	
	2022	2021
	(in thousands)	
Opening balance	$ 584	$ 175
Investments during the period	-	260
Loan to granted associates	4,131	441
Business Combinations	(3,156)	-
Interest from loans to associates	161	2
Share in net loss of associated companies	(1,508)	(272)
Exchange rate differences	(77)	(22)
Total	$ 135	$ 584

NOTE 14 – INCOME (LOSS) PER SHARE

The following table sets forth the calculation of basic and diluted loss per share for the periods indicated:

	Years ended December 31,	
	2022	2021
	(in thousands, except per share data)	
Basic and diluted:		
Net loss attributable to Orgenesis Inc.	$ 14,889	$ 18,053
Weighted average number of common shares outstanding	25,096,284	24,273,658
Net loss per share	$ 0.59	$ 0.74

For the year ended December 31, 2022, and December 31, 2021, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive. Diluted loss per share does not include 6,753,539 shares underlying outstanding options and warrants and 3,097,691 shares upon conversion of convertible loans for the year ended December 31, 2022, because the effect of their inclusion in the computation would be anti-dilutive. Diluted loss per share does not include 5,919,739 shares underlying outstanding options and warrants and 1,518,397 shares upon conversion of convertible loans for the year ended December 31, 2021, because the effect of their inclusion in the computation would be antidilutive.

NOTE 15 – STOCK-BASED COMPENSATION

a. Global Share Incentive Plan

The Company's stockholders have approved the 2017 Equity Incentive Plan (the "2017 Plan") under which, the Company had reserved a pool of 3,000,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this Plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of December 31, 2022, total options granted under this plan are 3,023,518 and the total options that are available for grants under this plan are 450,164.

On May 23, 2012, the Company's board of directors adopted the Global Share Incentive Plan 2012 (the "2012 Plan") under which, the Company had reserved a pool of 1,000,000 shares of the Company's common stock, which may be issued at the discretion of the Company's board of directors from time to time. Under this plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with the vesting schedule that will be determined by the Company's board of directors for each grant. The maximum contractual life term of the options is 10 years. As of December 31, 2022, total options granted under this plan are 1,415,008 and the total options that are available for grants under this plan are 161,974.

b. Options Granted to Employees and Directors

Below is a table summarizing all of the options grants to employees and Directors made during the years ended December 31, 2022, and December 31, 2021:

	Year Ended	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Employees	December 31, 2022	440,250	$2-$2.01	Quarterly over a period of two years	$ 559	10 years
Directors	December 31, 2022	84,650	1.86	On the one-year anniversary	$ 100	10 years
Employees	December 31, 2021	277,000	$2.96-$5.12	Quarterly over a period of two years	$ 812	10 years
Directors	December 31,2021	84,650	$ 2.89	On the one-year anniversary	$ 149	10 years

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on expected term. The expected option term is calculated using the simplified method, as the Company concludes that its historical share option exercise experience does not provide a reasonable basis to estimate its expected option term. The fair value of each option grant is based on the following assumptions:

	Years Ended December 31,	
	2022	2021
Value of one common share	$ 1.86-$2.01	$ 2.89-$5.12
Dividend yield	0%	0%
Expected stock price volatility	70%-71%	71%-77%
Risk free interest rate	3.61%-3.85%	0.96%-1.34%
Expected term (years)	5.5-5.56	5.5-5.56

A summary of the Company's stock options granted to employees and directors as of December 31, 2022 and December 31, 2021 is presented below:

	Years Ended December 31			
	2022		2021	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the period	3,210,005	4.05	2,917,667	4.05
Changes during the period:				
Granted	524,900	1.98	361,650	4.19
Exercised*	(510,017)	0.01	(13,750)	4.63
Expired	(125,426)	8.8	(20,813)	5.67
Forfeited	(63,997)	4.13	(34,749)	4.67
Cancelled	-	-	-	-
Options outstanding at end of the period	3,035,465	4.17	3,210,005	4.05
Options exercisable at end of the period	2,565,919	4.51	2,777,563	4.00

*During the year ended December 31, 2022, the Company received $6 thousand from the exercise of employee options for the purchase of 510,017 shares of the Company's Common Stock at a weighted average price of $0.012. During the year ended

December 31, 2021, the Company received $64 thousand from the exercise of employee options for the purchase of 13,750 shares of the Company's Common Stock at a weighted average price of $4.63.

