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NORTHWEST BIOTHERAPEUTICS INC

FORM 10-K

(Annual Report)

Filed 03/05/24 for the Period Ending 12/31/23

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CIK	0001072379
Symbol	NWBO
SIC Code	2834 - Pharmaceutical Preparations
Fiscal Year	12/31

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

FORM 10-K

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

For the fiscal year ended December 31, 2023

☐ 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: 001-35737

NORTHWEST BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3306718**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814
(Address of principal executive offices) (Zip Code)
(240) 497-9024
(Registrant's telephone number, including area code)

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 $0.001 per share	NWBO	OTCQB

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 (the "Exchange Act") 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 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 check mark 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 Exchange Act). Yes☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $17,219,000 on June 30, 2023.

As of February 28, 2024, the registrant had1,189,970,308 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2024.

NORTHWEST BIOTHERAPEUTICS, INC.
FORM 10-K

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PART I

This Report on Form 10-K for Northwest Biotherapeutics, Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “intend,” “anticipate,” believe,” “estimate” and “continue” or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions, and our actual results may differ materially from those anticipated in these forward-looking statements. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Factors that may cause such differences include, but are not limited to, those discussed under Item 1A of this Report, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change.

Unless the context otherwise requires, “Northwest Biotherapeutics,” the “Company,” “we,” “us,” “our” and similar names refer to Northwest Biotherapeutics, Inc. DCVax® is a registered trademark of the Company.

ITEM 1. BUSINESS.

Overview

We are a biotechnology company focused on developing personalized immune therapies for cancer. We have developed a platform technology, DCVax®, which uses activated dendritic cells to mobilize a patient’s own immune system to attack their cancer.

Our lead product, DCVax®-L, is designed to treat solid tumor cancers in which the tumor can be surgically removed. We have completed a 331-patient international Phase III trial of DCVax-L for Glioblastoma multiforme brain cancer (GBM), published the results in the JAMA Oncology peer reviewed journal, and on December 20, 2023 we submitted a Marketing Authorization Application (MAA) for commercial approval in the U.K. We plan to conduct clinical trials of DCVax-L for other solid tumor cancers in the future, when resources permit. Our second product, DCVax®-Direct, is designed to treat inoperable solid tumors. A 40-patient Phase I trial has been completed, and included treatment of a diverse range of more than a dozen types of cancers. We plan to work on preparations for Phase II trials of DCVax-Direct as resources permit.

The Company’s programs and operations continue to be impacted by supply chain issues and backlogs.These involve service firms and also vendors and suppliers of a wide variety of items, ranging from major equipment to particular reagents required for the manufacturing process. Shortages of certain key materials and supplies have also occurred. The Company is hopeful that the various backlog circumstances will improve in 2024.

The DCVax Technology

Our platform technology, DCVax, is a personalized immune therapy that uses a patient’s own dendritic cells, or DCs, the master cells of the immune system, as the therapeutic agent. The patient’s DCs are obtained through a blood draw, or leukapheresis. The DCs are then activated and loaded with biomarkers (“antigens”) from the patient’s own tumor. For DCVax-L, the antigen loading process takes place during the manufacturing of the product. For DCVax-Direct, the antigen loading process takes place *in situ* in the tumor after the product is directly injected into the patient’s inoperable tumor. The loading of antigens into the DCs “educates” the DCs about what the immune system needs to target.

Manufacturing of DCVax

We use a batch manufacturing technology for our DCVax products, and we believe this manufacturing approach is a key part of the practicality of our product and its economic feasibility. Generally, we are able to produce enough doses for the patient’s treatment regimen through just one manufacturing process. When a batch of DCVax product has been made, we then cryopreserve it.

Both of these technologies, the personalized batch manufacturing for each patient and the cryopreservation, are essential elements of our manufacturing model and product economics. Together, they enable us to usually incur the high costs of manufacturing just one

time for each patient, and then store the multi-year or multi-dose quantity of product, frozen, in single doses. This makes DCVax effectively an “off the shelf” product for the patient after the initial manufacturing, even though it is personalized, and we anticipate that this will enable the pricing of DCVax to be in line with other new cancer drugs. We also believe that both economies of scale and automation will further enhance the product economics. The manufacturing process today is also rapid: about eight days for DCVax-L, and seven days for DCVax-Direct, followed by quality control and release testing (including a sterility test that may take a couple of weeks).

As previously reported, we have been developing a manufacturing facility in Sawston, U.K. The Sawston facility contains a total of 88,345 square feet on two floors. The initial production capacity comprises two manufacturing suites, occupying approximately 4,400 square feet on the ground floor. These two suites, together with some additional support and storage space, have anticipated potential capacity to produce dendritic cell vaccines for about 40 to 45 patients per month, or approximately 450 to 500 patients annually. The buildout of Phases 1A and 1B of the facility have been completed. We also continue to conduct production activities in the GMP (clean room) facility in London.

On March 20, 2023, a MIA license was approved by the MHRA for commercial manufacturing of cell therapy products at the GMP facility in Sawston, U.K. A license from the Human Tissue Authority (HTA) for collection and handling of tumor tissue and immune cells had previously been obtained in October 2021, and a license for manufacturing products for clinical trials and compassionate use in the Sawston facility was approved by MHRA in December 2021.

Major progress was made in 2023 in the development of the Flaskworks system for a “closed” manufacturing process for DCVax-L. We completed the evaluation of three fundamentally different process approaches that the Flaskworks system could take, and chose the one that we believe will be optimal both operationally and to facilitate regulatory approval. We also completed most of the functional optimization of the Flaskworks system itself. A specialized contractor was engaged to produce GMP-compliant (i.e., clinical grade) versions of the prototype Flaskworks machine made with GMP grade materials. When the GMP-grade units are delivered, Advent BioServices will undertake qualification and validation of those units, conduct engineering runs and collect data, and apply to regulators for approval to use the system to produce DCVax-L for patients. As previously reported, the Company views the Flaskworks program and system as a centerpiece of efforts toward scale-up for potential commercial operations.

The initial production capacity occupies only a limited portion of the total space in the Sawston facility. In light of this, and in light of our obligation in connection with the buildout loan from the Cambridge development authority to make the Sawston facility benefit the regional business ecosystem and not just us, on December 31, 2021 we entered into a sub-lease for a small portion of the space to our contract manufacturer, Advent BioServices. For further details, please see Note 10 below. It is anticipated that, as and when feasible, the subleased space may enable some production of third-party cell therapy products. Such production of other products will fulfill the loan-related commitment to the Cambridge authority, will help support the capital-intensive Sawston facility costs and, in light of the growing demand for cell therapy manufacturing capacity, could substantially increase the asset value of the Sawston facility.

All of the development activities and licensing for the Sawston facility have been carried out or managed by Advent BioServices, who is also the contract operator of the facility.

Intellectual Property and Orphan Drug Designation

We have an integrated strategy for protection of our technology through both patents and other mechanisms, such as Orphan Drug status. As of December 31, 2023, we have 31 issued patents and 54 pending patent applications worldwide, grouped into 8 patent families. Of these, 27 issued patents and 39 pending patent applications directly relate to our DCVax products. In the United States and Europe, some of our patents and applications relate to compositions and the use of products, while other patents and applications relate to other aspects such as manufacturing. For example, in the United States, we have six issued patents and four pending patent applications that relate to the composition and/or use of our DCVax products. We also have other US patents and applications that cover, among other things, a potential method for determining the immunopotency of our dendritic cells produced by our manufacturing processes and an automated system which we believe will help enable the scale-up of production for large numbers of patients on a cost-effective basis. Similarly, in Europe, we have five patents, validated as 15 national patents, issued by and four pending patent applications with the European Patent Office (“EPO”) that cover our DCVax products, and other patents and applications that cover aspects such as manufacturing, a potential method for determining immunopotency of our manufactured products, and the automated system. In Japan, we have seven issued patents and four pending patent applications relating to our DCVax products, as well as manufacturing related patents. Patents have been granted or are pending in other foreign jurisdictions which may be potential future markets for our DCVax products.

During 2023, 5 new patents were issued to us as part of our worldwide patent portfolio. The newly issued patents cover methods for manufacturing dendritic cells related to our DCVax products, as well as encompassing certain methods of use and compositions which may be potential future markets for related DCVax products.

Additionally, with the acquisition of Flaskworks, we gained ownership of a portfolio of patents and patent applications which include those held by Flaskworks as well as patents and patent applications exclusively licensed by Flaskworks from Northeastern University. The portfolio includes a total of thirteen patent families, with issued patents and pending applications worldwide. Collectively these patents and patent applications cover key aspects of the design and function of automated cell culture systems.

The expiration dates of the issued US patents in our portfolio involved in our current business range from 2024 to 2036 and pending applications may involve longer time periods. The expiration date of the issued European patent involved in our current business is 2036, and pending applications may involve longer time periods. For some of the earlier dates, we plan to seek extensions of the patent life, and believe we have reasonable grounds for doing so.

Also, during 2023, various patents and patent applications were exclusively in-licensed from various academic institutions. These include patents and patent applications related to enhanced versions of dendritic cells (certain vaccine compositions, immunogenic peptide antigens, and cell - based immunotherapy compositions and methods for their use.

In addition to our patent portfolio, we have obtained Orphan Drug designation for our lead product, DCVax-L for glioma brain cancers. Such designation brings with it a variety of benefits, including potential market exclusivity for seven years in the US and ten years in Europe if our product is the first of its type to reach the market.

This market exclusivity applies regardless of patents (i.e., even if the company that developed it has no patent coverage on the product). In addition, the time period for such market exclusivity does not begin to run until product sales begin. In contrast, the time period of a patent begins when the patent is filed and runs down during the years while the product is going through development and clinical trials.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. A large and growing number of companies are actively involved in the research and development of immune therapies or cell-based therapies for cancer. In addition, many big pharma companies are rapidly commercializing checkpoint inhibitor drugs to “take the brakes off” patients’ immune responses to cancer. Other novel technologies for cancer are approved and commercially available, such as the Optune electro-therapy device, various biologics and various oncolytic virus therapies and gene therapies. Additionally, many companies are actively involved in the research and development of monoclonal antibody-based and bi-specific or tri-specific antibody-based cancer therapies. Currently, a substantial number of antibody-based drugs are approved for commercial sale for cancer therapy, and a large number of additional ones are under development. Many other third parties compete with us in developing alternative therapies to treat cancer, including: biopharmaceutical companies; biotechnology companies; pharmaceutical companies; academic institutions; and other research organizations, as well as some medical device companies.

We face extensive competition from companies developing new treatments for brain cancer. These include a variety of immune therapies, as mentioned above, as well as a variety of small molecule drugs and biologics. There are also a number of existing drugs used for the treatment of brain cancer that may compete with our product, including, Avastin® (Roche Holding AG), Gliadel® (Eisai Co. Ltd.), and Temodar® (Merck & Co., Inc.), as well as the Optune electro-therapy device (Novocure) and oncolytic viruses. Both checkpoint inhibitor drugs and T cell-based therapies are pursuing clinical trials for solid tumors, including brain cancer, as well.

Most of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing and sales than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they enter into collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and collaborators, as well as in acquiring technologies complementary to our programs, and in obtaining sites for our clinical trials and enrolling patients.

Corporate Information

We were formed in 1996 and incorporated in Delaware in July 1998. Our principal executive offices are located in Bethesda, Maryland, and our telephone number is (240) 497-9024. Our website address is *www.nwbio.com*. The information on our website is not part of this report. We have included our website address as a factual reference and do not intend it to be an active link to our website.

Available Information

Our website address is www.nwbio.com. We make available, free of charge through our website, 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 as soon as is reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (the "SEC"), but other information on our website is not incorporated into this report. The SEC maintains an Internet site that contains these reports at www.sec.gov.

Human Capital

The Company continues to operate with a lean staff, supplementing its full-time employees with consultants with various expertise. The Company began the year with 22 full-time employees (FTEs) and ended the year on December 31, 2023 with 25 FTEs. The Company's internal workforce is approximately gender equal. As in the past, the Company relied upon specialists in the areas of manufacturing, construction and construction management, clinical trial management, data validation and analysis, scientific advisory, regulatory advisory, legal, financial accounting and tax, and information technology. For the Company's international operations in the UK, the Company relies on a contracted workforce. To attract and retain talent, the Company offers a competitive pay and benefits package.

ITEM 1A. RISK FACTORS

Our business, financial condition, operating results and prospects are subject to the following material risks. Additional risks and uncertainties not presently foreseeable to us may also impair our business operations. If any of the following risks actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, the trading price of our common stock could decline, and our stockholders may lose all or part of their investment in the shares of our common stock.

Risks Related to our Operations

We will need to raise substantial funds, on an ongoing basis, for general corporate purposes and operations, including our clinical trials. Such funding may not be available or may not be available on acceptable terms.

We will need substantial additional funding, on an ongoing basis, in order to continue execution of our clinical trials, to move our product candidates towards commercialization, to continue prosecution and maintenance of our large patent portfolio, to continue development and optimization of our manufacturing and distribution arrangements, and for other corporate purposes. Any financing, if available, may include restrictive covenants and provisions that could limit our ability to take certain actions, preference provisions for the investors, and/or discounts, warrants, anti-dilution rights, the provision of collateral, or other incentives. Any financing will involve issuance of equity and/or debt, and such issuances will be dilutive to existing shareholders. There can be no assurance that we will be able to complete any of the financings, or that the terms for such financings will be acceptable. If we are unable to obtain additional funds on a timely basis or on acceptable terms, we may be required to curtail or cease some or all of our operations at any time.

We are likely to continue to incur substantial losses and may never achieve profitability.

As of December 31, 2023, we had net cash outflows (losses) from operations, since inception. We may never achieve or sustain profitability.

Our auditors have issued a "going concern" audit opinion.

Management has determined and our independent auditors have indicated in their report on our December 31, 2023 financial statements that there is substantial doubt about our ability to continue as a going concern. We have received such a "going concern" opinion each of the preceding years for more than a decade. A "going concern" opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the

recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

Maintaining a strong control environment, free of material weaknesses, is dependent on our ability to retain an adequate number of qualified personnel and/or consultants to perform such control activities and other factors. Our management and our independent auditors have identified one material weakness for the year ended December 31, 2023.

We have remediated past material weaknesses and we pursue ongoing efforts to strengthen our internal controls. Maintaining a consistently strong control environment requires the ability to attract and retain sufficient qualified personnel and/or consultants and other factors. We may not be able to attract or retain sufficient numbers of qualified personnel. In connection with the preparation of our financial statements for the year ended December 31, 2023, our management and our independent auditor identified a material weakness, which involved applying an incorrect valuation method using the market price actually paid for certain convertible notes rather than a Monte Carlo formula, as described more fully in “Item 9A. Controls and Procedures” of Part I of this Form 10-K.

If we do not successfully maintain a strong controlled environment this could lead to heightened risk for financial reporting mistakes and irregularities, and/or lead to a loss of public confidence in our internal controls that could have a negative effect on the market price of our common stock. In addition, our ability to retain or attract qualified individuals to serve on our Board and to take on key management or other roles within our Company is uncertain.

As a company with a novel technology and unproven business strategy, an evaluation of our business and prospects is difficult.

We are still in the process of developing our product candidates through clinical trials. Our technology is novel and involves mobilizing the immune system to fight a patient’s cancer. Immune therapies have been pursued by many parties for decades, and have experienced many failures. In addition, our technology involves personalized treatment products, a new approach to medical products that involves new product economics and business strategies, which have not yet been shown to be commercially feasible or successful. We have not yet gone through scale-up of our operations to commercial scale. The novelty of our technology, product economics, and business strategy, and the limited scale of our operations to date, makes it difficult to assess our prospects for generating revenues commercially in the future.

We will need to expand our management and technical personnel as our operations progress, and we may not be able to recruit such additional personnel and/or retain existing personnel.

As of December 31, 2023, we had a total of 25 full-time employees: 23 full-time employees in the US, one full-time employee in Europe and one full-time employee in Canada. Of this group, only four employees are considered Management. Additional personnel are retained on a consulting or contractor basis. Many biotech companies would typically have a larger number of employees by the time they reach late-stage clinical trials. Such trials and other programs require extensive management capabilities, activities and skill sets, including scientific, medical, regulatory (for FDA and foreign regulatory counterparts), manufacturing, distribution and logistics, site management, reimbursement, business, financial, legal, public relations outreach to both the patient community and physician community, intellectual property, administrative, regulatory (SEC), investor relations and other resources.

In order to fully perform all these diverse functions, at many sites across the U.S. and in Europe, we may need to expand our management, technical and other personnel. However, with respect to management and technical personal, the pool of such personnel with expertise and experience with living cell products, such as our DCVax immune cell product, is very limited. In addition, we are a small company with limited resources, our business prospects are uncertain and our stock price is volatile. For some or all of such reasons, we may not be able to recruit all the management, technical and other personnel we need, and/or we may not be able to retain all of our existing personnel. In such event, we may have to continue our operations with a small team of personnel, and our business and financial results may suffer.

We rely at present on third-party contract manufacturers. As a result, we may be at risk for issues with manufacturing agreements, capacity limitations and/or supply disruptions, and/or issues with product equivalency.

We rely upon specialized contract manufacturers, operating in specialized GMP (clean room) manufacturing facilities, to produce all of our DCVax products. We have worked with several such manufacturers, in several different locations, during various periods of our

clinical trials and our compassionate treatment programs, including Advent BioServices, Cognate BioServices and the Fraunhofer Institute.

We will need to enter into new contractual agreements for manufacturing at our Sawston, U.K. facility and new agreements for commercial production in any locations. We may encounter difficulties reaching such agreements, or the terms of such agreements may not be favorable. Following negotiations, if it is necessary or desirable to change our facility design and development arrangements or our manufacturing arrangements, that could involve increased facility costs and/or increased costs related to manufacturing of our products and could result in delays in our programs or applications for various regulatory approvals. In addition, after such contracts are in place, the third-party contractors may have capacity limitations and/or supply disruptions, and as a client we may not be able to prevent such limitations or disruptions, and not be able to control or mitigate the impact on our programs.

We have been in breach of the services agreements with our contract manufacturers on numerous occasions, primarily for untimely payment or non-payment. Our breaches of the services agreements may not be tolerated in the future as they have been in the past, and if we continue to breach the services agreements, for non-payment or otherwise, the contract manufacturers could cease providing services and/or terminate these agreements.

Our intention is for the Sawston, U.K. facility to manufacture DCVax products for both the UK and other regions. However, this may not turn out to be feasible, for regulatory, operational and/or logistical reasons. It is also unclear whether or how Brexit will affect or interfere with these plans in regard to Europe.

Problems with the manufacturing facilities, processes or operations of our contract manufacturer(s) could result in a failure to produce, or a delay in producing adequate supplies of our DCVax product candidates. A number of factors could cause interruptions or delays, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters or otherwise, changes in FDA, U.K. or European regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA, U.K. or European regulators, or by us that results in the halting or slowdown of production of components or finished products due to regulatory issues, our manufacturers going out of business or failing to produce product as contractually required, insufficient technical personnel and/or specialized facilities to produce sufficient products, and/or other factors. A number of factors could also cause possible issues about the equivalency of DCVax product produced in different facilities or locations, which could make it necessary for us to perform additional studies and incur additional costs and delays. Because manufacturing processes for our DCVax product candidates are highly complex, require specialized facilities (dedicated exclusively to DCVax production) and personnel that are not widely available in the industry, involve equipment and training with long lead times, and are subject to lengthy regulatory approval processes, alternative qualified production capacity may not be available on a timely basis or at all. Also, as noted above, our contract manufacturer(s) could choose to terminate their agreements with us if we are in breach, or if we undergo a change of control. Difficulties, delays or interruptions in the manufacturing and supply and delivery of our DCVax product candidates could require us to stop enrolling new patients into clinical trials, and/or require us to stop the trials or other programs, stop the treatment of patients in the trials or other programs, increase our costs, damage our reputation and, if our product candidates are approved for sale, cause us to lose revenue or market share if our manufacturers are unable to timely meet market demands.