The following table presents summary information concerning the options granted and exercisable to employees and directors outstanding as of December 31, 2022 (in thousands, except per share data):

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
0.0012	230,189	1.64	449	230,189	-
1.86	84,650	9.99	7	-	-
2.89	84,650	8.96	-	84,650	245
2	357,252	9.42	-	90,440	181
2.01	72,500	9.96	-	-	-
2.96	53,125	8.62	-	53,125	157
2.99	429,950	7.17	-	429,950	1,286
3.14	2,500	6.91	-	2,500	8
4.42	50,000	4.93	-	50,000	221
4.5	32,500	6.47	-	32,500	146
4.6	157,488	7.20	-	157,488	724
4.7	6,250	7.03	-	4,167	20
4.8	483,337	3.94	-	483,337	2,320
5.02	58,563	7.40	-	40,188	202
5.07	51,000	6.03	-	51,000	259
5.1	57,375	6.04	-	57,375	293
5.12	109,250	7.81	-	84,125	431
5.99	317,050	5.81	-	317,049	1,898
6	16,667	1.59	-	16,667	100
6.84	12,000	7.38	-	12,000	82
7.2	83,334	4.43	-	83,334	600
8.36	250,001	5.50	-	250,001	2,090
8.91	15,000	5.46	-	15,000	134
9	20,834	0.54	-	20,834	187
	3,035,465	6.23	456	2,565,919	11,584

Costs incurred with respect to stock-based compensation for employees and directors for the years ended December 31, 2022 and December 31, 2021 were $917 thousand and $1,349 thousand, respectively. As of December 31, 2022, there was $670 thousand of unrecognized compensation costs related to non-vested employees and directors stock options, to be recorded over the next 2 years.

c. Options Granted to Consultants and service providers

Below is a table summarizing all the compensation granted to consultants and service providers during the years ended December 31, 2022 and December 31, 2021:

	Year of grant	No. of options granted	Exercise price	Vesting period	Fair value at grant (in thousands)	Expiration period
Non-employees	2022	28,335	$ 2	Quarterly over a period of two years	$ 48	10 years
Non-employees	2021	7,500	$ 2.96	Quarterly over a period of two years	$ 22	10 years

The fair value of options granted during 2022 and 2021 to consultants and service providers, was computed using the Black-Scholes model. The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on historical volatility of the Company, by statistical analysis of the weekly share price for past periods based on the expected term period, the expected term is the contractual term of each grant. The underlying data used for computing the fair value of the options are as follows:

	Years Ended December 31,	
	2022	2021
Value of one common share	$ 2	$ 2.96
Dividend yield	0%	0%
Expected stock price volatility	84%	145%
Risk free interest rate	3.6%-3.61%	1.47%
Expected term (years)	10	10

A summary of the Company's stock options granted to consultants and service providers as of December 31, 2022, and December 31, 2021 is presented below:

	Years Ended December 31,			
	2022		2021	
	Number of Options	Weighted Average Exercise Price $	Number of Options	Weighted Average Exercise Price $
Options outstanding at the beginning of the year	547,691	5.89	549,141	5.89
Changes during the year:				
Granted	28,335	2.00	7,500	2.96
Expired	(58,851)	12.85	-	-
Forfeited	-	-	(8,950)	3.88
Cancelled	-	-	-	-
Options outstanding at end of the year	517,175	4.88	547,691	5.89
Options exercisable at end of the year	453,005	5.11	467,689	6.20

The following table presents summary information concerning the options granted and exercisable to consultants and service providers outstanding as of December 31, 2022 (in thousands, except per share data):

Exercise Price $	Number of Outstanding Options	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value $	Number of Exercisable Options	Aggregate Exercisable Options Value $
			(in thousands)		(in thousands)
2	28,335	9.46	-	-	-
2.96	7,500	8.96	-	-	-
2.99	35,000	7.22	-	35,000	105
3.36	136,775	3.32	-	136,775	459
4.09	25,000	6.76	-	25,000	102
4.42	5,125	4.93	-	5,125	23
4.5	13,335	6.53	-	5,000	23
4.6	20,000	7.96	-	4,000	18
4.8	16,668	3.94	-	16,668	80
5.07	5,000	6.19	-	1,000	5
5.3	15,000	5.70	-	15,000	80
5.99	16,670	5.81	-	16,670	100
6	90,000	1.59	-	90,000	540
6.84	7,500	7.38	-	7,500	51
7	70,000	6.83	-	70,000	490
8.34	8,600	5.52	-	8,600	72
8.43	8,333	5.05	-	8,333	70
11.52	8,334	0.26	-	8,334	96
	517,175	4.89	-	453,005	2,314

Costs incurred with respect to options granted to consultants and service providers for the years ended December 31, 2022 and December 31, 2021 were $64 thousand and $122 thousand, respectively. As of December 31, 2022, there was $115 thousands of unrecognized compensation costs related to non-vested consultants and service providers, to be recorded over the next 3.03 years.

d. Warrants and Shares Issued to Non-Employees

The fair value of Common Stock issued was the share price of the shares issued at the day of grant.