The manufacturing of our product candidates will have to be greatly scaled up for commercialization, and neither we nor our contract manufacturers have experience with such scale-up.

As is the case with any clinical trial, our Phase III clinical trial of DCVax-L for GBM involves a number of patients that is a small fraction of the number of potential patients for whom DCVax-L may be applicable in the commercial market. The same will be true of our other clinical programs with DCVax-L or other DCVax product candidates. If our DCVax-L and/or other DCVax product candidates are approved for commercial sale, it will be necessary to greatly scale up the volume of manufacturing, far above the level needed for clinical trials. Neither we nor our contract manufacturers have experience with such scale-up. In addition, there are likely only a few consultants or advisors in the industry who have such experience and can provide guidance or assistance, because active immune therapies such as DCVax are a fundamentally new category of product in two major ways: these active immune therapy products consist of living cells, not chemical or biologic compounds, and the products are personalized. To our knowledge, very few such products have successfully completed the necessary scale-up for commercialization. For example, Dendreon Corporation encountered substantial difficulties trying to scale up the manufacturing of its Provenge® product for commercialization. To our knowledge, even the CAR-T products which are being commercialized have so far only scaled up to moderate product volumes.

The necessary specialized facilities, equipment and personnel may not be available or obtainable for the scale-up of manufacturing of our product candidates.

The manufacture of living cells requires specialized facilities, equipment and personnel which are entirely different than what is required for the manufacturing of chemical or biologic compounds. Scaling up the manufacturing of living cell products to volume levels required for commercialization will require enormous amounts of these specialized facilities, equipment and personnel - especially where, as in the case of our DCVax product candidates, the product is personalized and must be made for each patient individually. Since living cell products are so new, and have barely begun to reach commercialization, the supply of the specialized facilities and personnel needed for them is not widely available and therefore is in the process of being developed. However, there has been a sharp increase in the demand for these specialized facilities and personnel, as large numbers of companies seek to develop T cell and other immune cell products. It may not be possible for us or our manufacturers to obtain all of the specialized facilities and personnel needed for commercialization of our DCVax product candidates, or even for further sizeable trials. This could delay or halt our commercialization and/or further substantial trials.

We are anticipating that the production systems developed by Flaskworks may play an important role in enabling scale-up of production and reducing the number of GMP (clean room) suites and personnel needed for scale-up. However, the Flaskworks systems are still undergoing development and optimization, and have not been operated at commercial scale to date. It could turn out that the Flaskworks systems are not capable of or suitable for substantial scale-up, or not acceptable to regulatory authorities for such scale-up. It could also turn out that deployment the Flaskworks system does not reduce the number of GMP suites and personnel needed for DCVax production as anticipated.

Our technology is novel, involves complex immune system elements, and may not prove to be effective.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Over the course of several decades, there have been many different immune therapy product designs - and many product failures and company failures. To our knowledge, to date, only a couple of active immune therapies have been approved by the FDA, including one dendritic cell therapy and a couple of CAR-T cell therapies. The human immune system is complex, with many diverse elements, and the state of scientific understanding of the immune system is still limited. Some immune therapies previously developed by other parties showed surprising and unexpected toxicity in clinical trials. Other immune therapies developed by other parties delivered promising results in early clinical trials but failed in later stage clinical trials.

Although we believe the Phase III trial results are positive and encouraging, other parties, including doctors, patients, regulators and/or payers may not view the trial results positively. Further, although the safety profile of our DCVax-L product was excellent in both the Phase 3 clinical trial and the early-stage clinical trials, toxicity may be seen as we treat larger numbers of patients. If such toxicity occurs, it could limit, delay or stop further clinical development or commercialization of our DCVax-L product.

We have only conducted the Phase I portion of our first-in-man Phase I/II clinical trial with our DCVax Direct product, after prior early-stage trials with DCVax-L and DCVax-Prostate. Although the early results have not indicated any significant toxicity, we do not yet know what efficacy or toxicity DCVax-Direct may show in a larger sample of human patients. This product may not ultimately be found to be effective, and/or it may be found to be toxic, which could limit, delay or stop clinical development or commercialization of DCVax-Direct.

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

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

- the duration of the clinical trial;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required and ability to enroll eligible patients;

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

Late-stage clinical trials, such as our Phase III clinical trial for GBM patients, are especially expensive, typically requiring tens or hundreds of millions of dollars, and take years to reach their outcomes. Such outcomes often fail to reproduce the results of earlier trials. It is often necessary to conduct multiple late-stage trials (including multiple Phase III trials) in order to obtain sufficient results to support product approval, which further increases the expense and time involved. Sometimes trials are further complicated by changes in requirements while the trials are under way (for example, when the standard of care changes for the disease that is being studied in the trial, or when there are changes in the scientific understanding of the disease or the treatment, and/or changes in the competitive landscape.) For example, while the Company's lead program, the Phase III clinical trial of DCVax-L for brain cancer, has been under way, there has been a very large proliferation of new treatments in various stages of development, as well as some new product approvals, for brain cancer. Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than we expect, or may never gain approval, either of which could delay or stop the commercialization of our DCVax product candidates.

We have limited experience in conducting and managing clinical trials, or collecting, confirming and analyzing trial data, and we rely on third parties to conduct these activities.

We rely on third parties to assist us, on a contract services basis, in managing and monitoring all of our clinical trials as well as the collection, confirmation and analysis of the trial data. We do not have experience conducting late-stage clinical trials, or collecting, validating and analyzing trial data by ourselves without third party service firms, nor do we have experience in supervising such third parties in managing late - stage, multi-hundred patient clinical trials, and collecting, validating and analyzing the data, other than in our current Phase III trial for GBM. Our lack of experience and/or our reliance on these third-party service firms may result in delays or failure to complete these trials and/or the data collection, validation and analyses successfully or on time. If the third parties fail to perform, we may not be able to find sufficient alternative suppliers of those services in a reasonable time period, or on commercially reasonable terms, if at all.

We may fail to comply with regulatory requirements.

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

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

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

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

Our operations under early access programs may not be successful.

There is not much accumulated or available experience, information or precedents in regard to early access programs, especially for new types of treatments such as immune therapies. Establishing operations under an early access program will require us to establish and implement new operational, contractual, financial and other arrangements with physicians, hospitals, patients and others. We may not be successful in establishing and implementing such arrangements, and/or such arrangements may not be financially satisfactory or viable.

We may not be successful in negotiating reimbursement.

If our DCVax-L product obtains regulatory approval for commercialization, such commercialization will be difficult and may not be feasible unless we obtain coverage by health insurance and/or national health systems for reimbursement of our product price. Obtaining such coverage by health insurance and/or national health systems will be difficult, and we do not have experience with such processes. Our DCVax-L product is a fully personalized, individual product and, as such, is expected to be expensive. In addition, our DCVax-L product involves a cost structure (with much of the costs upfront, in connection with the manufacturing of the personalized DCVax-L product for a patient) that is different than traditional drugs and may require different reimbursement arrangements. These factors may make our negotiations for reimbursement more difficult. We may not be successful in negotiating or obtaining reimbursement or obtaining it on acceptable or viable terms.

Our product candidates will require a different distribution model than conventional therapeutic products, and this may impede commercialization of our product candidates.

Our DCVax product candidates consist of living human immune cells. Such products are entirely different from chemical or biologic drugs, and require different handling, distribution and delivery than chemical or biologic drugs. One crucial difference is that the biomaterial ingredients (immune cells and tumor tissue) from which we make DCVax products and the finished DCVax products themselves are subject to time constraints in the shipping and handling. The biomaterial ingredients come from the medical centers to the manufacturing facility fresh and not frozen, and must arrive within a certain window of time and in usable condition. Performance failures by the medical center or the courier company can result in biomaterials that are not usable, in which case it may not be possible

to make DCVax product for the patient involved. The finished DCVax products are frozen and must remain frozen throughout the process of distribution and delivery to the medical center or physician's office, until the time of administration to the patient, and cannot be handled at room temperature until then or their viability will be lost. In addition, our DCVax product candidates are personalized and they involve ongoing treatment cycles over several years for each patient. Each product shipment for each patient must be tracked and managed individually. For all of these reasons, among others, we will not be able to simply use the distribution networks and processes that already exist for conventional drugs. It may take time for shipping companies, hospitals, pharmacies and physicians to adapt to the requirements for handling, distribution and delivery of these products, which may adversely affect our commercialization.

Our product candidates will require different marketing and sales methods and personnel than conventional therapeutic products. Also, we lack sales and marketing experience. These factors may result in significant difficulties in commercializing our product candidates.

The commercial success of any of our product candidates will depend upon the strength of our sales and marketing efforts. We do not have a marketing or sales force and have no experience in marketing or sales of products like our lead product, DCVax-L for GBM, or our additional product, DCVax-Direct. To fully commercialize our product candidates, we will need to recruit and train marketing staff and a sales force with technical expertise and ability to manage the distribution of our DCVax-L for GBM. As an alternative, we could seek assistance from a corporate partner or a third-party services firm with a large distribution system and a large direct sales force. However, since our DCVax products are living cell, immune therapy products, and these are a fundamentally new and different type of product than are on the market today, we would still have to train such partner's or such services firm's personnel about our products and would have to make changes in their distribution processes and systems to handle our products. We may be unable to recruit and train effective sales and marketing forces or our own, or of a partner or a services firm, and/or doing so may be more costly and difficult than anticipated. Such factors may result in significant difficulties in commercializing our product candidates, and we may be unable to generate significant revenues.

The availability and amount of potential reimbursement for our product candidates by government and private payers is uncertain and may be delayed and/or inadequate.

The availability and extent of reimbursement by governmental and/or private payers is essential for most patients to be able to afford expensive treatments, such as cancer treatments. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there have been very few products similar to ours to date., We are aware of only a couple of active immune therapies that have reached the stage of reimbursement decision making processes, including one dendritic cell therapy and a couple of CAR-T cell therapies. Although CMS has approved coverage and reimbursement for a couple of these products, and private payers seem to be following suit in the US, there remain substantial questions and concerns about reimbursement for these products, especially outside the US.

Reimbursement agencies in Europe can be even more conservative than CMS in the U.S. A number of cancer drugs which have been approved for reimbursement in the U.S. have not been approved for reimbursement in certain European countries, and/or the level of reimbursement approved in Europe is lower than in the U.S. Reportedly, in Europe reimbursement for certain immune therapies was initially declined, and reportedly involved difficult negotiations. The same could happen with respect to our DCVax products.

Various factors could increase the difficulties for our DCVax products to obtain reimbursement. Costs and/or difficulties associated with the reimbursement of Provenge and/or T cell therapies could create an adverse environment for reimbursement of other immune therapies, such as our DCVax products. Approval of other competing products (drugs and/or devices) for the same disease indications could make the need for our products and the cost-benefit balance seem less compelling. The cost structure of our product is not a typical cost structure for medical products, as the majority of our costs are incurred up front, when the manufacturing of the personalized product is done. Our atypical cost structure may not be accommodated in any reimbursement for our products. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected.

The manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our product to patients) are also important. If the reimbursement for such services is inadequate, that may lead to physician resistance and adversely affect our ability to market or sell our products.

The methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary pressures facing the Medicare program. For example, the Medicare Prescription Drug, Improvement, and Modernization Act, or Medicare Modernization Act, enacted in 2003, provided for a change in reimbursement methodology that has reduced the Medicare reimbursement rates for many drugs, including oncology therapeutics. The Affordable Care Act may also result in changes in reimbursement arrangements that adversely affect the prospects for reimbursement of our products.

In markets outside the U.S., the prices of medical products are subject to direct price controls and/or to reimbursement with varying price control mechanisms, as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Competition in the biotechnology and biopharmaceutical industry is intense, rapidly expanding and most of our competitors have substantially greater resources than we do.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. A growing number of other companies, such as Juno, Kite, Sotio, AiVita, Mendus, Medicenna and many others, are actively involved in the research and development of immune therapies or cell-based therapies for cancer. In addition, other novel technologies for cancer are under development or commercialization, such as checkpoint inhibitor drugs (which are being rapidly developed by numerous big pharma companies including BMS, Merck, Pfizer, Astra Zeneca, Roche and others) and various T cell-based therapies (which are also being rapidly developed by numerous companies with extraordinary resource backing), as well as the electro-therapy device of NovoCure. Additionally, many companies are actively involved in the research and development of monoclonal antibody-based cancer therapies. Currently, a substantial number of antibody-based products are approved for commercial sale for cancer therapy, and a large number of additional ones are under development, including late-stage trials. Many other third parties compete with us in developing alternative therapies to treat cancer, including: biopharmaceutical companies; biotechnology companies; pharmaceutical companies; academic institutions; and other research organizations, as well as some medical device companies (e.g., NovoCure and MagForce Nano Technologies AG).

We face extensive competition from companies developing new treatments for brain cancer. These include a variety of immune therapies, as mentioned above (including T cell-based therapies and checkpoint inhibitor drugs), as well as a variety of small molecule drugs and biologics drugs. There are also a number of existing drugs used for the treatment of brain cancer that may compete with our product, including, Avastin® (Roche Holding AG), Gliadel® (Eisai Co. Ltd.), and Temodar® (Merck& Co., Inc.), as well as NovoCure’s electrotherapy device.

Most of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing and sales than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they enter into collaborative arrangements with large and established companies.

These third parties compete with us in recruiting and retaining qualified scientific and management personnel and collaborators, as well as in acquiring technologies complementary to our programs, and in obtaining sites for our clinical trials and enrolling patients.

Our competitors may complete their clinical development more rapidly than we and our products do, may develop more effective or affordable products, or may achieve earlier or longer patent protection or earlier product marketing and sales. Any products developed by us may be rendered obsolete and non-competitive.

Competing generic medicinal products may be approved.

In the E.U., there exists a process for approval of generic biological medicinal products once patent protection and other forms of data and market exclusivity have expired. Arrangements for approval of generic biologics products exist in the U.S. as well, and the FDA has begun approving bio-similar products. Other jurisdictions may approve generic biologic medicinal products as well. If generic biologic medicinal products are approved, competition from such products may substantially reduce sales of our products.

We may be exposed to potential product liability claims, and our existing insurance may not cover these claims, in whole or in part. In addition, insurance against such claims may not be available to us on reasonable terms in the future, if at all.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing, marketing, sale and use of therapeutic products. We have insurance coverage, but this insurance may not cover any claims made. In the future, insurance coverage may not be available to us on commercially reasonable terms (including acceptable cost), if at all. Insurance that we obtain may not be adequate to cover claims against us. Regardless of whether they have any merit or not, and regardless of their eventual outcome, product liability claims may result in substantially decreased demand for our product candidates, injury to our reputation, withdrawal of clinical trial participants or physicians, and/or loss of revenues. Thus, whether or not we are insured, a product liability claim or product recall may result in losses that could be material.

We may be subject to environmental regulatory requirements, and could fail to meet such requirements, and we do not carry insurance against environmental damage or injury claims.

We may need to store, handle, use and dispose of controlled hazardous, radioactive and biological materials in our business. Our development activities may result in our becoming subject to regulatory requirements, and if we fail to comply with applicable requirements, we could be subject to substantial fines and other sanctions, delays in research and production, and increased operating costs. In addition, if regulated materials were improperly released at our current or former facilities or at locations to which we send materials for disposal, we could be liable for substantial damages and costs, including cleanup costs and personal injury or property damages, and we could incur delays in research and production and increased operating costs.

Insurance covering certain types of claims of environmental damage or injury resulting from the use of these materials is available but can be expensive and is limited in its coverage. We have no insurance specifically covering environmental risks or personal injury from the use of these materials and if such use results in liability, our business may be seriously harmed.

Collaborations play an important role in our business and could be vulnerable to competition or termination.

We work with scientists and medical professionals at a variety of academic and other institutions, some of whom have conducted research for us or have assisted in developing our research and development strategy. These scientists and medical professionals are collaborators, not our employees. They may have commitments to, or contracts with, other institutions or businesses (including competitors) that limit the amount of time they have available to work with us. We have little control over these individuals. We can only expect that they devote time to us and our programs as required by any license, consulting or sponsored research agreements we may have with them. In addition, these individuals may have arrangements with other companies to assist in developing technologies that may compete with our products. If these individuals do not devote sufficient time and resources to our programs, or if they provide substantial assistance to our competitors, our business could be seriously harmed.

The success of our business strategy may partially depend upon our ability to develop and maintain our collaborations and to manage them effectively. Due to concerns regarding our ability to continue our operations or the commercial feasibility of our personalized DCVax product candidates, these third parties may decide not to conduct business with us or may conduct business with us on terms that are less favorable than those customarily extended by them. If either of these events occurs, our business could suffer significantly.

We may have disputes with our collaborators, which could be costly and time consuming. Failure to successfully defend our rights could seriously harm our business, financial condition and operating results. We intend to continue to enter into collaborations in the future. However, we may be unable to successfully negotiate any additional collaboration and any of these relationships, if established, may not be scientifically or commercially successful.

Our business could be adversely affected by new legislation and/or product related issues.

Changes in applicable legislation and/or regulatory policies or discovery of problems with the product, production process, site or manufacturer may result in delays in bringing products to market, the imposition of restrictions on the product’s sale or manufacture, including the possible withdrawal of the product from the market, or may otherwise have an adverse effect on our business.

Our business could be adversely affected by animal rights activists.

Our business activities have involved animal testing and could involve further such testing, as such testing is required before new medical products can be tested in clinical trials in human patients. Animal testing has been the subject of controversy and adverse publicity. Some organizations and individuals have attempted to stop animal testing by pressing for legislation and regulation in these areas. To the extent that the activities of such groups are successful, our business could be adversely affected. Negative publicity about us, our pre-clinical trials and our product candidates could also adversely affect our business.

Multiple late-stage clinical trials of DCVax-L for GBM, our lead product, may be required before we can obtain regulatory approval.

Typically, companies conduct multiple late-stage clinical trials of their product candidates before seeking product approval. Our current Phase III 331-patient clinical trial of DCVax-L for GBM is our first late-stage trial. We may be required to conduct additional late-stage trials with DCVax-L for GBM before we can obtain product approval. This would substantially delay our commercialization, and might not be possible to carry out, due to development and/or approval of competing products, lack of funding, and/or other factors. In addition, our Phase III trial of DCVax-L was placed on a partial clinical hold for new screening for enrollment in 2015. Although the FDA lifted its hold in February 2017 as previously reported by the Company, the Company had already closed enrollment with 331 of the planned 348 patients. Since we did not enroll the last 17 of the planned 348 patients, this could adversely affect the statistical and other analyses of our Phase III trial results and could make it more difficult to seek product approval or more likely that further trials could be required. In addition, a rapidly growing number of products are under development for brain cancer, including immunotherapies such as checkpoint inhibitor drugs and T cell-based therapies, and some (e.g., NovoCure's device) have been approved in the U.S. It is possible that the standard of care for brain cancer could change before we are able to seek approval for commercialization. This could necessitate further clinical trials with our DCVax-L product candidate for brain cancer, which may not be feasible.

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

Our products and our ongoing development activities are subject to regulation by regulatory authorities in the countries in which we and our collaborators and distributors wish to test, manufacture or market our products. For instance, the FDA will regulate our product in the U.S. and equivalent authorities, such as the MHRA and EMA will regulate in Europe and other jurisdictions. Regulatory approval by these authorities will be subject to the evaluation of data relating to the quality, efficacy and safety of the product for its proposed use, and there can be no assurance that the regulatory authorities will find our data sufficient to support product approval of DCVax-L or DCVax-Direct. In addition, the endpoint against which the data is measured must be acceptable to the regulatory authorities, and the statistical analysis plan for how the data will be evaluated must also be acceptable to the regulatory authorities. The statistical analysis plan that we submitted to regulators for the Phase III trial embodies a different primary endpoint and secondary endpoint than did the original Protocol for the trial. Under the Protocol the primary endpoint was progression free survival, or PFS, and the secondary endpoint was overall survival, or OS. Both of these endpoints were confounded: the PFS endpoint by pseudo-progression, and the OS endpoint by the "crossover" provision in the trial design, which allowed all of the patients in the trial to cross over to DCVax-L treatment after tumor recurrence (while remaining blinded as to which treatment they received before tumor recurrence). The statistical analysis plan uses external control patients rather than within-study controls. There can be no assurance that regulatory authorities will allow a product approval to be based upon this approach.

The time period required to obtain regulatory approval varies between countries. In the U.S., for products without "Fast Track" status, it can take up to 18 months after submission of an application for product approval to receive the FDA's decision. Even with Fast Track status, FDA review and decision can take up to 12 months. At present, we do not have Fast Track status for our lead product, DCVax-L for GBM. We may apply for Fast Track status, but there can be no assurance that FDA will grant us such status for DCVax-L.

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 clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements as well as case load at the regulatory agency at the time.

We may not obtain or maintain the benefits associated with orphan drug status, including market exclusivity.

Although our lead product, DCVax-L for GBM, has been granted orphan drug status in both the U.S. and the E.U., we may not receive the benefits associated with orphan drug designation (including the benefit providing for market exclusivity for a number of years). This may result from a failure to maintain orphan drug status or result from a competing product reaching the market that has an orphan

designation for the same disease indication. Under U.S. and E.U. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the U.S. for seven years or from being sold in the E.U. for ten years. Also, in the E.U., even after orphan status has been granted, that status is re-examined shortly prior to the product receiving any regulatory approval. The EMA must be satisfied that there is evidence that the product offers a significant benefit relative to existing therapies, in order for the therapeutic product to maintain its orphan drug status. Accordingly, our product candidates will have to re-qualify for orphan drug status prior to any potential product approval in the E.U. and may have to do so elsewhere as well.

Our intellectual property rights may be overturned, narrowed or blocked, and may not provide sufficient commercial protection for our product candidates, or third parties may infringe upon our intellectual property.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Patent laws afford only limited protection and may not protect our rights to the extent necessary to sustain any competitive advantage we may have. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in those countries. Moreover, patents and patent applications relating to living cell products are relatively new, involve complex factual and legal issues, and are largely untested in litigation - and as a result, are uncertain. Our pending and future patent applications may not result in patents being issued which adequately protect our technology or products or which effectively prevent others from commercializing the same or competitive technologies and products. As a result, we may not be able to obtain meaningful patent protection for our commercial products, and our business may suffer as a result. Third parties may challenge our existing patents, and such challenges could result in overturning or narrowing some of our patents. Even if our patents are not challenged, third parties could assert that their patents block our use of technology covered by some or all of our patents.

As of December 31, 2023, we had 31 issued patents and 54 pending patent applications worldwide relating to some of our product candidates and related matters such as manufacturing processes. The issued patents expire at various dates from 2024 to 2036. Our issued patents may be challenged, and such challenges may result in reductions in scope, cancellations or invalidations. Our pending patent applications may not result in issued patents. Moreover, our patents and patent applications do not cover all of our product candidates, and may not be sufficient to prevent others from using substantially similar technologies or from developing competing products. We also face the risk that others may independently develop similar or alternative technologies, or design around our patented technologies. As a result, no assurance can be given that any of our pending or future patent applications will be granted, that the scope of any patent protection currently granted or that may be granted in the future will exclude competitors or provide us with competitive advantages, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold.

We have taken security measures (including execution of confidentiality agreements) to protect our proprietary information, especially proprietary information that is not covered by patents or patent applications. These measures, however, may not provide adequate protection for our trade secrets or other proprietary information. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

We may be exposed to claims or lawsuits that our products infringe patents or other proprietary rights of other parties.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market, sell our product candidates, and use our proprietary technologies without infringing the proprietary rights of third parties. We have not conducted a comprehensive freedom-to-operate review to determine whether our proposed business activities or use of certain of the technology covered by patent rights owned by us would infringe patents issued to third parties.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. The patent landscape is especially uncertain in regard to cell therapy products, as it involves complex legal and factual questions for which important legal principles remain unresolved. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings, Inter Partes Reexamination, or Post Grant Review before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party’s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. 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 access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. If the infringement is found to be willful, we could be liable for treble damages. 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. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We have already been exposed to one patent lawsuit by a large company, which we vigorously defended. Our defense resulted in the plaintiff withdrawing nearly all of the claims it filed, and in settlement of the last claims without our paying the plaintiff anything. However, the litigation was expensive and time consuming. In the past, we have also been exposed to claims (without a lawsuit) by a competitor asserting or implying (and commentaries by third parties based on the claims by our competitor) that a patent issued to our competitor covers our products. We obtained and publicly reported legal advice that those claims were without merit. However, in the future, we could again be exposed to claims by third parties - with or without merit - that our products infringe their intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

DCVax is our only technology in clinical development.

Unlike many pharmaceutical companies that have a number of products in development, and which utilize many different technologies, we are dependent on the success of our DCVax platform technology. While the DCVax technology has a wide scope of potential use and is embodied in several different product lines for different clinical situations, if the core DCVax technology is not effective or is toxic or is not commercially viable, our business could fail. We do not currently have other technologies that could provide alternative support for us.

Risks Related to our Common Stock

The market price of our common stock is volatile and can be adversely affected by several factors.

The share prices of publicly traded biotechnology and emerging pharmaceutical companies, particularly companies without consistent product revenues and earnings, can be highly volatile and are likely to remain highly volatile in the future. The price which investors may realize in sales of their shares of our common stock may be materially different than the price at which our common stock is quoted and will be influenced by a large number of factors, some specific to us and our operations, and some unrelated to our operations. Such factors may cause the price of our stock to fluctuate frequently and substantially. Such factors may include large purchases or sales of our common stock, shorting of our stock, positive or negative events, commentaries or publicity relating to our company, management or products, or other companies, management or products, including other immune therapies for cancer or immune therapies or cancer therapies generally, positive or negative events relating to healthcare and the overall pharmaceutical and biotech sector, the publication of research by securities analysts and changes in recommendations of securities analysts, legislative or regulatory changes, and/or general economic conditions. In the past, shareholder litigation, including class action litigation, has been brought against other companies that experienced volatility in the market price of their shares and/or unexpected or adverse developments in their business. Whether or not meritorious, litigation brought against a company following such developments can result in substantial costs, divert management’s attention and resources, and harm the company’s financial condition and results of operations.

Our Common Stock is considered a “penny stock” and may be difficult to sell.

The Commission has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to specific exemptions. Historically, the price of our

Common Stock has fluctuated greatly. As of the date of this filing, the market price of our common stock is less than $5.00 per share, and therefore is a “penny stock” according to Commission rules. The “penny stock” rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser’s written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common stock and may result in decreased liquidity for our common stock and increased transaction costs for sales and purchases of our common stock as compared to other securities.

The requirements of the Sarbanes-Oxley Act of 2002 and other U.S. securities laws impose substantial costs and may drain our resources and distract our management.

We are subject to certain of the requirements of the Sarbanes-Oxley Act of 2002, as well as the reporting requirements under the Exchange Act. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We have tested and concluded that we have remediated the identified material weaknesses in our internal controls that were reported over the years. The substantial efforts and resources the Company has invested achieved remediation of the previously identified weaknesses. However, requirements continue to become more stringent, requiring even more time and resources to be invested to maintain a controlled environment, which is difficult for a small company like ours. Continued additional investments and management time to meet these requirements will be necessary since control weaknesses raise the risk of future material errors in the company’s financial statements. We may not be able to maintain effective controls over time. If we have material weaknesses in the future, this may subject us to SEC enforcement action, which could include monetary fines or other equitable remedies that could be detrimental to the ongoing business of the Company.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the market price of our common stock.

We have not paid any cash dividends on our common stock to date in our history, and we do not intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Also, any credit agreements which we may enter into with institutional lenders may restrict our ability to pay dividends. Therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of our common stock. Such increases in the trading price of our stock may not occur.

Our certificate of incorporation and bylaws and Delaware law, have provisions that could discourage, delay or prevent a change in control.

Our certificate of incorporation and bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 100,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. No preferred stock is currently outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our certificate of incorporation and bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the Board of Directors with the ability to alter the bylaws without stockholder approval;

- establish staggered terms for board members;
- place limitations on the removal of directors; and
- provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

We are also subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits "business combinations" between a publicly-held Delaware corporation and an "interested stockholder," which is generally defined as a stockholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such stockholder became an interested stockholder.

A substantial number of shares of common stock may be sold in the market, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act. As of December 31, 2023, 1,175.5 million shares of our common stock are issued and outstanding. In addition, as of December 31, 2023, 11.4 million shares of our common stock are issuable upon exercise of outstanding warrants, and 126.8 million shares of our common stock are issuable upon exercise of outstanding options.

We may have claims and lawsuits against us that may result in adverse outcomes.

From time to time, we may be subject to a variety of claims and lawsuits. In the past, we were engaged in several shareholder litigations. We believed that that the claims were without merit, fought them vigorously and resolved them. We have also had several small litigations, for example relating to certain payables. Litigation and claims are subject to inherent uncertainties, and adverse rulings or outcomes could occur, and/or could lead to further claims or litigation. Adverse outcomes or further litigation could result in significant monetary damages or injunctive relief that could adversely affect our business and may divert management time and attention from our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. We require third-party service providers with access to personal, confidential or proprietary information to implement and maintain comprehensive cybersecurity practices consistent with applicable legal standards and industry best practices. Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share. The Company is currently in the process of implementing a more formalized cybersecurity program.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 4800 Montgomery Lane, Bethesda, Maryland, where we lease and occupy an aggregate of approximately 7,097 square feet of office space. The lease covering this property is currently scheduled to expire in August 2024.

Our research and development operations are mainly based in Sawston, U.K., where we lease and occupy an aggregate of approximately 88,000 square feet of building. The lease covering this property is currently scheduled to expire in December 2038.

We believe that our existing facilities are adequate for our immediate needs and that, should it be needed, additional space can be leased to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

On December 1, 2022, we filed a Complaint in the United States District Court for the Southern District of New York against certain market makers. The Complaint alleges that the defendants engaged in manipulation of the Company's stock, in violation of the Securities Exchange Act of 1934 and common law fraud, over a period of years. On March 20, 2023, the defendants filed a Motion to Dismiss the Complaint. On April 10, 2023 we filed an Amended Complaint against Canaccord Genuity LLC, Citadel Securities LLC, G1 Execution Services LLC, GTS Securities LLC, Instinet LLC, Lime Trading Corp., and Virtu Americas LLC (*Northwest Biotherapeutics Inc. v. Canaccord, et al.,* No. 1:22-cv-10185-GHW-GWG).

Following defendant's filing of a new Motion to Dismiss and various filings on both sides, an oral argument on defendants' latest Motion to Dismiss was held on November 14, 2023. The Magistrate Judge issued an 85 page Recommendation and Results Opinion (R&R) for review by the Senior Judge. The Magistrate Judge found that the Company had adequately plead all of the elements of its claim of market manipulation, with the exception of producing enough details for calculating actual damages, known as loss causation. On that basis, he granted defendant's motion to dismiss without prejudice, subject to the Company's right to replead on just the question of loss causation, finding that such a filing would not be futile.

On February 14, 2024, the Senior Judge issued an opinion accepting all the recommendations and findings of the R&R, and gave the Company 30 days to file this limited amendment no later than March 15, 2024. The Company expects to provide the requested information, is currently drafting its response, and plans to continue to pursue this case vigorously.

As previously reported, three stockholders filed in the Delaware Court of Chancery three similar derivative lawsuits against the Company and certain of its directors and officers, including J. Cofer Black, Marnix L. Bosch, Alton L. Boynton, Leslie J. Goldman, Jerry Jasinowski, Navid Malik, and Linda F. Powers (the "Individual Defendants"), alleging the Individual Defendants (i) breached their fiduciary duties, and (ii) were unjustly enriched by director and officer compensation awarded in 2020 to the Individual Defendants—notwithstanding the fact that approximately 90% of shareholders voted to approve of the Company's executive compensation (the same compensation that these three stockholders are seeking to challenge) twice (both through its Say on Pay vote at the Company's Annual Meeting in 2021, and again in a binding vote at the Company's Annual Meeting in 2022) and approximately 90% of shareholders also voted to approve the director awards at the 2022 Annual Meeting. On March 31, 2022, the Delaware Court of Chancery consolidated these actions into a single action under the caption In re Northwest Biotherapeutics, Inc. Stockholder Litigation (the "Derivative Action").

On November 17, 2023, the court issued an oral decision denying the motion to dismiss. On December 20, 2023, Gibson Dunn filed an answer to the Consolidated Amended Complaint on behalf of the Company. On December 28, 2023, the Individual Defendants, represented by separate counsel, filed their response to the Consolidated Amended Complaint. The parties are currently in the midst of discovery.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market for Common Equity and Related Stockholder Matters

Our common stock trades on OTCQB under the trading symbols "NWBO" effective December 19, 2016. No assurance can be given that an active market will exist for our common stock.

As of January 31, 2024, there were approximately 46,111 holders of record of our common stock. Such holders may include any broker or clearing agencies as holders of record, and in such cases exclude the individual stockholders whose shares are held by such brokers or clearing agencies.

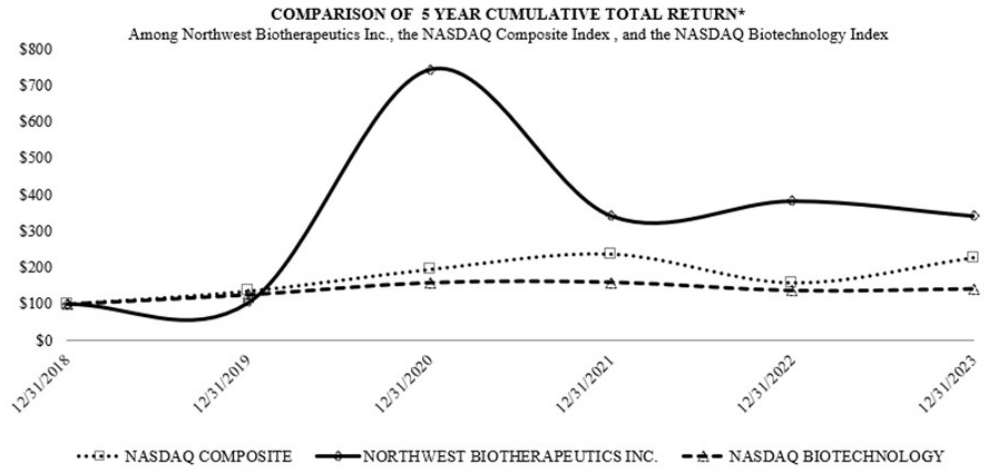
Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings, if any, to fund the ongoing development and growth of our business. We do not currently anticipate paying any cash dividends in the foreseeable future.

Stock Performance Graph

The following shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act, except to the extent we specifically incorporate it by reference into such filing.

This graph compares the cumulative total return on our Common Stock with that of the NASDAQ Composite and the NASDAQ Biotechnology index. This chart adjusts prices for stock splits and assumes the reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



* $100 invested on December 31, 2018 in stock or index, including reinvestment of dividends.

	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023
Northwest Biotherapeutics Inc.	100.00	104.57	742.09	340.63	381.75	340.63
NASDAQ Composite	100.00	135.23	194.24	235.78	157.74	226.24
NASDAQ Biotechnology	100.00	124.97	157.10	158.27	136.15	140.88

Recent Sales of Unregistered Securities

During the year ended December 31, 2023, the Company issued the following equity securities pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, or the provisions of Rule 506 of Regulation D promulgated under the Securities Act. Except as set forth in such note, the Company did not utilize an underwriter or a placement agent for any of these offerings of its securities. The proceeds were used for general corporate purposes.

During the year ended December 31, 2023, the Company issued an aggregate of 1.0 million shares of Series C convertible preferred stock (the “Series C Shares”) to accredited investors for gross proceeds of approximately $14.3 million. During the year ended December 31, 2023, the Company extinguished approximately $1.0 million outstanding debt in lieu of partial consideration received for issuance the Series C Shares. The Company received approximately $13.3 million net proceeds from issuance of the Series C Shares.

During the year ended December 31, 2023, the Company converted 1.2 million shares of Series C Shares to 30.8 million common shares.

During the year ended December 31, 2023, the Company issued 16,000 shares of Series C Shares at fair value of $0.2 million to a consultant for services provided.

During the year ended December 31, 2023, the Company issued an aggregate of 12.8 million shares of common stock to accredited investors for $2.9 million cash from the exercise of warrants issued in the past with an exercise price between $0.153 and $2.00.

During the year ended December 31, 2023, the Company issued an aggregate of 37.0 million shares of common stock to accredited investors in lieu of cash payments of $19.1 million of debt, including $1.8 million of accrued interest.

During the year ended December 31, 2023, the Company issued an aggregate of 4.5 million shares of common stock to Advent BioServices as a result of completion of the two one-time milestones (obtaining a commercial manufacturing license from the MHRA and completion of drafting application) at fair value of $3.2 million, of which $0.6 million was recognized during the year ended December 31, 2023 and $2.6 million had already been recognized (but not paid) in 2022.

During the year ended December 31, 2023, the Company issued an aggregate of 0.6 million shares of common stock at fair value of $0.3 million to two staff employees. These shares were fully vested on the grant date.

During the year ended December 31, 2023, the Company issued 0.1 million shares of common stock at fair value of $50,000 to a consultant for services provided.

ITEM 6. [RESERVED]

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

You should read this discussion together with the Financial Statements, related Notes and other financial information included elsewhere in this Form 10-K. The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," and elsewhere in this Form 10-K. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

The following Management's Discussion and Analysis provides a historical and prospective narrative on the Company's financial condition, and results of operations for the year ended December 31, 2023 as compared to the year ended December 31, 2022. The discussion of the Company's financial condition and results of operations for the year ended December 31, 2022 compared to the same period in 2021 is included in Part II, Item 7. Below includes Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10–K for the year ended December 31, 2023.

We are a biotechnology company focused on developing personalized immune therapies for cancer. We have developed a platform technology, DCVax®, which uses activated dendritic cells to mobilize a patient's own immune system to attack their cancer. Our lead product, DCVax®-L, is designed to treat solid tumor cancers in which the tumor can be surgically removed. Our additional product, DCVax®-Direct, is designed to treat inoperable solid tumors.