During the twelve months ended December 31, 2021, the Company issued 25,000 shares of common stock to a service provider.

NOTE 16 – TAXES

a. Corporate taxation in the U.S.

The corporate U.S. Federal Income tax rate applicable to the Company and its US subsidiaries is 21%.

As of December 31, 2022, the Company has an accumulated tax loss carryforward of approximately $22 million (as of December 31, 2021, approximately $29 million).

For U.S. federal income tax purposes, net operating losses ("NOLs") arising in tax years beginning after December 31, 2017, the Internal Revenue Code of 1986, as amended (the "Code") limits the ability to utilize NOL carryforwards to 80% of taxable income in tax years beginning after December 31, 2020. In addition, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and twenty-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods as well as the new limitation on use of NOLs may significantly impact the Company's valuation allowance assessments for NOLs generated after December 31, 2017.

In addition, utilization of the NOLs may be subject to substantial annual limitation under Section 382 of the Code due to an "ownership change" within the meaning of Section 382(g) of the Code. An ownership change subjects pre-ownership change NOL carryforwards to an annual limitation, which significantly restricts the ability to use them to offset taxable income in periods following the ownership change. In general, the annual use limitation equals the aggregate value of the Company's stock at the time of the ownership change multiplied by a specified tax-exempt interest rate.

b. Corporate taxation in Israel

The Israeli Subsidiaries are taxed in accordance with Israeli tax laws. The corporate tax rate applicable to 2022 and 2021 are 23%.

As of December 31, 2022, the Israeli Subsidiaries has an accumulated tax loss carryforward of approximately $10 million (as of December 31, 2021, approximately $11 million). Under the Israeli tax laws, carryforward tax losses have no expiration date.

c. Corporate taxation in Belgium

The Belgian Subsidiaries are taxed according to Belgian tax laws. The corporate tax rates applicable to 2022, 2021 are 25%.

As of December 31, 2022, the Belgian Subsidiary has an accumulated tax loss carryforward of approximately $7 million (€7 million), (as of December 31, 2021 $8 million). Under the Belgian tax laws there are limitation on accumulated tax loss carryforward deductions of Euro 1 million per year.

d. Corporate taxation in Korea

The basic Korean corporate tax rates are currently: 10% on the first KRW 200 million of the tax base, 20% up to KRW 20 billion, 22% up to KRW 300 billion and 25% for tax base above KRW 300 billion. In addition, the local income tax rate is 1% on the first KRW 200 million of taxable income, 2% on taxable income over KRW 200 million up to KRW 20 billion, 2.2% of taxable income over KRW 20 billion up to 300 billion and 2.5% on taxable income over KRW 300 billion.

As of December 31, 2022, the Korean subsidiary has an accumulated tax loss carryforward of approximately $3 million (KRW 4,404 million), (as of December 31, 2021, approximately $3 million). Under the Korean tax laws accumulated tax loss can be carry forwarded for 15 years.

e. Deferred Taxes

The following table presents summary of information concerning the Company's deferred taxes as of the years ending December 31, 2021 and December 31, 2021:

	December 31,	
	2022	2021
	(U.S. dollars in thousands)	
Deferred tax assets (liabilities), net:		
Net operating loss carry forwards	$ 10,387	$ 11,451
Research and development expenses	1,893	1,273
Equity compensation	1,616	2,631
Employee benefits	191	197
Property, plants and equipment	(55)	(206)
Leases asset	191	186
Lease liability	(132)	(134)
Loans	50	26
Partnership Investment	2,582	-
Intangible assets	(2,252)	(2,738)
Other	385	119
	14,856	12,805
Valuation allowance	(14,753)	(12,805)
Net deferred tax liabilities	$ 103	$ -

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forwards losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not considered more likely than not achievable, the Company and all its subsidiaries except the OBI Subsidiary have recorded full valuation allowance.