During 2023, we completed or made substantial progress on all of the key areas that we outlined at the Annual Meeting in December 2022 as priorities for the following 12-18 months, as well as some additional areas not outlined at the Annual Meeting.

Sawston Facility Development. We continued the development of our GMP facility in Sawston UK. We believe that the facility is a major asset and that the ongoing development is materially further enhancing its value.

- The MIA license was approved by the Medicines and Healthcare Products Agency (MHRA), authorizing commercial manufacturing in the facility as well as global imports and exports - the culmination of several years of work.
- The buildout of Phase 1B of the facility, which had begun in 2022, was completed. This included a large new Process Development (PD) lab that helped substantially with the Flaskworks development activities during the remainder of the year. The new PD lab will also be useful for future work on next-generation technologies, including as part of collaborations that are under development.
- Controlled GMP cryostorage: existing capacity for 3 million vials.
- Engineering and technical analyses were carried out for development of new Grade C labs in which the Flaskworks system may be deployed at lower cost and greater quantities of production than the existing manufacturing processes in Grade B labs.

Product Release Improvements. We continued to streamline processes related to product release. After manufacturing, medical products must go through a range of "release tests" - i.e., quality control and other tests (composition, purity, potency, sterility, etc.) to be approved for release for use in patients. In order for scale-up of manufacturing to be effective, the product release process must also be streamlined and scaled up so that it is not a bottleneck. This is an important part of overall preparations for commercialization and is particularly critical for autologous (personalized) products, for which each "batch" of product that is released is only for one patient. We have been

working on this for years and made substantial progress in 2023. Activities have included partial automation and acquiring specialized equipment and bringing in-house some key tests previously conducted by outside specialized vendors.

Flaskworks. Major progress was made in 2023 in the development of the Flaskworks system for a “closed” manufacturing process for DCVax-L. We completed the evaluation of three fundamentally different process approaches that the Flaskworks system could take, and chose the one that we believe will be optimal both operationally and to facilitate regulatory approval. We also completed most of the functional optimization of the Flaskworks system itself. A specialized contractor was engaged to produce GMP-compliant (i.e., clinical grade) versions of the prototype Flaskworks machine made with GMP grade materials. When the GMP-grade units are delivered, Advent BioServices will undertake qualification and validation of those units, conduct engineering runs and collect data, and apply to regulators for approval to use the system to produce DCVax-L for patients. As previously reported, the Company views the Flaskworks program and system as a centerpiece of efforts toward scale-up for potential commercial operations.

Supply chain issues and equipment backlogs continue to be factors affecting operations both for Advent and for Flaskworks. However, the work of both Advent and Flaskworks is progressing in spite of these issues.

Intellectual Property. We further strengthened our intellectual property portfolio in three ways during 2023: we achieved issuance of certain patents previously filed, we filed new patent applications based on our own work, and we in-licensed patents and patent applications from other parties. We are continuing to build an IP portfolio that we believe will provide a strong foundation to help us build a leading franchise in dendritic cells and active immunotherapies. This includes enhanced versions of dendritic cells, combinations of other agents with dendritic cells, manufacturing methods and processes, and related IP.

Collaborations. The Company continued active discussions on certain combination treatment regimens and is planning for certain strategic trials with such combination treatments. Some of these would be in connection with the Company’s in-licensing of intellectual property and others would be separate collaborations. The Company anticipates proceeding with such an initial combination during 2024 when it is able to free up sufficiently from the MAA review process and the inspections processes.

Expansion of the SAB: addition of Dr. Linda Liau. We were pleased to expand our Scientific Advisory Board during 2023 with the addition of Dr. Linda Liau, Chairman of the Neurosurgery Department at UCLA and the Principal Investigator in the Phase 3 trial of DCVax-L for GBM.

Mechanism of Action data and analyses. During 2023, we completed and publicly presented key information about the mechanism of action (MoA) of DCVax-L. We have undertaken such analyses over time, as technology tools have advanced - including recent advances in proteomics. The analyses completed and presented in 2023 provided strong support for what we believe are the keys to the treatment effects observed with DCVax-L and are the key differentiators of DCVax-L vs. other cancer treatments for glioblastoma (GBM) and other solid tumors: namely, that DCVax-L is a *broad-spectrum* treatment and it is aiming at personalized tumor *targets that are actually present* on the patient’s version of the tumor. The MoA studies showed that the dendritic cells in DCVax-L processed and presented well over 600 peptide antigens (all drawn from a sample of the patient’s own tumor) to the T cells. The antigens presented by the DCs become targets for T cells to attack. The MoA studies also showed that a very large number and diversity of T cells responded, and that the depth and breadth of the T cell response increased over time following DCVax-L treatments, ranging ranged from several hundred to as many as 1200 different T cell clones. Each T cell clone addresses a distinct tumor target. We believe that the data from these MoA studies provide important support for the extended survival seen in our Phase 3 clinical trial of DCVax-L for GBM and will be helpful in the regulatory review of our MAA application for commercial approval.

Continued compassionate use (Specials) patients. We continued treating compassionate use cases of GBM patients. We believe these treatments are helpful for the patients, and these cases are also helping us prepare for real world circumstances that we are likely to encounter in potential commercialization and that are much more diverse than in clinical trials. For example, the compassionate use cases include patients who have continued to receive DCVax-L treatments over many years (including having a second batch of DCVax-L doses made after the first batch of doses was exhausted), patients who are older than the age range in the clinical trials, and a patient with an enormous (14 cm.) GBM tumor of which only half could be removed by surgery and the remaining half regressed with treatment by DCVax-L and nutritional support for the immune system (case study accepted for peer reviewed publication).

Continued survival follow-up on patients in the Phase 3 trial. The contract research organization (CRO) managing the Phase 3 trial continued to conduct long-term follow-up on patients from the Phase 3 trial as there are still patients alive.

Drafting and submission of the MAA. We worked with consultants throughout the year to draft the MAA application package and supporting documents and exhibits. Advent BioServices undertook much of the work with specialized consultants to prepare the CMC (product related) sections of the MAA and those supporting documents and exhibits. The MAA was completed and filed with the UK MHRA on December 20, 2023.

Activities associated with the MAA. In parallel with the drafting of the MAA itself, in 2023 we undertook a large-scale program of preparations for inspections. The regulatory authorities will conduct comprehensive inspections of the CRO, the TMF, the database provider, the sponsor, key trial site hospitals, the contract manufacturer and others. The Company worked throughout most of 2023 with large teams of consultants on preparations for inspection readiness of all parties and the TMF. Multiple mock inspections were arranged and were conducted by former regulatory agency inspectors in Q4. Further inspection readiness preparations are expected to continue to be a major focus of the Company and the large teams of consultants in the first half of 2024. During 2023 the Company also devoted substantial efforts to preparations for launching the two required pediatric clinical trials.

Lawsuit against market makers. The Company continued vigorously pursuing its lawsuit against certain market makers whom the Company believes have engaged in manipulation of its stock. Following the Company's filing of its Complaint in December 2022, during 2023 the case proceeded through multiple rounds of court filings as described in Item 3 Legal Proceedings above. The Company plans to continue the vigorous pursuit of the case.

Future directions. In the future, we also plan to restart our DCVax®-Direct clinical development program as soon as resources permit.

Critical Accounting Policies and Estimates

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

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

Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy that prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1 - defined as observable inputs such as quoted prices for identical instruments in active markets;
- Level 2 - quoted prices for similar assets and liabilities in active markets or inputs that are observable
- Level 3 - inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

We account for the issuance of common stock purchase warrants issued in connection with the equity offerings in accordance with the provisions of ASC 815, Derivatives and Hedging ("ASC 815"). We classify as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). We account for certain common stock warrants outstanding as a liability at fair value and adjust the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our consolidated statements of operations. The fair value of the warrants issued by us has been estimated using Monte Carlo simulation and or a Black Scholes model. The warrant liabilities are valued using Level 3 valuation inputs.

Derivative Financial Instruments

The Company has derivative financial instruments that are not hedges and do not qualify for hedge accounting. Changes in the fair value of these instruments are recorded in other income (expense), net in the Consolidated Statements of Operations and Comprehensive Loss.

Impairment of Long-Lived Assets

The Company assesses its long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts may not be fully recoverable. To analyze recoverability, the Company projects undiscounted net future cash flows over the remaining lives of such assets. If these projected cash flows are less than the carrying amounts, an impairment loss would be recognized, resulting in a write-down of the assets with a corresponding charge to earnings. The impairment loss is measured based upon the difference between the carrying amounts and the fair values of the assets. Assets to be disposed of are reported at the lower of the carrying amounts or fair value less cost to sell. Management determines fair value using the discounted cash flow method or other accepted valuation techniques.

As of December 31, 2023 and 2022, the undiscounted net future cash flows of the U.K. property were greater than the carrying value. Therefore, no impairment loss was considered necessary.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 to determine if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate if it has sufficient authorized shares. Certain contracts were classified as liabilities as the result of the instruments containing a potentially indeterminable number of shares and, most recently, due to the Company entering into agreements providing for the potential issuance of more shares than authorized. While temporary agreements are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the earliest grant date of potentially dilutive instruments. Pursuant to ASC 815, issuance of stock-based awards to the Company's employees, non-employees or directors are not subject to the sequencing policy.

On January 9, 2023, the Company filed a Certificate of Amendment of its Seventh Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of the State of Delaware, which effected an increase in the Company's authorized shares of common stock, from 1.2 billion to 1.7 billion, par value $0.001 per share. As a result of this increase in authorized shares, the liability-classified warrants were reclassified to equity. Approximate 141 million warrants to purchase shares of the Company's common stock were classified as liabilities through January 8, 2023.

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for any incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt financing, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend.

Convertible Notes under Fair Value Option

We account for certain convertible notes issued from August to October 2023 on an instrument-by-instrument basis under the fair value option ("FVO") election of ASC Topic 825, Financial Instruments ("ASC 825"). The convertible notes accounted for under the FVO election are each debt host financial instruments containing embedded features wherein the entire financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in the estimated fair value of the convertible notes are recorded as a component of Other (expense) income in the consolidated statements of operations, except that the change in estimated fair value attributable to a change in the instrument-specific credit risks is recognized as a component of other comprehensive income. As a result of electing the FVO, issuance costs related to the convertible notes are expensed as incurred.

Stock Based Compensation

Share-based compensation cost is recorded for all option grants and awards of non-vested stock based on the grant date fair value of the award using the Black-Scholes option-pricing model and is recognized over the service period required for the award.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term - The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility - The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate - The Company bases the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend - The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

We recognize forfeitures when they occur.

Recently Issued Accounting Standards Not Yet Adopted

Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 "Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820.

For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. We will adopt ASU 2022-03 effective January 1, 2024. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements.

Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively. We do not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

Results of Operations

Operating costs:

Our operating costs and expenses consist primarily of research and development (R&D) expenses. R&D expenses include clinical trial expenses, and increased costs after completion of a Phase III trial, especially for the extensive preparations, and teams of expert consultants, required for an application for product approval.

In addition to clinical trial and post-trial costs, our operating costs may include ongoing work relating to our DCVax products, including R&D, product characterization, manufacturing process development, quality control process development, and related matters. Additional substantial costs relate to the development and expansion of manufacturing capacity.

Our operating costs also include the costs of preparations for the launch of new or expanded clinical trial programs, such as our anticipated trials of combination treatment regimens. The preparation costs include payments to regulatory consultants, lawyers, statisticians, sites and others, evaluation of potential investigators, the clinical trial sites and the CROs managing the trials and other service providers, and expenses related to institutional approvals, clinical trial agreements (business contracts with sites), training of medical and other site personnel, trial supplies and other.

Our operating costs also include legal and accounting costs in operating the Company.

The foregoing operating costs include the costs for Flaskworks' ongoing operations and intellectual property filings, and the operations of our subsidiaries in the U.K., the Netherlands and Germany.

Research and development:

R&D expenses include costs for substantial external scientific personnel, technical and regulatory advisers, and others, costs of laboratory supplies used in our internal research and development projects, travel, regulatory compliance, and expenditures for preclinical and clinical trial operation and management when we are actively engaged in clinical trials.

Because we are a company with no commercial product sales revenue, we do not allocate research and development costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

General and administrative:

General and administrative expenses include personnel related salary and benefit expenses, cost of facilities, insurance, travel, legal services, property and equipment and amortization of stock options and warrants.

For the Years Ended December 31, 2023, 2022 and 2021

We recognized a net loss of $62.6 million, $105.0 million and a net income of $179.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. The net loss of $62.6 million and $105.0 million for the years ended December 31, 2023 and 2022 included a non-cash gain of $1.5 million and a non-cash loss of $25.8 million from change in fair value derivative liabilities and convertible notes, respectively. The net income of $179.1 million for the year ended December 31, 2021 included a non-cash gain of $239.3 million from change in fair value derivative liabilities.

Net cash used in operations was $53.6 million, $52.8 million and $38.3 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Research and development expense

For the years ended December 31, 2023, 2022 and 2021, research and development expense was $27.7 million, $35.5 million and $20.3 million, respectively. The increase in R&D in 2023 and 2022 as compared to 2021 was mainly reflected extensive one-time activities, which were started in mid of 2022 and fully completed as of December 31, 2023.

The R&D expenses in 2023 and 2022 primarily reflected extensive one-time activities (i) to accomplish a number of pre-requisites that are required before making an application for regulatory of DCVax-L, (ii) to prepare the application package and (iii) to prepare other materials, such as the Trial Master File, to be inspection-ready in addition to the application package. The pre-requisites and preparations included developing, submitting and obtaining regulatory approval for a Pediatric Investigation Plan (PIP), preparing and qualifying for manufacturing licenses required for the Sawston facility, completing the technology transfer from the London facility (where the Company had done all its manufacturing before 2022) to the Sawston facility to enable GMP manufacturing to begin in February 2022 at Sawston (while also continuing in the London facility), and six workstreams related to product matters involving Comparability, Stability, Potency, Product Profile, Mechanism of Action and Fill/Finish which are needed for the application package to seek regulatory approval of DCVax-L.

The 2023 and 2022 R&D expenses we incurred for these activities included payments to numerous teams of specialized external consultants and the CRO, as well as to Advent BioServices. The majority of the payments to Advent were for one-time expenses for ten key one-time milestones for pre-requisites and preparations for the MAA application for product approval. These included three milestones for obtaining the three licenses required for the Sawston facility, six milestones for the six product workstreams, and 1 milestone related to preparing key portions of an application for regulatory approval of the DCVax-L product.

During the year ended December 31, 2023, we completed the last three one-time milestones (obtaining a commercial manufacturing license from the MHRA, completion of drafting and submission of the application to MHRA for product approval), and recognized additional $1.5 million in research and development expense.

During the year ended December 31, 2022, we paid $3.0 million for the cash component of seven milestones, and accrued $4.7 million for the cash component of future milestones. We issued 7.5 million shares at fair value of $5.9 million for the stock component of eight milestones, and we accrued $3.6 million for the stock component of future milestones.

General and Administrative Expense

General and administrative expenses were $29.7 million, $33.4 million and $33.4 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The decrease of $3.6 million in 2023 compared to 2022 was mainly related to a decrease of $1.6 million in consulting, legal and professional fees, a decrease of $0.7 million in compensation expenses and a $0.9 million reduction in our director and officer insurance expenses.

Expenses incurred in 2022 and 2021 were consistent with rounding, but there was a slight decrease of approximate $46,000 which was mainly related to a decrease of $7.0 million stock-based compensation that represented the vesting of a portion of previously granted equity-based awards, and that was recognized in general and administrative expense, and offset by an increase of approximately $1.8 million related to legal and professional expenses, an increase of $1.5 million in insurance premiums, an increase of $1.6 million related

to accrued but unpaid employees' bonus for 2021 and 2022 performances and an increase of $1.7 million of travel and conference expenses.

Change in Fair Value of Derivatives

We recognized a non - cash income of $3.6 million, a non - cash loss of $25.8 million and a non - cash gain of $239.3 million for the years ended December 31, 2023, 2022 and 2021, respectively. The non - cash loss was primarily due to the increase of our stock price, and the non - cash gain was primarily due to the decrease of our stock price. Our closing stock prices as of December 31, 2023, 2022 and 2021 were as follows:

December 31, 2023	December 31, 2022	December 31, 2021
$ 0.70	$ 0.78	$ 0.70

Change in Fair Value of Convertible Notes

We elected the fair value option to fair value certain convertible notes under the guidance in ASC 825 during the year ended December 31, 2023 (see Note 7). We recognized a non-cash loss of $2.0 million change in fair value of the convertible notes during the year ended December 31, 2023.

Debt Extinguishment

During the year ended December 31, 2023, we issued approximately 37.0 million shares of common stock with a fair value of $24.7 million to certain lenders in lieu of cash payments of $19.1 million of debt, including $1.8 million of accrued interest. We also extinguished Share liabilities of $1.1 million and recognized additional $0.8 million in Share liabilities. We recognized an approximately $5.3 million debt extinguishment loss during the year ended December 31, 2023 from the debt redemption.

During the year ended December 31, 2023, we issued approximately 56,000 shares of Series C preferred stock with a fair value of $1.0 million to certain lenders in lieu of cash payments of $0.9 million in debt, including $0.1 million of accrued interest. We recognized an approximately $0.1 million debt extinguishment loss.

During the year ended December 31, 2022, we recognized approximately $2.7 million net debt extinguishment loss. We issued approximately 18.1 million shares of common stock at fair value of $13.8 million to certain lenders in lieu of cash payment of $11.3 million debt, including $1.8 million accrued interest. We also extinguished approximately $0.2 million embedded derivative liability upon the conversion. We recognized approximately $2.3 million debt extinguishment loss. Additionally, pursuant to exchange agreements executed various holders, the Company is required to potentially issue additional common stock (the "Share liability") if the stock price is less than the price defined in the exchange agreement as of the true-up date. We recognized additional $0.7 million debt extinguishment loss related to the Share liability during the year ended December 31, 2022. During the year ended December 31, 2022, we also issued approximately 0.2 million shares of Series C preferred stock at fair value of $3.5 million to certain lenders in lieu of cash payments of $3.4 million debt, including $0.4 million accrued interest. We recognized approximately $0.1 million debt extinguishment loss. We also recognized $0.4 million debt extinguishment gain from PPP loan forgiveness during the year ended December 31, 2022.

During the year ended December 31, 2021, we entered into multiple note extension agreements whereby the maturity dates of the notes were extended for an additional 2-4 months. Certain amendments were accounted for as a debt extinguishment. We recognized $0.2 million debt extinguishment loss from the amendment.

Inducement Expense

During the year ended December 31, 2021, we recorded inducement expense of $0.6 million, which was related to certain warrants exercise.

Interest expense

During the years ended December 31, 2023, 2022 and 2021, we recorded interest expense of $5.2 million, $6.1 million, and $5.0 million, respectively.

Foreign currency transaction (loss) gain

During the years ended December 31, 2023, 2022, and 2021, we recognized foreign currency transaction income of $2.0 million, a loss of $3.3 million and a loss of $1.7 million, respectively. The gain was due to the weakening of the U.S. dollar relative to the British pound sterling. The loss was due to the strengthening of the U.S. dollar relative to the British pound sterling.

Liquidity and Capital Resources

We have experienced recurring losses from operations since inception. We have not yet established an ongoing source of revenues and must cover our operating expenses through debt and equity financings to allow us to continue as a going concern. Our ability to continue as a going concern depends on the ability to obtain adequate capital to fund operating losses until we generate adequate cash flows from operations to fund our operating costs and obligations. If we are unable to obtain adequate capital, we could be forced to cease operations.

We depend upon our ability, and will continue to attempt, to secure equity and/or debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Our management determined that there was substantial doubt about our ability to continue as a going concern within one year after the consolidated financial statements were issued, and management's concerns about our ability to continue as a going concern within the year following this report persist.

Contingent Contractual Payment

The following table summarizes our contractual obligations as of December 31, 2023 (in thousands):

	Payment Due by Period			
	Total	**Less than 1 Year**	**1 to 2 Years**	**3 to 5 Years**
Short term convertible notes payable (1)				
6% unsecured	$ 250	$ 250	$ —	$ —
8% unsecured	3,466	3,466	—	—
10% unsecured	524	524	—	—
Short term convertible notes payable at fair value (2)				
11% unsecured	11,133	11,133		
Short term notes payable (3)				
8% unsecured	3,652	3,652	—	—
12% unsecured	910	910	—	—
Long term notes payable (4)				
8% unsecured	23,179	—	23,179	—
6% secured	606	29	577	—
Operating leases (5)	3,812	944	717	2,151
Minimum commitment obligation (6)	5,746	—	5,746	—
Total	**$ 53,278**	**$ 20,908**	**$ 30,219**	**$ 2,151**

(1) The obligations related to short-term convertible notes were approximately $4.2 million as of December 31, 2023, which included remaining contractual unpaid interest of $0.3 million.

(2) The obligations related to certain short-term convertible notes at fair value were approximately $11.1 million as of December 31, 2023, which included remaining contractual unpaid interest of $0.4 million.

(3) The obligations related to short-term notes were approximately $4.6 million as of December 31, 2023, which included unpaid interest of $0.5 million.

(4) The obligations related to long-term notes were approximately $23.8 million as of December 31, 2023, which included unpaid interest for the next two years of approximately $2.0 million.

(5) The operating lease obligations during the next two years included approximately $0.2 million for our offices in Maryland and U.K. Approximately £1.0 million ($1.3 million) in lease obligations during the next two years and approximately £1.6 million ($2.3 million) for the next three to five years related to the Vision Centre in the U.K. that we leased back in December 2018.

(6) The minimum commitment obligation included minimum required payments to Advent BioServices under the current Manufacturing Services Agreement. The Manufacturing Services Agreement remains in force until five years after the first commercial sales of DCVax-L products pursuant to a marketing authorization, accelerated approval or other commercial approval, unless cancelled. Either party may terminate this agreement without cause upon 12 months' prior written notice. During the notice period services would still be provided. Minimum required payments for this notice period are anticipated total approximately £4.5 million ($5.7 million).

Operating Activities

We used $53.6 million, $52.8 million and $38.3 million in cash for operating activities during the years ended December 31, 2023, 2022 and 2021, respectively. The increase in cash used in operating activities was primarily attributable to an increase in clinical trial related expenditures.

Investing Activities

We spent approximately $3.4 million, $2.9 million and $6.0 million in cash for purchases of equipment in the UK and the build-out of our facility in Sawston, UK during the years ended December 31, 2023, 2022 and 2021, respectively.

Financing Activities

We received approximately $13.3 million and $18.7 million cash from issuances of 1.0 million and 1.2 million shares of Series C convertible preferred stock during the years ended December 31, 2023 and 2022, respectively.

We received approximately $9.5 million and $4.1 million in cash proceeds from issuances of common stock and warrants, in both public and private offerings during the years ended December 31, 2022 and 2021, respectively.

We received approximately $1.7 million, $11.1 million and $20.0 million of cash proceeds from the exercise of warrants and options during the years ended December 31, 2023, 2022 and 2021, respectively.

We received approximately $20.0 million, $5.6 million and $29.7 million in cash proceeds from the issuance of multiple notes payable during the years ended December 31, 2023, 2022 and 2021, respectively.

We received approximately $13.3 million cash proceeds from issuance of convertible notes payable to individual lenders during the year ended December 31, 2023.

We received $5.0 million from issuance of non-dilutive funding agreements during the year ended December 31, 2023.

We made aggregate debt payments of $0.4 million, $5.5 million and $5.8 million during the years ended December 31, 2023, 2022 and 2021, respectively.

We made repayment of $0.2 million of investor advances during the years ended December 31, 2023.

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

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The full text of our audited consolidated financial statements as of December 31, 2023 and 2022 and for the fiscal years ended December 31, 2023, 2022 and 2021, begins on page F-1 of 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

We, the management of Northwest Biotherapeutics, Inc. (the "Company"), are responsible for establishing and maintaining adequate internal control over financial reporting of the Company.

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including to our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15 under the Exchange Act, our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2023. In making this assessment, the Company's management used the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Based on our evaluation, management concluded that, because of a material weakness identified relating to valuation of the Company's debt and derivative liabilities, which primarily involved applying an incorrect valuation method using the market price actually paid for certain convertible notes rather than a Monte Carlo formula, which resulted in a revision of prior period financial statement within the current annual report (see Note 14), our internal control over financial reporting was not effective as of December 31, 2023.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management of the Company, including our CEO and Principal Financial and Accounting Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. Based on this assessment, we determined that our internal control over financial reporting was not effective as of December 31, 2023 due solely to the material weakness over the valuation of debt and derivative liabilities which primarily involved applying an incorrect valuation method using the market price actually paid for certain convertible notes rather than using a Monte Carlo valuation formula. As a result, a correction for the quarter ended September 30, 2023 has been made for less than $5 million (see Note 14).

Management took corrective action during the quarter ended December 31, 2023. The Company believes the weakness has been addressed, but it will need to be tested in the first quarter of 2024, before the weakness can be considered fully remediated.

Cherry Bekaert, LLP, the Company's independent registered public accounting firm, was appointed by the Company's Board of Directors and ratified by the Company's stockholders. They were engaged to render an opinion regarding the fair presentation of the Company's consolidated financial statements as well as conducting an audit of internal control over financial reporting for the period ending December 31, 2023. Their reports included at F-2 of this Form 10-K are based upon audits conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States).

Changes in Internal Control Over Financial Reporting

Other than the material weakness described above, there were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2023 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 information required by Item 10 is hereby incorporated by reference from our 2024 Proxy Statement under the captions “Election of Directors” and “Code of Ethics.” To the extent that we do not file the 2024 Proxy Statement prior to the end of the 120-day period following December 31, 2023, we will amend this Annual Report on Form 10-K to provide the required information.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS-EQUITY COMPENSATION PLAN INFORMATION

Information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant's Amendment No. 1 to the Registration Statement on Form S-1(File No. 333-134320) on July 17, 2006).
3.2	Third Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on June 22, 2007).
3.3	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 filed with the Registrant's Current Report on Form 8-K on June 22, 2007).
3.5	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant's Quarterly Report on Form 10-Q on May 21, 2012).
3.6	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on September 26, 2012).
3.61	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on January 13, 2023).
3.7	Amendment to Third Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on December 11, 2012).
3.8	Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on December 21, 2017).
3.9	Amended and Restated Certificate of Designations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on January 4, 2018).
3.91	Certificate of Elimination of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K on July 26, 2022).
3.92	Certificate of Designations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 filed with the Registrant's Current Report on Form 8-K on July 26, 2022).
4.1	Description of Securities
4.2	Form of common stock certificate (incorporated by reference to Exhibit 4.1 filed with the Registrant's Amendment No. 3 to the Registration Statement on Form S-1 (Registration No. 333-67350) on November 14, 2001).
4.3	Form of Warrant Agency Agreement by and between Northwest Biopharmaceuticals, Inc. and Computershare Trust Company, N.A. and Form of Warrant Certificate (incorporated by reference to Exhibit 4.2 filed with the Registrant's Form S-1 on December 4, 2012).
10.49	Series E Common Stock Purchase Warrant (incorporated by reference as Exhibit 10.2 filed with the Company's Current Report on Form 8-K/A on September 19, 2016).
10.50	Registration Rights Agreement dated August 22, 2016 (incorporated by reference as Exhibit 10.3 filed with the Company's Current Report on Form 8-K/A on September 19, 2016).
10.64	Form of Warrant Repricing Letter Agreement dated August 7, 2017 by and between Northwest Biotherapeutics, Inc. and a certain institutional investor (incorporated by reference as Exhibit 10.1 filed with the Company's Current Report on Form 8-K on August 7, 2017).
10.65	Form of Series A Common Stock Purchase Warrant (incorporated by reference as Exhibit 10.2 filed with the Company's Current Report on Form 8-K on August 7, 2017).
10.66	Form of Securities Purchase Agreement, dated September 20, 2017, by and between Northwest Biotherapeutics, Inc. and certain institutional investors (incorporated by reference as Exhibit 10.1 filed with the Company's Current Report on Form 8-K on September 22, 2017).
10.67	Form of Class A Common Stock Purchase Warrant (incorporated by reference as Exhibit 10.2 filed with the Company's Current Report on Form 8-K on September 22, 2017).
10.70	Form of Class D-1 Common Stock Purchase Warrant (incorporated by reference as Exhibit 10.1 filed with the Company's Current Report on Form 8-K on December 7, 2017).
10.72	Form of Subscription Agreement (incorporated by reference as Exhibit 10.3 filed with the Company's Current Report on Form 8-K on December 7, 2017).
10.73	Settlement and Amendment Agreement (2016 Obligations Agreement), dated as of December 31, 2017, by and between Northwest Biotherapeutics, Inc. and Cognate BioServices, Inc.
10.74	Settlement and Amendment Agreement (2017 Obligations Agreement), dated as of December 31, 2017, by and between Northwest Biotherapeutics, Inc. and Cognate BioServices, Inc.

10.75	Note and Loan Agreement, dated as of March 14, 2018, by and between Northwest Biotherapeutics, Inc. and Linda F. Powers.
10.76	Note and Loan Agreement, dated as of March 19, 2018, by and between Northwest Biotherapeutics, Inc. and Linda F. Powers.
10.78	Form of Loan Agreement, dated as of November 7, 2018, by and between Northwest Biotherapeutics, Inc. and a Group of Private Lenders.
10.79	Contract Relating to Sale of Spicers, Sawston, Cambridge, dated as of December 5, 2018, by and between Aracaris Capital Limited and Huawei Technologies Research & Development (UK) Limited.
10.80	Lease Relating to Vision Centre, Sawston, Cambridge, by and between Aracaris Capital Limited and Aracaris Limited, dated as of December 14, 2018.
10.81	Equity Compensation Plan, dated May 29, 2020.
10.82	Note and Loan Agreement, dated August 14, 2021, by and between Northwest Biotherapeutics, Inc. and Iliad Research and Trading L.P.
10.83	Agreement to acquire Flaskworks, L.L.C, August 28, 2020.
10.84	Change in Registrant's Accountants (incorporated by reference as Exhibit 16.1 filed with the Company's Current Report on Form 8-K January 26, 2021).
10.85	Loan Agreement, dated March 1, 2021, by and between Northwest Biotherapeutics, Inc. and Streeterville Capital, L.L.C.
10.86	Loan Agreement, dated November 22, 2021, by and between Northwest Biotherapeutics, Inc. and Streeterville Capital, L.L.C (incorporated by reference to Exhibit 10.86 filed with the Registrant's Annual Report on Form 10 - K on March 1, 2022).
10.87	Sub-lease Agreement, dated December 31, 2021, by and between Aracaris Ltd. and Northwest Biotherapeutics, Inc. (collectively the "Sub-Lessor") and Advent BioServices, Ltd. (the "Sub-Lessee").
10.88	Loan Agreement, dated September 26, 2022, by and between Northwest Biotherapeutics, Inc. and Streeterville Capital, L.L.C (incorporated by reference to Exhibit 10.88 filed with the Registrant's Annual Report on Form 10 - K on February 28, 2023).
10.89	Loan Agreement, dated March 2, 2023, by and between Northwest Biotherapeutics, Inc. and Streeterville Capital, L.L.C.
10.90	Loan Agreement, dated November 10, 2023, by and between Northwest Biotherapeutics, Inc. and Streeterville Capital, L.L.C.
21.1	Subsidiaries of the Registrant.
23.1	Independent Registered Public Accounting Firm's Consent.
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Schema Document.
101.CAL	Inline XBRL Calculation Linkbase Document.
101.DEF	Inline XBRL Definition Linkbase Document.
101.LAB	Inline XBRL Label Linkbase Document.
101.PRE	Inline XBRL Presentation Linkbase Document.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

*Confidential information in this exhibit has been omitted and filed separately with the SEC pursuant to a confidential treatment request.

ITEM 16. FORM 10–K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

NORTHWEST BIOTHERAPEUTICS, INC.
(Registrant)

Date: March 5, 2024

By: /s/ Linda F. Powers
Linda F. Powers,
President and Chief Executive Officer
Principal Executive Officer
Principal Financial and Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda F. Powers Linda F. Powers	President and Chief Executive Officer Principal Executive Officer Principal Financial and Accounting Officer	March 5, 2024
/s/ Alton L. Boynton Alton L. Boynton	Director	March 5, 2024
/s/ Navid Malik Dr. Navid Malik	Director	March 5, 2024
/s/ Jerry Jasinowski Jerry Jasinowski	Director	March 5, 2024
/s/ J. Cofer Black J. Cofer Black	Director	March 5, 2024

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

NORTHWEST BIOTHERAPEUTICS, INC.

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Northwest Biotherapeutics, Inc.
Bethesda, Maryland

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheets of Northwest Biotherapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, comprehensive income, stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria because a material weakness in internal control over financial reporting existed as of that date as the Company did not maintain effective control over the valuation of debt and derivatives.

A material weakness is a control deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in the Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not effect our opinion on those consolidated financial statements.

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

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting included in Item 9A— *Controls and Procedures* in the Company's 2023 Annual Report on Form 10-K. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included

evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

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

Critical Audit Matter Description

As disclosed in Notes 4, 5, 7, 10, and 11 to the consolidated financial statements, the Company had various debt, derivative, mezzanine equity and equity transactions, including both related party and non-related party stock-based compensation and convertible notes elected to be carried at fair value, where management evaluated required accounting considerations, significant estimates, and judgements around certain features, the possibility of conversion or redemption, and the valuation of certain components of the financings, including the valuation around certain freestanding and embedded derivatives. Certain features were initially measured at fair value and have been subsequently remeasured to fair value at each reporting period.

There is no current observable market for these types of features and, as such, the Company determined the fair value of the freestanding instruments or embedded derivatives using the Black-Scholes-Merton model or the Monte Carlo option pricing model, as applicable, to measure the fair value of the debt and/or equity instrument both with and without the derivative liability features. As a result, a high degree of auditor judgment and effort was required in performing audit procedures to evaluate the various components of these instruments.

How the Critical Audit Matter was Addressed in the Audit

Our principal audit procedures performed to address this critical audit matter included the following:

- We tested the design and operating effectiveness of the internal controls related to the debt, derivative liabilities, mezzanine equity and equity transactions, including both related party and non-related party stock-based compensation and convertible notes elected to be carried at fair value, processes.

- We obtained a listing of all debt, derivative liabilities, mezzanine equity and equity transactions, including both related party and non-related party stock-based compensation and convertible notes elected to be carried at fair value, and management's accounting analysis supporting these transactions. We evaluated the conclusions reached to ensure these were recorded in accordance with the relevant accounting guidance.

- We identified and evaluated the accounting considerations in determining the nature of the various features and weighting of evidence, the potential bifurcation of these instruments, and considerations related to the determination of the fair value of the various debt and equity instruments and the conversion and redemption features that include valuation models and assumptions utilized by management. We reviewed the fair value models used, significant assumptions, and underlying data used in the models and evaluated whether the estimates and assumptions were consistent with audit evidence obtained.

- We evaluated the disclosures surrounding debt, derivative liabilities, mezzanine equity and equity transactions, including both related party and non-related party stock-based compensation and convertible notes elected to be carried at fair value, to ensure these were disclosed in accordance with the relevant accounting guidance.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2021.

Cherry Bekaert LLP
Tampa, Florida
March 5, 2024

NORTHWEST BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,126	$ 6,965
Prepaid expenses and other current assets	1,999	2,460
Total current assets	4,125	9,425
Non-current assets:		
Property, plant and equipment, net	17,278	13,418
Construction in progress	—	2,028
Right-of-use asset, net	4,183	4,189
Indefinite-lived intangible asset	1,292	1,292
Goodwill	626	626
Other assets	361	345
Total non-current assets	23,740	21,898
TOTAL ASSETS	**$ 27,865**	**$ 31,323**
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,244	$ 10,687
Accounts payable and accrued expenses to related parties and affiliates	3,544	6,955
Convertible notes, net	3,765	135
Convertible notes at fair value	12,771	—
Notes payable, net	3,944	15,403
Contingent payable derivative liability	9,188	8,668
Warrant liability	944	80,559
Investor advances	7	2,566
Share liability	483	678
Lease liabilities	314	354
Total current liabilities	45,204	126,005
Non-current liabilities:		
Notes payable, net of current portion, net	20,312	5,991
Lease liabilities, net of current portion	4,454	4,370
Contingent payment obligation	4,950	—
Total non-current liabilities	29,716	10,361
Total liabilities	74,920	136,366
COMMITMENTS AND CONTINGENCIES (Note 12)		
Mezzanine equity:		
Series C Convertible Preferred Stock, 10,000,000 shares designated; 1.2 million and 1.4 million shares issued and outstanding as of December 31, 2023 and 2022, respectively; aggregate liquidation preference of $17.0 million	18,718	23,060
Stockholders' deficit:		
Preferred stock ($0.001 par value); 100,000,000 shares authorized as of December 31, 2023 and 2022, respectively	—	—
Common stock ($0.001 par value); 1,700,000,000 shares authorized; 1,175.5 million and 1,068.4 million shares issued and outstanding as of December 31, 2023 and 2022, respectively	1,175	1,068
Additional paid-in capital	1,291,316	1,164,885
Stock subscription receivable	(79)	(79)
Accumulated deficit	(1,359,721)	(1,297,122)
Accumulated other comprehensive income	1,536	3,145
Total stockholders' deficit	(65,773)	(128,103)
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	**$ 27,865**	**$ 31,323**

See accompanying notes to the consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share data)

	For the years ended December 31,		
	2023	**2022**	**2021**
Revenues:			
Research and other	$ 1,932	$ 1,683	$ 1,005
Total revenues	1,932	1,683	1,005
Operating costs and expenses:			
Research and development	27,730	35,511	20,308
General and administrative	29,710	33,353	33,399
Total operating costs and expenses	57,440	68,864	53,707
Loss from operations	(55,508)	(67,181)	(52,702)
Other income (expense):			
Change in fair value of derivative liabilities	3,644	(25,821)	239,347
Change in fair value of share liabilities	(78)	33	—
Change in fair value of convertible notes	(2,021)	—	—
Loss from extinguishment of debt	(5,403)	(2,691)	(165)
Interest expense	(5,241)	(6,068)	(5,011)
Inducement expense	—	—	(647)
Foreign currency transaction gain (loss)	2,008	(3,304)	(1,696)
Total other (loss) income	(7,091)	(37,851)	231,828
Net (loss) income	(62,599)	(105,032)	179,126
Deemed dividend related to warrant modification	(1,774)	—	—
Net (loss) income attributable to common stockholders	$ (64,373)	$ (105,032)	$ 179,126
Other comprehensive income (loss)			
Foreign currency translation adjustment	(1,609)	2,788	1,505
Total comprehensive (loss) income	$ (65,982)	$ (102,244)	$ 180,631
Net (loss) income per share applicable to common stockholders			
Basic	$ (0.06)	$ (0.10)	$ 0.21
Diluted	$ (0.06)	$ (0.10)	$ (0.06)
Weighted average shares used in computing basic loss per share	1,119,191	1,015,852	873,517
Weighted average shares used in computing diluted loss per share	1,119,191	1,015,852	1,007,869