The changes in valuation allowance are comprised as follows:

	December 31,	
	2022	2021
	(U.S dollars in thousands)	
Balance at the beginning of year	$ (12,805)	$ (11,932)
Change during the year	(1,948)	(873)
Balance at end of year	$ (14,753)	$ (12,805)

f. Reconciliation of the Theoretical Tax Expense to Actual Tax Expense

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for valuation allowance with respect to tax benefits from carry forward tax losses.

g. Uncertain Tax Provisions

ASC Topic 740, "Income Taxes" requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. As of December 31, 2022, the Company has not accrued a provision for uncertain tax positions.

NOTE 17 – REVENUES

Disaggregation of Revenue

The following table disaggregates the Company's revenues by major revenue streams.

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenue stream:		
POCare development services	$ 14,894	$ 32,192
Cell process development services and hospital services	11,212	3,310
POCare cell processing	9,919	-
Total	$ 36,025	$ 35,502

A breakdown of the revenues per customer what constituted at least 10% of revenues is as follows:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenue earned:		
Customer A (Greece)	8,936	4,693
Customer B (United States)	8,316	6,491
Customer C (United Arab Emirates)	5,271	6,969
Customer D (Korea)	3,873	7,703

Contract Assets and Liabilities

Contract assets are mainly comprised of accounts receivable net of allowance for doubtful debts, which includes amounts billed and currently due from customers.

The activity for accounts receivable is comprised of:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Balance as of beginning of period	$ 15,245	$ 3,085
Business combination TLABS	(1,339)	-
Additions	35,103	34,570
Collections	(12,728)	(22,333)
Exchange rate differences	(98)	(77)
Balance as of end of period	$ 36,183	$ 15,245

The activity of the related party included in the accounts receivable activity above is comprised of:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Balance as of beginning of period	$ 1,972	$ 744
Additions	1,284	3,856
Collections	(1,070)	(2,628)
Ceased to be a related party	(2,186)	-
Balance as of end of period	$ -	$ 1,972

The activity for contract liabilities is comprised of:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Balance as of beginning of period	$ 59	$ 59
Additions	11	-
Balance as of end of period	$ 70	$ 59

NOTE 18 – COST OF REVENUES, DEVELOPMENT SERVICES AND RESEARCH AND DEVELOPMENT EXPENSES

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Salaries and related expenses	$ 11,206	$ 10,977
Stock-based compensation	616	729
Subcontracting, professional and consulting services	5,655	12,796
Lab expenses	2,685	3,513
Depreciation expenses, net	1,017	874
Other research and development expenses	6,010	7,755
Less grant	(123)	-
Total	$ 27,066	$ 36,644

NOTE 19 – FINANCIAL EXPENSES, NET

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Interest expense on convertible loans	$ 1,824	$ 943
Foreign exchange loss, net	145	574
Other expense (income)	2	(225)
Total	$ 1,971	$ 1,292

NOTE 20 – RELATED PARTIES TRANSACTIONS

a. Related Parties presented in the consolidated statements of comprehensive loss

	Years ended December 31,	
	2022	2021
	(in thousands)	
Stock-based compensation expenses to executive officers	$ 111	$ 247
Stock-based compensation expenses to Board Members	$ 152	$ 265
Compensation of executive officers	$ 669	$ 4,422
Management and consulting fees to Board Members	$ 380	$ 380
Revenues from customer	$ 1,284	$ 3,856
Financial income	$ 126	$ 64

b. Related Parties presented in the consolidated balance sheets

	December 31,	
	2022	2021
	(in thousands)	
Executive officers' payables	$ 80	$ 51
Non-executive directors' payable	$ 558	$ 178
Loan to Related Party	$ -	$ 3,064
Accounts receivable, net	$ -	$ 1,972

NOTE 21 – SUBSEQUENT EVENTS

a) Convertible loan agreements

On January 10, 2023 (the "Effective Date"), the "Company" entered into the following agreements: (i) a convertible loan agreement (the "NewTech Convertible Loan Agreement") with NewTech Investment Holdings, LLC (the "NewTech Lender"), pursuant to which the NewTech Lender loaned the Company $4,000,000 (the "NewTech Loan Amount"), and (ii) a convertible loan agreement (the "Malik Convertible Loan Agreement", together with the NewTech Convertible Loan Agreement, the "Convertible Loan Agreements") with Ariel Malik (the "Malik Lender", together with the NewTech Lender, the "Lenders"), pursuant to which the Malik Lender loaned the Company $1,000,000 (the "Malik Loan Amount", together with the NewTech Loan Amount, the "Loan Amount").