See accompanying notes to the consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
(in thousands)

	Mezzanine equity Series C Covertible Preferred Stock		Common Stock		Additional Paid-in	Subscription	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Par value	Capital	Receivable	Deficit	Income (Loss)	Deficit
Balances at January 1, 2021	**—**	**$ —**	**829,631**	**$ 830**	**$1,008,665**	**$ (79)**	**$(1,371,216)**	**$ (1,148)**	**$ (362,948)**
Issuance of common stock for cash	—	—	6,272	6	4,064	—	—	—	4,070
Issuance of common stock and warrants for conversion of debt and accrued interest	—	—	5,145	5	7,495	—	—	—	7,500
Warrants and stock options exercised for cash	—	—	86,910	87	19,888	—	—	—	19,975
Reclassification of warrant liabilities related to warrants exercised for cash	—	—	—	—	68,692	—	—	—	68,692
Cashless warrants and stock options exercise	—	—	20,439	20	(20)	—	—	—	—
Reclassification of warrant liabilities related to cashless warrants exercise	—	—	—	—	2,369	—	—	—	2,369
Stock-based compensation	—	—	48	—	15,571	—	—	—	15,571
Reclassification of warrant liabilities based on authorized shares	—	—	—	—	(59,851)	—	—	—	(59,851)
Net income	—	—	—	—	—	—	179,126	—	179,126
Cumulative translation adjustment	—	—	—	—	—	—	—	1,505	1,505
Balances at December 31, 2021	**—**	**—**	**948,445**	**948**	**1,066,873**	**(79)**	**(1,192,090)**	**357**	**(123,991)**
Issuance of Series C convertible preferred stock for cash	1,157	18,669	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock in lieu of debt redemption	203	3,527	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock by common stock warrant exercise	55	329	—	—	—	—	—	—	—
Issuance of common stock for cash	—	—	13,147	13	9,676	—	—	—	9,689
Warrants exercised for cash	—	—	45,298	45	11,060	—	—	—	11,105
Reclassification of warrant liabilities related to warrants exercised for cash	—	535	—	—	24,434	—	—	—	24,434
Cashless warrants and stock options exercise	—	—	34,224	34	(34)	—	—	—	—
Reclassification of warrant liabilities related to cashless warrants exercise	—	—	—	—	26,800	—	—	—	26,800
Issuance of common stock for conversion of debt and accrued interest	—	—	18,139	19	13,787	—	—	—	13,806
Stock-based compensation	—	—	9,141	9	12,289	—	—	—	12,298
Net loss	—	—	—	—	—	—	(105,032)	—	(105,032)
Cumulative translation adjustment	—	—	—	—	—	—	—	2,788	2,788
Balances at December 31, 2022	**1,415**	**23,060**	**1,068,394**	**1,068**	**1,164,885**	**(79)**	**(1,297,122)**	**3,145**	**(128,103)**
Issuance of Series C convertible preferred stock for cash	952	13,330	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock in lieu of debt redemption	56	1,013	—	—	—	—	—	—	—
Series C convertible preferred stock conversion	(1,230)	(18,915)	30,756	31	18,884	—	—	—	18,915
Warrants and stock options exercised for cash	—	—	12,800	13	2,907	—	—	—	2,920
Cashless warrants and stock options exercise	—	—	21,327	21	(21)	—	—	—	—
Reclassification of warrant liabilities to stockholders' deficit	—	—	—	—	76,258	—	—	—	76,258
Issuance of common stock for conversion of debt and accrued interest	—	—	37,018	37	24,615	—	—	—	24,652
Stock-based compensation	16	230	5,164	5	4,173	—	—	—	4,178
Reclass earned but unissued milestone shares from equity to liability	—	—	—	—	(1,065)	—	—	—	(1,065)
Net loss	—	—	—	—	—	—	(62,599)	—	(62,599)
Warrants modfication	—	—	—	—	2,454	—	—	—	2,454
Deemed dividend related to warrants modification	—	—	—	—	(1,774)	—	—	—	(1,774)
Cumulative translation adjustment	—	—	—	—	—	—	—	(1,609)	(1,609)
Balances at December 31, 2023	**1,209**	**$ 18,718**	**1,175,459**	**$ 1,175**	**$1,291,316**	**$ (79)**	**$(1,359,721)**	**$ 1,536**	**$ (65,773)**

See accompanying notes to the consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,		
	2023	**2022**	**2021**
Cash Flows from Operating Activities:			
Net loss	$ (62,599)	$ (105,032)	$ 179,126
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	1,525	1,252	324
Amortization of debt discount	2,372	2,771	2,301
Change in fair value of derivatives	(3,644)	25,821	(239,347)
Change in fair value of share liability	78	(33)	—
Change in fair value of convertible notes	2,021	—	—
Loss from extinguishment of debt	5,403	2,691	165
Inducement expense	—	—	647
Amortization of operating lease right-of-use asset	208	248	262
Stock-based compensation for services	4,408	12,298	15,498
Warrant modifications associated with convertible notes under fair value option	286	—	—
Subtotal of non-cash charges	12,657	45,048	(220,150)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	501	(397)	3,475
Other non-current assets	(12)	625	(179)
Accounts payable and accrued expenses	50	3,492	77
Related party accounts payable and accrued expenses	(4,476)	3,354	(674)
Lease liabilities	242	135	26
Net cash used in operating activities	(53,637)	(52,775)	(38,299)
Cash Flows from Investing Activities:			
Purchase of equipment and construction in progress	(3,437)	(2,902)	(6,015)
Net cash used in investing activities	(3,437)	(2,902)	(6,015)
Cash Flows from Financing Activities:			
Proceeds from issuance of Series C convertible preferred stock	13,330	18,669	—
Proceeds from issuance of Series C convertible preferred stock by common stock warrant exercise, net of debt redemption	—	52	—
Proceeds from issuance of common stock	—	9,465	4,070
Proceeds from exercise of warrants and options	1,717	11,105	19,975
Proceeds from investor advance	7	2,566	250
Proceeds from issuance of notes payable, net	20,000	5,600	29,665
Proceeds from issuance of convertible notes payable, net	13,339	—	—
Proceeds from contingent payment obligation	4,950	—	—
Repayment of notes payable	(385)	(5,489)	(5,828)
Repayment of investor advances	(200)	—	—
Net cash provided by financing activities	52,758	41,968	48,132
Effect of exchange rate changes on cash and cash equivalents	(523)	5,505	1,368
Net (decrease) increase in cash and cash equivalents	(4,839)	(8,204)	5,186
Cash and cash equivalents, beginning of the year	6,965	15,169	9,983
Cash and cash equivalents, end of the year	$ 2,126	$ 6,965	$ 15,169
Supplemental disclosure of cash flow information			
Interest payments on notes payable	$ (55)	$ (912)	$ (1,730)

See accompanying notes to the consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,		
	2023	**2022**	**2021**
Supplemental schedule of non-cash investing and financing activities:			
Cashless warrants and stock options exercise	$ 21	$ 34	$ 20
Reclassification of warrant liabilities related to warrants exercised for cash	$ —	$ 24,969	$ 68,692
Reclassification of warrant liabilities to stockholders' deficit	$ 76,258	$ —	$ —
Reclassification of warrant liabilities related to cashless warrants exercise	$ —	$ 26,800	$ 2,369
Reclassification of warrant liabilities based on authorized shares		$ —	$ 59,851
Reclassisifcation of investor advances to convertible notes payable	$ 1,163	$ —	$ —
Reclassisifcation of investor advances to stockholders' deficit	$ 1,203	$ —	$ —
Issuance of common stock for conversion of debt and accrued interest	$ 24,652	$ 11,541	$ 7,487
Issuance of Series C convertible preferred stock in lieu of debt redemption	$ 1,013	$ 3,408	$ —
Exercise common stock warrants by debt redemption	$ —	$ 277	$ —
Series C convertible preferred stock conversion	$ 18,915	$ —	$ —
Capital expenditures included in accounts payable	$ 178	$ 699	$ 33
Capital expenditures included in accounts payable and accrued expenses to related parties and affiliates	$ —	$ —	$ 370
Issuance of common shares to settle accrued service liability	$ —	$ —	$ 73
Reclassification between shares payable and equity	$ —	$ 250	$ —
Reclass earned but unissued milestone shares from equity to liability	$ 1,065	$ —	$ —
Deemed dividend related to warrant modification	$ 1,774	$ —	$ —
Debt discout related to warrant modificaiton	$ 394	$ —	$ —

See accompanying notes to the consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

1. Organization and Description of Business

Northwest Biotherapeutics, Inc. and its wholly owned subsidiaries Flaskworks, Northwest Biotherapeutics Limited (formerly known as Aracaris Ltd), Aracaris Capital, Ltd, Northwest Biotherapeutics B.V., and NW Bio GmbH (collectively, the "Company", "we", "us" and "our") were organized to discover and develop innovative immunotherapies for cancer. The Company has developed DCVax® platform technologies for both operable and inoperable solid tumor cancers. The Company has wholly owned subsidiaries in Boston, the U.K., the Netherlands and Germany. On August 28, 2020, the Company acquired Flaskworks, LLC ("Flaskworks"), a company that has developed a system designed to close and automate the manufacturing of cell therapy products such as DCVax®. On July 24, 2023, the Company's wholly-owned U.K. subsidiary changed its name from Aracaris Ltd to Northwest Biotherapeutics Limited.

The Company relies upon contract manufacturers for production of its DCVax products, research and development services, distribution and logistics, and related services, in compliance with the Company's specifications and the applicable regulatory requirements.

The Company has completed a Phase 3 clinical trial of its DCVax®-L product for glioblastoma brain cancer, has publicly reported the results in a peer reviewed publication in a medical journal as well as at a medical conference, and has submitted an application for regulatory approval of the product in the U.K.

2. Financial Condition, Going Concern and Management Plans

The Company has incurred annual net operating losses since its inception. The Company had a net loss of $62.8 million for the year ended December 31, 2023. The Company used approximately $53.6 million of cash in its operating activities during the year ended December 31, 2023.

The Company does not expect to generate material revenue in the near future from the sale of products and is subject to all of the risks and uncertainties that are typically faced by biotechnology companies that devote substantially all of their efforts to research and development ("R&D") and clinical trials and do not yet have commercial products. The Company expects to continue incurring annual losses for the foreseeable future. The Company's existing liquidity is not sufficient to fund its operations, anticipated capital expenditures, working capital and other financing requirements until the Company reaches significant revenues. Until that time, the Company will need to obtain additional equity and/or debt financing, especially if the Company experiences downturns in its business that are more severe or longer than anticipated, or if the Company experiences significant increases in expense levels resulting from being a publicly-traded company or from expansion of operations. If the Company attempts to obtain additional equity or debt financing, the Company cannot assume that such financing will be available to the Company on favorable terms, or at all.

Because of recurring operating losses and operating cash flow deficits, there is substantial doubt about the Company's ability to continue as a going concern within one year from the date of this filing. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP") and include the assets, liabilities, revenues and expenses of the wholly owned subsidiaries in Germany, United Kingdom and Netherlands. All intercompany transactions and accounts have been eliminated in consolidation.

Consolidation

The Company's policy is to consolidate all entities in which it can vote a majority of the outstanding voting stock. In addition, the Company consolidates entities that meet the definition of a variable interest entity ("VIE") for which the Company is the primary beneficiary, if any. The primary beneficiary is the party who has the power to direct the activities of a VIE that most significantly impact the entity's economic performance and who has an obligation to absorb losses of the entity or a right to receive benefits from the entity that could potentially be significant to the VIE.

As of December 31, 2023 and 2022, the Company did not consolidate any VIE's as the Company has concluded that it is not the primary beneficiary.

Use of Estimates

In preparing consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates.

On an ongoing basis, the Company evaluates its estimates and judgments, including valuing equity securities in share-based payment arrangements, estimating the fair value of financial instruments recorded as derivative liabilities, useful lives of depreciable assets and whether impairment charges may apply. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in a financial institution, which at times may exceed the Federal depository insurance coverage ("FDIC") of $250,000. As of December 31, 2023, of the total $2.1 million in cash and cash equivalents, $36,000 was held by foreign subsidiaries. As of December 31, 2022, of the total $7.0 million in cash and cash equivalents, $0.4 million was held by foreign subsidiaries. The Company had not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Property, Plant and Equipment

Property and equipment are stated at cost. Depreciation and amortization are provided for using straight-line methods, in amounts sufficient to charge the cost of depreciable assets to operations over their estimated service lives. Repairs and maintenance costs are charged to operations as incurred.

Costs for capital assets not yet placed into service are capitalized as construction in progress on the consolidated balance sheets and will be depreciated once placed into service. In October 2021, approval was received from the UK Human Tissue Authority ("HTA") of a license for collection and processing of human cells and tissues for medical purposes at the Company's Sawston, UK facility. In December 2021, approval was received from the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") of a license for manufacture at the Sawston facility of GMP (clinical grade) cell therapy products for compassionate use and trials. All costs associated with the facility buildout (Phase 1A) were reclassified from construction in progress to leasehold improvements, and the costs began to be amortized over the estimated useful life of the asset and/or leasehold lease. The Company incurred additional construction works related to Phase 1B build out during the year ended December 31, 2022, which was completed and placed in use in 2023.

The Company assesses its long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts may not be fully recoverable. To analyze recoverability, the Company projects undiscounted net future cash flows over the remaining lives of such assets. If these projected undiscounted net future cash flows are less than the carrying amounts, an impairment loss would be recognized, resulting in a write-down of the assets with a corresponding charge to earnings. The impairment loss is measured based upon the difference between the carrying amounts and the fair values of the assets.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. The Company's intangible asset with an indefinite life is related to in-process research and development ("IPR&D") programs acquired in the Flaskworks Acquisition, as the Company expects future research and development on these programs to provide the Company with substantial benefit for a period that extends beyond the foreseeable horizon. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. The Company does not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite lived and would then be amortized based on their respective estimated useful lives at that point in time.

The Company has one operating segment and one reporting unit. The Company reviews goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values. No impairment charge was recognized for the year ended December 31, 2023 and 2022.

Fair Value of Financial Instruments

ASC 820, Fair Value Measurements, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount 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. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The Company accounts for the issuance of common stock purchase warrants issued in connection with the equity offerings in accordance with the provisions of ASC 815, Derivatives and Hedging ("ASC 815"). The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company accounts for certain common stock warrants outstanding as a liability at fair value and adjusts the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in its Consolidated Statements of Operations and Comprehensive Loss. The fair value of the warrants issued by the Company has been estimated using Monte Carlo simulation and or a Black Scholes model. The warrant liabilities are valued using Level 3 valuation inputs (see Note 4).

Derivative Financial Instruments

The Company has derivative financial instruments that are not hedges and do not qualify for hedge accounting. Changes in the fair value of these instruments are recorded in other income (expense), on a net basis in the Consolidated Statements of Operations and Comprehensive Loss.

Convertible Notes under Fair Value Option

The Company accounts for certain convertible notes issued from August to October 2023 on an instrument-by-instrument basis under the fair value option ("FVO") election of ASC Topic 825, Financial Instruments ("ASC 825"). The convertible notes accounted for under the FVO election are each debt host financial instruments containing embedded features wherein the entire financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in the estimated fair value of the convertible notes are recorded as a component of Other (expense) income in the consolidated statements of operations, except that the change in estimated fair value attributable to a change in the instrument-specific credit risks is recognized as a component of other comprehensive income. As a result of electing the FVO, issuance costs related to the convertible notes are expensed as incurred.

Contingent Payable Derivative Liability

During the year ended December 31, 2019, the Company entered into a settlement agreement with Cognate BioServices, resolving past matters and providing for the restart of DCVax®-Direct Production.

As part of this overall settlement, the Company also provided a contingent note payable (the "Contingent Payable Derivative") of $10.0 million, which is only payable upon the Company's first financing after DCVax product approval in or outside the U.S. If such product approval has not been obtained by the seventh anniversary of the agreement, such Contingent Payable Derivative will expire without becoming payable.

On a quarterly basis, management makes estimates for key performance milestones and uses the expected dates as the inputs for valuation. The fair value of the Contingent Payable Derivative has been estimated using Monte Carlo simulation, which are valued using Level 3 valuation inputs.

Leases

The Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines whether an arrangement is or contains a lease at contract inception. Operating leases with a duration greater than one year are included in right-of-use assets, lease liabilities, and lease liabilities, net of current portion in the Company's consolidated balance sheets. Right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset.

The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. Variable lease expenses are recorded when incurred.

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

Foreign Currency Translation and Transactions

The Company has operations in the United Kingdom and Netherlands in addition to the U.S. The Company translated its assets and liabilities into U.S. dollars using end of period exchange rates, and revenues and expenses are translated into U.S. dollars using weighted average rates. Foreign currency translation adjustments are reported as a separate component of accumulated other comprehensive income (loss) within stockholders' equity deficit.

The Company converts receivables and payables denominated in other than the Company's functional currency at the exchange rate as of the balance sheet date. The resulting transaction exchange gains or losses related to intercompany receivable and payables, are included in other income and expense.

Comprehensive Loss

The Company reports comprehensive loss and its components in its consolidated financial statements. Comprehensive loss consists of net loss and foreign currency translation adjustments, affecting stockholders' equity deficit that, under U.S, GAAP, is excluded from net loss.

Revenue Recognition

The Company recognizes revenue in accordance with the terms stipulated under the applicable service contract. In various situations, the Company receives certain credits against invoices for manufacturing of patient treatments by its contract manufacturer. These payments are assessed and recognized in accordance with ASC 606 in the period when the performance obligation had been met.

Accrued Outsourcing Costs

Substantial portions of our preclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively "CROs"). These CROs generally bill monthly or quarterly for services performed, or bill based upon milestones achieved. For clinical studies, expenses are accrued when services are performed. The Company monitors patient enrollment, the progress of clinical studies and related activities through internal reviews of data that is tracked by the CROs under contractual arrangements, correspondence with the CROs and visits to clinical sites.

Research and Development Costs

Research and development costs are charged to operations as incurred and consist primarily of clinical trial related costs (including costs for collection, validation and analysis of trial results), related party manufacturing costs, consulting costs, contract research and development costs, clinical site costs and compensation costs.

Income Taxes

The Company evaluates its tax positions and estimates its current tax exposure along with assessing temporary differences that result from different book to tax treatment of items not currently deductible for tax purposes. These differences result in deferred tax assets and liabilities on the Company's Consolidated Balance Sheets, which are estimated based upon the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates that will be in effect when these differences reverse. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company's Consolidated Statements of Comprehensive Loss become deductible expenses under applicable income tax laws or loss or credit carryforwards are utilized. Accordingly, realization of the Company's deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized.

The Company must assess the likelihood that the Company's deferred tax assets will be recovered from future taxable income, and to the extent the Company believes that recovery is not more likely than not, the Company must establish a valuation allowance. Management judgment is required in determining the Company's provision for income taxes, the Company's deferred tax assets and liabilities and any valuation allowance recorded against the Company's net deferred tax assets. Excluding foreign operations, the Company recorded a full valuation allowance at each balance sheet date presented because, based on the available evidence, the Company believes it is more likely than not that it will not be able to utilize all of its deferred tax assets in the future. The Company intends to maintain the full valuation allowance until sufficient evidence exists to support the reversal of the valuation allowance.

Stock-Based Compensation

The Company measures stock-based compensation to employees, consultants, and Board members at fair value on the grant date of the award. Compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. For awards that have a performance condition, compensation cost is measured based on the fair value of the award on the grant date, the date performance targets are established, and is expensed over the requisite service period for each separately vesting tranche when achievement of the performance condition becomes probable. The Company assess the probability of the performance conditions being met on a continuous basis. Forfeitures are recognized when they occur. Prior to January 1, 2019, share-based compensation cost for non-employees was re-measured at every reporting period.

The Company estimates the fair value of stock option grants that do not contain market-based vesting conditions using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term - The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility - The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate - The Company bases the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend - The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company is also required to make estimates as to the probability of achieving the specific performance conditions. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's consolidated results of operations.

Debt Extinguishment

The Company accounts for the income or loss from extinguishment of debt by comparing the difference between the reacquisition price and the net carrying amount of the debt being extinguished and recognizes this as gain or loss when the debt is extinguished. The gain or loss from debt extinguishment is recorded in the consolidated statements of operations under "other income (expense)" as loss from extinguishment of convertible debt.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 whereby in the event that reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was previously the result of certain financial instruments with a potentially indeterminable number of shares and most recently due to the company committing more shares than authorized. While temporary suspensions are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the earliest grant date of potentially dilutive instruments. Pursuant to ASC 815, issuance of stock-based awards to the Company's employees, nonemployees or directors are not subject to the sequencing policy.

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for any incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt financing, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend.

Income (Loss) per Share

Basic income (loss) per share is computed on the basis of the weighted average number of shares outstanding for the reporting period. Diluted income (loss) per share is computed on the basis of the weighted average number of common shares plus dilutive potential common shares outstanding using the treasury stock method. Diluted weighted average shares reflect the dilutive effect, if any, of potential common shares. To the extent their effect is dilutive, employee equity awards and other commitments to be settled in common stock are included in the calculation of diluted income per share based on the treasury stock method. Potential common shares are excluded from the calculation of dilutive weighted average shares outstanding if their effect would be anti-dilutive at the balance sheet date based on a treasury stock method or due to a net loss.

Recently Issued Accounting Standards Not Yet Adopted

Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 "Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820.

For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company will adopt ASU 2022-03 effective January 1, 2024. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements.

Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

4. Fair Value Measurements

In accordance with ASC 820 (Fair Value Measurements and Disclosures), the Company uses various inputs to measure the fair value of liabilities related to certain embedded conversion feature associated with convertible debt, share liability, and contingent payable to Cognate BioServices on a recurring basis to determine the fair value of these liabilities. The Company also elects the FVO for certain eligible financial instruments, such as convertible notes, in order to simplify the accounting treatment.

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of December 31, 2023 and December 31, 2022 (in thousands):

	Fair value measured at December 31, 2023			
	Fair value at December 31, 2023	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Warrant liability	$ 944	$ —	$ —	$ 944
Contingent payable derivative liability	9,188	—	—	9,188
Convertible notes at fair value	12,771			12,771
Share liability	483			483
Total fair value	$ 23,386	$ —	$ —	$ 23,386

	Fair value measured at December 31, 2022			
	Fair value at December 31, 2022	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Warrant liability	$ 80,559	$ —	$ —	$ 80,559
Embedded redemption option	807	—	—	807
Contingent payable derivative liability	8,668	—	—	8,668
Share liability	678			678
Total fair value	$ 90,712	$ —	$ —	$ 90,712

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2023 and 2022.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2023 and 2022. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long- dated volatilities) inputs (in thousands).

	Warrant Liability	Embedded Redemption Option	Contingent Payable Derivative Liability	Share Liability	Convertible Notes At Fair Value	Total
Balance - January 1, 2022	**$106,784**	**$ 988**	**$ 8,232**	**$ —**	**$ —**	**$116,004**
Additional warrant liability	184	7	—	—	—	191
Additional share liability	—	—	—	711	—	711
Debt redemption	—	(213)	—	—	—	(213)
Reclassification of warrant liabilities	(51,769)	—	—	—	—	(51,769)
Change in fair value	25,360	25	436	(33)	—	25,788
Balance – December 31, 2022	**80,559**	**807**	**8,668**	**678**	**—**	**90,712**
Additional share liability	—	—	—	818	—	818
Issuance of convertible notes at fair value	—	—	—	—	10,750	10,750
Redemption of share liability	—	—	—	(1,091)	—	(1,091)
Reclassification of warrant liabilities	(76,258)	—	—	—	—	(76,258)
Change in fair value	(3,357)	(807)	520	78	2,021	(1,545)
Balance - December 31, 2023	**$ 944** [(1)]	**$ —**	**$ 9,188**	**$ 483**	**$ 12,771**	**$ 23,386**

(1) The remaining balance of $0.9 million in warrant liability as of December 31, 2023 was related to certain conditional rights to independently purchase shares from the Company in a future raise of capital (the “Piggy-back Rights”). The Company accounted for the Piggy-back Rights as a freestanding financial instrument, which was classified as a liability at fair value on the Consolidated Balance Sheet.

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company’s warrant liabilities and embedded conversion feature (excluding the piggy-back right, which was based on key milestone estimates, see Note 8 for piggy-back rights) that are categorized within Level 3 of the fair value hierarchy as of December 31, 2023, January 9 2023 (the reclassification date) and December 31, 2022 is as follows:

	As of December 31, 2023		As of January 9, 2023
	Share Liability	Contingent Payable Derivative Liability	Warrant Liability
Strike price	$ 0.64	$ 0.70 *	$ 0.31
Contractual term (years)	0.1	1.0	1.5
Volatility (annual)	71 %	71 %	87 %
Risk-free rate	5.6 %	5.2 %	4.3 %
Dividend yield (per share)	0 %	0 %	0 %

	As of December 31, 2022		
	Warrant Liability	Share Liability	Contingent Payable Derivative Liability
Strike price	$ 0.31	$ 0.78 *	$ 0.78 *
Contractual term (years)	1.5	0.1	0.6
Volatility (annual)	86 %	76 %	77 %
Risk-free rate	4.3 %	2.0 %	4.8 %
Dividend yield (per share)	0 %	0 %	0 %

* Contingent payable derivative liability based on stock price as of December 31, 2023 and 2022.

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

5. Stock-Based Compensation

The following table summarizes total stock-based compensation expense recognized for the years ended December 31, 2023, 2022 and 2021 (in thousands). The related party amounts were for milestone incentives that either were earned or are deemed probable to be achieved in the future and become issuable at that time (as detailed below in Restricted Stock Awards).

	For the years ended December 31,		
	2023	2022	2021
Research and development	$ 2,987	$ 1,918	$ 7,607
Research and development - related party			
Milestones achieved [1]	687	5,870	—
Future milestones [2]	—	3,573	—
General and administrative	734	937	7,964
Total stock-based compensation expense	**$ 4,408**	**$ 12,298**	**$ 15,571**

The related party amounts were for milestone incentives that either were earned or are deemed probable to be achieved in the future and become issuable at that time (as detailed below in Restricted Stock Awards).

(1) During the year ended December 31, 2023, the Company recognized the remaining $0.7 million stock-based compensation related to the achieved milestones: obtaining a commercial manufacturing license from the MHRA, completion of drafting key portions of the application for product approval and submission the application for product approval to MHRA. The Company had previously recognized $3.6 million stock-based compensation related to these milestones as of December 31, 2022.

During the year ended December 31, 2022, for eight milestones that were earned, the Company recognized and expensed approximately $5.9 million for 7.5 million shares.

(2) During the year ended December 31, 2022, the Company recognized and expensed (but did not issue shares for) the pro-rata portion of one-time milestones that were achieved in 2023 of $3.6 million.

During the year ended December 31, 2022, the Company reversed approximately $1.4 million and $0.3 million of stock-based compensation expense in research and development and general and administrative, respectively, which were related to the cancellation of certain unvested performance-based awards.

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted. The weighted average assumptions used in calculating the fair values of stock options that were granted during the years ended December 31, 2023, 2022 and 2021:

	For the years ended December 31,		
	2023	2022	2021
Exercise price	$ 0.51	$ 0.65	$ 0.92
Expected term (years)	6.4	3.9	5.3
Expected stock price volatility	86 %	99 %	97 %
Risk-free rate	4.5 %	3.3 %	1.0 %
Dividend yield (per share)	0 %	0 %	0 %

The total unrecognized compensation cost was approximately $4.7 million as of December 31, 2023 and will be recognized over the next 1.7 years.

Stock Options

Equity Compensation Plan

On May 29, 2020, the Board of Directors of the Company approved a new equity compensation plan (the "Plan"). The Company's prior plan was adopted in 2007, was updated in amended and restated plans that were approved by shareholders in 2012 and 2013 and expired in 2017 (the "Prior Plan").

The Plan is substantially similar to the Prior Plan. The Plan has a 10-year life, and allows for awards to employees, directors and consultants of the Company. The Plan allows for any type of equity security to be awarded, as did the Prior Plan. The awards and their terms (including vesting) will be determined by the Board and applicable Committees, as was the case under the Prior Plan. The Plan establishes a pool of potential equity compensation equal to twenty percent of the outstanding securities of the Company, which is on an evergreen basis as under the Prior Plan.

On February 25, 2022, the Company amended its existing Equity Compensation Plan, which was adopted in 2020 as previously reported. The amendment provides that the possible forms of awards under the Plan include awards paid in cash or awards paid in a combination of cash and equity, in addition to the existing provisions for awards made in any form of equity. The amendment also clarifies that a delegation of authority from the Board to a Committee may be either a general delegation or a delegation for a specific occasion.

The following table summarizes stock option activity for the Company's option plans during the years ended December 31, 2023, 2022 and 2021 (in thousands, except per share number):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Outstanding as of January 1, 2021	308,840	$ 0.33	8.9	$ 372,219
Granted [1]	910	0.92	8.6	—
Cash exercised	(183)	0.25	—	—
Cashless exercise	(4,720)	0.25	—	—
Outstanding as of December 31, 2021	304,847	0.33	8.0	114,803
Granted [2]	8,005	0.65	4.4	—
Cashless exercised	(8,187)	0.27	—	—
Forfeited/expired	(3,402)	0.88	—	—
Outstanding as of December 31, 2022	301,263	0.34	7.0	135,225
Granted [3]	20,220	0.51	6.0	—
Cash exercised	(150)	0.25	—	—
Cashless exercised	(3,857)	0.36	—	—
Expired	(400)	0.83	—	—
Outstanding as of December 31, 2023	317,076	$ 0.35	6.0	$ 114,097
Options vested [4]	280,023	$ 0.33	6.0	$ 104,780

(1) Awards granted to a staff employee and a member from the Scientific Advisory Board.

(2) Awards granted to Flaskworks employees and consultants.

(3) During the year ended December 31, 2023, the Company granted 20.2 million stock options (the "2023 Options") with an exercise price ranging from $0.47 to $0.57 per share, to key external consultants who provide services to the Company. The 2023 Options contain both service and performance vesting conditions, which will vest over a service period, generally during the term of consulting agreement, or upon achievement of specific milestones.

(4) An aggregate 153 million stock options held by Ms. Linda Powers, the Company's Chief Executive Officer, and Mr. Leslie Goldman, the Company's Senior Vice President, General Consul are subject to an agreement (the "Blocker Letter Agreement") under which they cannot exercise any options or warrants except upon at least 61 days' prior notice.

Restricted Stock Awards

Advent SOW 6

As previously reported, during April 2022, the Company's Board approved, and the Company entered into a Statement of Work #6 (the "SOW 6") with Advent BioServices, a related party of the Company, for five workstreams that are prerequisites for an application for regulatory approval of DCVax-L, for three required licenses for the Sawston facility and for drafting of key portions of the application for approval. The SOW provides for baseline costs and for one-time milestone incentives for successful completion of each of the workstreams, for the completion and submission of each application for product approval, and for obtaining regulatory approval of each of the three Sawston licenses. The milestone incentives will be a combination of cash and stock and are not paid until they are achieved. As also previously reported, the Company amended the SOW6 on September 26, 2022 (the "Amended SOW6") to (1) extend the service period through September 30, 2023, and (2) clarify the assessment and application of the milestones, and (3) add a sixth workstream. (The potential cost for all unearned stock awards for milestones not yet achieved was re-measured on the modification date and will be further re-measured until the date the milestone award is achieved and the stock awards are earned.) As of December 31, 2023, ten one-time milestones were achieved (i.e., for all six workstreams that are prerequisites for an application for product approval, for obtaining all three licenses required for the Sawston facility, and for the completion of key portions of the MAA application for product approval in the UK), the aggregate stock-based compensation under the Amended SOW 6 will be 13.5 million shares (including the shares already earned but not yet issued for the milestones already achieved) for an aggregate fair value of $10.1 million.

During the year ended December 31, 2022, seven milestones were completed, including five workstreams and the regulatory approvals of two licenses required for the Sawston facility. An eighth milestone was partly completed and the stock component of that milestone was earned, but the cash portion of that eighth milestone was not yet earned.

On September 26, 2023, the Company further amended the SOW 6 (the "Second Amended SOW 6") to extend the service period through March 31, 2024. As of the amendment date, the remaining unvested one-time milestone for submission of the application to MHRA for approval of DCVax-L was accounted as a Type I modification (probable to probable under FASB ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). The previously remaining unrecognized compensation expense for total $17,000 was fully recognized as of December 20, 2023.

During the year ended December 31, 2023, the remaining milestones related to the workstream for Mechanism of Action, obtaining the commercial manufacturing license from the MHRA, completion of key portions of the application and submission of application for product approval to MHRA were all completed. As of December 31, 2023, 1.5 million shares related to completed milestone (submission of the application to MHRA for approval) was not issued. As a result, the Company reclassed approximately $1.1 million from Additional Paid-in-Capital to Accounts Payable and accrued expenses to related parties and affiliates.

Employee Compensation

In August 2023, the Company issued 0.6 million shares of common stock as a bonus payment to two staff employees. These shares were fully vested on the grant date. However, 0.3 million shares are subject to lock-up restrictions, prohibiting their sale or transfer within six months of the grant date. The Company recognized $0.3 million stock-based compensation which is based on the Company's closing stock price on the grant date.

Other Service Agreement

During year ended December 31, 2023, the Company issued 16,000 shares of Series C convertible preferred stock to an unrelated vendor who provided professional services for the Company. The fair value of the Series C convertible preferred stock on the issuance date was approximately $0.1 million, which was expensed over a four-month service period.

On August 22, 2022, the Company issued 1.6 million shares of common stock to certain unrelated vendors who provided professional services for the Company. The fair value of the common shares on the issuance date was approximately $1.0 million and was recognized as part of general and administrative expenses.

NORTHWEST BIOTHERAPEUTICS, INC.
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6. Property, Plant and Equipment

Property, plant and equipment consist of the following at December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022	Estimated Useful Life
Leasehold improvements	$ 17,785	$ 13,070	Lesser of lease term or estimated useful life
Office furniture and equipment	487	300	3-5 years
Computer and manufacturing equipment and software	2,776	2,238	3-5 years
Land in the United Kingdom	86	82	NA
	21,134	15,690	NA
Less: accumulated depreciation	(3,856)	(2,272)	
Total property, plant and equipment, net	$ 17,278	$ 13,418	
Construction in progress	$ —	$ 2,028	

Depreciation expense was approximately $1.5 million, $1.3 million and $0.3 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The construction in progess related to expanding the operational portion of its UK facility (Phase 1B) were completed and placed in service as of December 31, 2023. All costs associated with the Phase 1B build out were reclassified from construction in progress to leasehold improvements effective June 2023 and are being amortized over the estimated useful life of the facility.

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

7. Notes Payable

2023 Activities

The following tables summarize outstanding debt as of December 31, 2023 (in thousands):

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Fair Value Adjustment	Carrying Value
Short term convertible notes payable							
6% unsecured	Due	6 %	$ 3.09	$ 135	$ —	$ —	$ 135
8% unsecured	Various	8 %	$0.50 - $0.70 *	3,486	(356)	—	3,130
10% unsecured	7/11/2024	10 %	$ 0.5 *	500	—	—	500
				4,121	**(356)**	**—**	**3,765**
Short term convertible notes at fair value							
11% unsecured	Various	11 %	$0.40 - $0.49 *	**10,750**	**—**	**2,021**	**12,771**
Short term notes payable							
8% unsecured	Various	8 %	N/A	3,539	(157)	—	3,382
12% unsecured	On Demand	12 %	N/A	562	—	—	562
				4,101	**(157)**	**—**	**3,944**
Long term notes payable							
8% unsecured	Various	8 %	N/A	21,224	(1,485)	—	19,739
6% secured	3/25/2025	6 %	N/A	573	—	—	573
				21,797	**(1,485)**	**—**	**20,312**
Ending balance as of December 31, 2023				**$ 40,769**	**$ (1,998)**	**$ 2,021**	**$40,792**

*These convertible notes are convertible into Series C preferred shares at $10.00 - $17.50 per share. Each Series C preferred share is convertible into common shares with 30 days' restriction period. The conversion price in common share equivalent is at $0.40 and $0.70 per share.

Promissory Note

On March 2, 2023, the Company entered into a Commercial Loan Agreement (the "March Commercial Loan") with a commercial lender for an aggregate principal amount of $11.0 million. The March Commercial Loan bears interest at 8% per annum with a 22-month term. There are no principal repayments during the first eight months of the term. The March Commercial Loan is amortized in 14 installments starting on November 2, 2023. The March Commercial Loan carries an original issue discount of $1.0 million.

On November 10, 2023, the Company entered into another Commercial Loan Agreement (the "November Commercial Loan") with the same commercial lender for an aggregate principal amount of $11.0 million. The November Commercial Loan bears interest at 8% per annum with a 24-month term. There are no principal repayments during the first twelve months of the term. The Commercial Loan is amortized in 12 installments starting on November 10, 2024. The November Commercial Loan carries an original issue discount of $1.0 million.

During the year ended December 31, 2023, the Company issued approximately 37.0 million shares of common stock with a fair value of $24.7 million to certain lenders in lieu of cash payments of $19.1 million of debt, including $1.8 million of accrued interest. In addition, pursuant to exchange agreements executed with various holders, the Company is required to potentially issue additional common stock (the "Share liability") if the stock price is less than the price, defined in the exchange agreement as of the true-up date (the "True-up Price"), or the lender is required to return common shares to the Company (the "Share receivable") if the stock price is greater than the True-up Price as of the true-up date. During the year ended December 31, 2023, the Company extinguished Share liabilities of $1.1 million and recognized additional $0.8 million in Share liabilities. The Company recognized an approximately $5.4 million debt extinguishment loss during the year ended December 31, 2023 from the debt redemption.

During the year ended December 31, 2023, the Company issued approximately 56,000 shares of Series C preferred stock with a fair value of $1.0 million to certain lenders in lieu of cash payments of $0.9 million in debt, including $0.1 million of accrued interest. The Company recognized an approximately $0.1 million debt extinguishment loss.