The terms of the NewTech Convertible Loan Agreement and the Malik Loan Agreement are identical. Interest is calculated at 8% per annum (based on a 365-day year); provided, that if an Event of Default (as defined in the Convertible Loan Agreements) has occurred and is continuing, the Outstanding Amount (as defined herein) will be calculated at 15.0% per annum. The Loan Amount and all accrued but unpaid interest thereon (collectively, the "Outstanding Amount") shall either (i) be repaid in cash or (ii) convert to shares of common stock, par value $0.0001 per share ("Common Stock"), of the Company on the third anniversary of the Effective Date (the "Maturity Date"). The Maturity Date may be extended by the Lender upon the written consent of the Lender. The Outstanding Amount may be prepaid by the Company in whole or in part at any time with the prior approval of the Lender.

At any time prior to or on the Maturity Date, any Lender may provide the Company with written notice to convert all or part of the Outstanding Amount into shares of the Company's Common Stock equal to the quotient obtained by dividing (x) the

Outstanding Amount by (y) a price equal to $2.464 per share (subject to adjustment for certain capital events, such as stock splits) (the "Conversion Price").

Under the terms of the Convertible Loan Agreements, the Company will use the proceeds from the Loan Amount to (i) redeem the loan amount referred to in note 9 (a) between the Company and the lender, and (ii) for general corporate purposes. The entire loan amount and accrued interest was repaid in January 2023.

The Company also agreed to issue the NewTech Lender warrants representing the right to purchase 405,844 shares of the Company's Common Stock, at an exercise price of $2.50 per share and the Malik Lender warrants representing the right to purchase 101,461 shares of the Company's Common Stock, at an exercise price of $2.50 per share. Such Warrants will be exercisable at any time beginning six months and one day after closing and ending 36 months after the closing date.

b) *Securities Purchase Agreement and Warrants*

On February 23, 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the issuance and sale of 1,947,368 shares of common stock, par value $0.0001 per share and warrants to purchase up to 973,684 shares of Common Stock at a purchase price of $1.90 per share of Common Stock and accompanying Warrants in a registered direct offering. The offering closed on February 27, 2023 and the Company received approximately $3.7 million, before deducting the placement agent's cash fee equal to 7% of the proceeds. The Company intends to use the net proceeds from the Offering for working capital and general corporate purposes, including the Company's therapy related activities.

NOTE 22 – LEGAL PROCEEDINGS

On January 18, 2022, a complaint (the "Complaint") was filed in the Tel Aviv District Court (the "Court") against the Company, the Israeli Subsidiary, Orgenesis Ltd., Prof. Sarah Ferber, Vered Caplan and Dr. Efrat Assa Kunik (collectively, the "defendants") by plaintiffs the State of Israel, as the owner of Chaim Sheba Medical Center at Tel Hashomer ("Sheba"), and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (collectively, the "plaintiffs"). In the Complaint, the plaintiffs are seeking that the Court issue a declaratory remedy whereby the defendants are required to pay royalties to the plaintiffs at the rate of 7% of the sales and 24% of any and all revenues in consideration for sublicenses related to any product, service or process that contains know-how and technology of Sheba and any and all know-how and technology either developed or supervised by Prof. Ferber in the field of cell therapy, including in the category of the point-of-care platform and any and all services and products in relation to the defendants' CDMO activity. In addition, the plaintiffs seek that the defendants provide financial statements and pay NIS 10 million to the plaintiffs due to the royalty provisions of the license agreement, dated February 2, 2012, between the Israeli Subsidiary and Tel Hashomer Medical Research, Infrastructure and Services Ltd. (the "License Agreement"). The Complaint alleges that the Company and the Israeli Subsidiary used know-how and technology of Sheba and know-how and technology either developed or supervised by Prof. Ferber while employed by Sheba in the field of cell therapy, including in the category of the point-of-care platform and the services and products in relation to the defendants' CDMO activity and are entitled to the payment of certain royalties pursuant to the terms of the License Agreement. The defendants have filed their statements of defense responding to this Complaint. The Company believes that the allegations in this Complaint are without merit and intends to vigorously defend itself against the claims. Since a material loss is not considered probable, no provision was made in the financial statements.

Except as described above, the Company is not involved in any pending material legal proceedings.