During the year ended December 31, 2023, the Company recognized $0.8 million change in fair value of embedded redemption option as this embedded feature had de minimis value based on the remaining life of the note and the next qualified financing.

Convertible Notes

In April 2023, the Company entered into several ten-month convertible notes (the "April Convertible Notes") with multiple investors (the "Holders") with an aggregate principal amount of $0.9 million for a purchase price of $0.8 million. The April Convertible Notes bear interest at 8% per annum and are convertible into Series C preferred shares at $13.75 per share at the Holders' sole option. The Series C preferred shares are convertible into common stock 30 days after the debt conversion date. Each Series C preferred share is convertible into 25 shares of common stock. The Company reclassed $0.7 million Investor advances that were received from the Holders in December 2022 to Convertible notes payable on the consolidated balance sheet as of December 31, 2023. As a result, the Company received net cash proceeds of $0.1 million.

On July 11, 2023, the Company entered into a one-year convertible note (the "July Convertible Note") with an individual investor with principal amount of $0.5 million. The Company received $0.5 million cash from the July Convertible Note. The July Convertible Note bears interest at 10% per annum and is convertible into Series C preferred shares at $12.50 per share at the holder's sole option.

During the year ended December 31, 2023, the Company entered into several one-year convertible note (the "One-Year Convertible Notes") with multiple investor (the "Holders") with aggregate principal amount of $2.6 million for an aggregate purchase price of $2.4 million. The Company reclassed $0.5 million Investor advances that were received from the Holders in December 2022 to convertible notes payable on the consolidated balance sheet as of December 31, 2023. As a result, the Company received net cash proceeds of $1.9 million. The One-Year Convertible Notes bear interest at 8% per annum and is convertible into Series C preferred shares between $12.50 to $17.50 per share at the Holders' sole option. The Series C preferred shares are convertible into common stock 30 days after the debt conversion date. Each Series C preferred share is convertible into 25 shares of common stock.

As additional consideration for entering into the April Convertible Notes and the One-Year Convertible Notes (collectively the "Convertible Notes"), the Company also agreed to amend some of the Holders' existing outstanding warrants. The exercise price of certain existing warrants was amended from $2.00 per share to price between $0.55 and $0.70 per share, or from $1.48 per share to price between $0.70 and $0.85 per share, and the maturity date was extended for an additional six to ten months. The incremental change in fair value resulting from the amendment was approximately $0.4 million, which was recognized as an additional debt discount to the Convertible Notes.

Convertible Notes at Fair Value

From August to October 2023, the Company entered into several one-year convertible notes (the "Convertible Notes") with multiple individual investors (the "Holders") with an aggregate principal amount of $10.8 million. The Convertible Notes bear interest at 11% per annum and are convertible into Series C preferred shares between $10.00 and $12.25 per share at the Holder's sole option. The Series C preferred shares are convertible into common stock 30 days after the debt conversion date. Each Series C preferred share is convertible into 25 shares of common stock. In addition, the Holders have an alternative option to convert the Convertible Notes into a non-dilutive financial instrument, which has the same terms at those in the non-dilutive funding agreements as described in Note 12.

One of the Convertible Notes also contains a conversion feature to allow the holder to convert the outstanding debt in lieu of cash payment to purchase common shares via cash exercise of the holder's existing warrants. In addition, the Company also agreed to amend the holder's existing warrants to extend the term of the warrant maturity date for an additional three months.

The Company elected the FVO to fair value the Convertible Notes under the guidance in ASC 825. As described in Note 14, the fair value of the Convertible Notes (as revised) was approximately $15.2 million as of September 30, 2023. The fair value of the Convertible Notes was approximate $12.8 million as of December 31, 2023. The Company recognized $2.0 million change in fair value of convertible notes for the year ended December 31, 2023. As a result of electing the FVO, issuance costs related to the convertible notes are expensed as incurred. Therefore, the incremental change in fair value resulting from the warrant amendment for $0.3 million was recognized as part of interest expenses on the consolidated statement of operations and comprehensive loss.

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

For the year ended December 31, 2023, interest expense related to notes payable totaled approximately $5.2 million including amortization of debt discounts totaling $2.4 million.

2022 Activities

The following tables summarize outstanding debt as of December 31, 2022 (in thousands):

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Embedded Redemption Option	Carrying Value
Short term convertible notes payable							
6% unsecured	Due	6 %	$ 3.09	$ 135	$ —	$ —	$ 135
				135	**—**	**—**	**135**
Short term notes payable							
8% unsecured	Various	8 %	N/A	14,540	(1,300)	807	14,047
9% unsecured	Various	9 %	N/A	793	—	—	793
12% unsecured	On Demand	12 %	N/A	563	—	—	563
				15,896	**(1,300)**	**807**	**15,403**
Long term notes payable							
8% unsecured	7/26/2024	8 %	N/A	5,505	(432)	—	5,073
6% secured	3/25/2025	6 %	N/A	918	—	—	918
				6,423	**(432)**	**—**	**5,991**
Ending balance as of December 31, 2022				**$ 22,454**	**$ (1,732)**	**$ 807**	**$21,529**

On September 26, 2022, the Company entered into a Commercial Loan Agreement (the “Commercial Loan”) with a commercial lender for an aggregate principal amount of $5.5 million. The Commercial Loan bears interest at 8% per annum with a 22-month term. There are no principal repayments during the first eight months of the term. The Commercial Loan is amortized in 14 installments starting on May 26, 2023. The Commercial Loan carries an original issue discount of $0.5 million.

During the year ended December 31, 2022, the Company entered into multiple four-month note agreements (the “Notes”) with various individual lenders (the “Holders”) with an aggregate principal amount of $0.6 million for net proceeds of $0.6 million. The Notes have a 9% interest rate, a 5% original issue discount (“OID”), and contain a conditional right to independently purchase shares from the Company in a future raise of Capital (the “Piggy-back Right”), under which the Company agrees that if it (i) publicly releases top line data from the Phase III trial of its DCVax®-L vaccine (such eventuality, the “Release”) and (ii) consummates the first private placement offering of its common stock following such Release (the “Next Offering”), then Holder shall have the conditional right, at its sole option, typically exercisable within seven (7) days following the Next Offering, to independently purchase from the Company up to a number of shares equal in value to (a) 50% of the principal amount of the loan, (b) 50% of the value of the exercised warrant shares, and (c) exchange some or all of the outstanding loan amount for a variable number of shares (the “Contingent Rights”). The Contingent Right (a) and (b) above shall be priced at a 12% discount from the Next Offering, resulting in either an elimination of, or a reduced cash amount repayable under the loan agreement. The Company accounted for the Contingent Right (a) and (b) as a freestanding financial instrument, which was classified as a liability at fair value on the Consolidated Balance Sheet with changes in fair value recognized in the Consolidated Statement of Operations. The Company accounted for the Contingent Right (c) as an embedded derivative liability at fair value, which requires it to be bifurcated, with changes in fair value recognized in the Consolidated Statement of Operations.

During the year ended December 31, 2022, the Company entered into multiple note extension agreements whereby the maturity date of the notes was extended for an additional two-four months.

The Company received two loans under the Coronavirus Aid, Relief and Economic Security (“CARES”) Act’s Paycheck Protection Program (“PPP”) in 2021 for the amount of $0.4 million. On February 22, 2022, the PPP loans were approved for forgiveness. The Company recorded approximately $0.4 million debt extinguishment gain from the forgiveness of these PPP loans.

During the year ended December 31, 2022, the Company issued approximately 18.1 million shares of common stock at fair value of $13.8 million to certain lenders in lieu of cash payments of $11.3 million debt, including $1.8 million accrued interest. The Company also extinguished approximately $0.2 million embedded derivative liability upon the conversion. The Company recognized approximately $2.3 million debt extinguishment loss during the year ended December 31, 2022. Additionally, pursuant to certain exchange agreement, the Company is required to potentially issue additional common stock (the “Share liability”) if the stock price is

less than certain price as defined in the exchange agreement as of the true-up date. The Company recognized additional $0.7 million debt extinguishment loss related to the Share liability during the year ended December 31, 2022.

During the year ended December 31, 2022, the Company issued approximately 0.2 million shares of Series C preferred stock at fair value of $3.5 million to certain lenders in lieu of cash payments of $3.4 million debt, including $0.4 million accrued interest. The Company recognized approximately $0.1 million debt extinguishment loss.

During the year ended December 31, 2022, the Company made aggregate cash payments of $6.4 million on notes payable, including $0.9 million of interest payment.

For the year ended December 31, 2022, interest expense related to notes payable totaled approximately $2.9 million including amortization of debt discounts totaling $2.8 million. The Company also accrued approximately $0.4 million interest expense related to German taxes during the year ended December 31, 2022 (see Note 12).

Interest Expenses Summary

The following table summarizes total interest expenses related to outstanding debt for the years ended December 31, 2023, 2022 and 2021, respectively (in thousands):

	For the years ended December 31,		
	2023	**2022**	**2021**
Interest expenses related to outstanding notes:			
Contractual interest	$ 2,560	$ 2,890	$ 2,347
Amortization of debt discount	2,372	2,771	2,301
Issuance cost from warrant modification	287	—	—
Total interest expenses related to outstanding notes	**5,219**	**5,661**	**4,648**
Interest expenses related to payables to Advent BioServices	—	—	140
Other interest expenses	22	407	223
Total interest expense	**$ 5,241**	**$ 6,068**	**$ 5,011**

The following table summarizes the principal amounts of the Company's debt obligations as of December 31, 2023 (in thousands):

	Payment Due by Period			
	Total	**Less than 1 Year**	**1 to 2 Years**	**3 to 5 Years**
Short term convertible notes payable				
6% unsecured	$ 135	$ 135	$ —	$ —
8% unsecured	3,486	3,486	—	—
10% unsecured	500	500	—	—
Short term convertible notes payable at fair value				
11% unsecured	10,750	10,750	—	—
Short term notes payable				
8% unsecured	3,539	3,539	—	—
12% unsecured	562	562	—	—
Long term notes payable				
8% unsecured	21,224	—	21,224	—
6% secured	573	—	573	—
Total	**$ 40,769**	**$ 18,972**	**$ 21,797**	**$ —**

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to the Consolidated Financial Statements

8. Net Earnings (Loss) per Share Applicable to Common Stockholders

Basic earnings (loss) per common share is computed by dividing net earnings (loss) by the weighted average number of common shares outstanding during the reporting period. Diluted earnings (loss) per common share is computed similar to basic earnings (loss) per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock. Diluted weighted average common shares include common stock potentially issuable under the Company's convertible notes, warrants and vested and unvested stock options.

For the year ended December 31, 2021, net income is adjusted for gain from change in fair value of warrant liabilities.

The following table sets forth the computation of earnings (loss) per share for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	For the years ended December 31,		
	2023	**2022**	**2021**
Net earnings (loss) - basic	$ (62,599)	$ (105,032)	$ 179,126
Reversal of gain due to change in fair value of warrant liability	—	—	(239,347)
Net loss - diluted	(62,599)	(105,032)	$ (60,221)
Weighted average shares outstanding - basic	1,119,191	1,015,852	873,517
Diluted shares- Options	—	—	38,496
Diluted shares- Warrants	—	—	95,780
Convertible notes and interest	—	—	76
Weighted average shares outstanding - diluted	1,119,191	1,015,852	1,007,869

The following securities were not included in the diluted earnings (loss) per share calculation because their effect was anti-dilutive as of the periods presented (in thousands):

	For the years ended December 31,		
	2023	**2022**	**2021**
Series C convertible preferred stock	30,220	35,384	—
Common stock options	317,076	301,263	266,350
Common stock warrants	105,241	141,048	129,689
Convertible notes and accrued interest	34,380	78	—
Potentially dilutive securities	**486,917**	**477,773**	**396,039**

9. Related Party Transactions

Advent BioServices Services Agreement

The Company had three operational programs with Advent: (a) an ongoing development and manufacturing program at the GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston GMP facility, and (c) a one-time program for specialized work, organized into ten sets of one-time milestones, for the following:

- Qualifying for and obtaining three required licenses for the Sawston facility: a license from the Human Tissue Authority to collect and process human cells and tissues, a license from the MHRA for manufacturing for clinical trials and compassionate use cases, and a license from the MHRA for commercial manufacturing.
- Six workstreams relating to product matters required for an application for regulatory approval of DCVax-L, including Comparability, Stability, Potency, Product Profile, Mechanism of Action and Fill/Finish.
- Drafting and submission of key portions of the application for product approval itself.

Each of the three operational programs is covered by a separate contract. The ongoing manufacturing in the London facility is covered by a Manufacturing Services Agreement ("MSA") entered into on May 14, 2018. The development and manufacturing program at the Sawston facility is covered by an Ancillary Services Agreement entered into on November 18, 2019. The specialized work associated with the ten one-time milestones is covered by an SOW 6 entered into under the Ancillary Services Agreement as of April 1, 2022 and amended on September 26, 2022 and September 26, 2023. The 2023 amendment extended the SOW 6 service period for about six months, through March 31, 2024.

The Ancillary Services Agreement establishes a structure under which the Company and Advent negotiate and agree upon the scope and terms for Statements of Work ("SOWs") for facility development activities and compassionate use program activities. After an SOW is agreed and approved by the Company, Advent will proceed with, or continue, the applicable services and will invoice the Company pursuant to the SOW. Since both the facility development and the compassionate use program involve pioneering and uncertainties in most aspects, the invoicing under the Ancillary Services Agreement is on the basis of costs incurred plus fifteen percent. The SOWs may involve ongoing activities or specialized one-time projects and related one-time milestone payments. The current Ancillary Services Agreement ended in July 2023. The Company subsequently extended the term by 12 months to July 2024 with no other changes.

SOW 6 provides for ongoing baseline costs for manufacturing at the Sawston facility and one-time milestone incentives for (a) regulatory approval of each of the three licenses required for the Sawston facility, (b) successful completion of each of the six workstreams and (c) completion of drafting key portions of an application for product approval. The milestone incentives are a combination of cash and stock, and are not paid until the milestone is achieved and earned.

During the year ended December 31, 2023, the Company paid an aggregate of $5.0 million in cash, of which $1.0 million was related to two milestones that were completed and fully expensed in 2022, but was unpaid as of December 31, 2022, $4.0 million was payment for four completed one-time milestones (MAA workstream for mechanism of Action, obtaining a commercial manufacturing license from the MHRA on March 2023 and completion of drafting key portions of the application and submit the application to MHRA for product approval). The Company issued 4.5 million common shares as a result of completion of the two one-time milestones (obtaining a commercial manufacturing license from the MHRA and completion of drafting application) at fair value of $3.2 million, of which $0.6 million was recognized during the year ended December 31, 2023 and $2.6 million had already been recognized (but not paid) in 2022.

As of December 31, 2023, $0.5 million was unpaid and 1.5 million common shares have been earned but not issued in regard to the completed milestone (submission of the application to MHRA for product approval).

The following table summarizes total research and development costs from Advent for the years ended December 31, 2023, 2022 and 2021, respectively (in thousands).

	For the years ended December 31,		
	2023	2022	2021
Advent BioServices			
Manufacturing cost in London	$ 6,580	$ 5,675	$ 6,625
Manufacturing cost at Sawston facility	8,306	5,766	792
SOW 6 one-time milestones - Shares			
Expensed and paid (milestone complete) (1)	578	5,120	—
Expensed and paid (partial milestone earned) (2)	—	750	—
Expensed but unpaid, not yet due (milestone not yet complete) (3)	—	3,573	—
Expensed and due, but unpaid (milestone complete) (4)	109	—	—
SOW 6 one-time milestones - Cash			
Expensed and paid (milestone complete) (5)	661	3,000	—
Expensed and due, but unpaid (milestone complete) (6)	139	1,000	—
Expensed but unpaid, not yet due (milestone not yet complete) (7)	—	3,700	—
Total	$ 16,372	$ 28,584	$ 7,417

(1) The payment for the year ended December 31, 2023 covers two one-time milestones: obtaining a commercial manufacturing license from the MHRA and drafting key portions of the application for product approval. The payment for the year ended December 31, 2022 covers seven one-time milestones: five workstreams (Comparability, Stability, Potency, Product Profile, Fill/Finish), and two

required licenses for the Sawston facility (licenses from the Human Tissue Authority and from the MHRA for manufacturing for clinical trials and compassionate use cases).

(2) The payment for the year ended December 31, 2022 covers the one-time milestone workstream: Mechanism of Action.

(3) The expense for the year ended December 31, 2022 covers the one-time milestone for obtaining a commercial manufacturing license from the MHRA, and the one-time milestone for drafting key portions of the application for product approval.

(4) The expense for the year ended December 31, 2023 covers the one-time milestone for submit application for product approval.

(5) The payment for the year ended December 31, 2023 covers three one-time milestone: Mechanism of Action, milestone for obtaining a commercial manufacturing license from the MHRA and drafting key portions of the application for product approval. The payment for the year ended December 31, 2022 covers five one-time milestones: three workstreams (Comparability, Potency, Fill/Finish), and two required licenses for the Sawston facility (licenses from the Human Tissue Authority and from the MHRA for manufacturing for clinical trials and compassionate use cases).

(6) The expense for the year ended December 31, 2023 covers the one-time milestone for submit application for product approval. The expense for the year ended December 31, 2022 covers the two one-time milestone workstreams: Product Profile and Stability.

(7) The expense for the year ended December 31, 2022 covers three one-time milestones: Mechanism of Action, milestone for obtaining a commercial manufacturing license from the MHRA, and the milestone for drafting key portions of the application for product approval.

Advent BioServices Sublease Agreement

On December 31, 2021, the Company entered into a Sub-lease Agreement (the “Agreement”) with Advent. The Agreement permits use by Advent of a portion of the space in the Sawston facility, which is leased by the Company under a separate head lease with a different counterparty (Huawei) that commenced on December 14, 2018. The Company subleased approximately 14,459 square feet of the 88,000 square foot building interior space, plus corresponding exterior support space and parking. The lease payments amount under the Agreement are two times the £5.75 (approximate $7.32 per square foot based on exchange rate as of December 31, 2023) rate per square foot payable under the head lease, but subject to a cap of $10 per square foot. Accordingly, the monthly lease payments under the Sublease are calculated based on $145,000 annually for 2023. The total lease payments paid by the Company for the facility, exterior spaces and parking under the head lease are 500,000 pounds per year and 550,000 pounds per year effective December 6, 2023. The term of the Agreement shall end on the same date as the head lease term ends.

During the years ended December 31, 2023 and 2022,the Company recognized sub-lease income of $145,000.

Related Party Accounts Payable

As of December 31, 2023 and 2022, there was approximately $0.3 million and $0.4 million of unpaid board compensation to one of our Directors that was included in the accounts payable to related party on the consolidated balance sheets, respectively.

As of December 31, 2023 and 2022, there were outstanding unpaid accounts payable and accrued expenses owed to Advent as summarized in the following table (in thousands). *These unpaid amounts are part of the Related Party expenses reported in the above section.*

	December 31, 2023	December 31, 2022
Advent BioServices - amount invoiced but unpaid	$ 1,668	$ 1,844
Advent BioServices - amount accrued but unpaid	1,601	4,736
Total payable and accrued, but unpaid to Advent BioServices	$ 3,269	$ 6,580

(1) This includes $1.1 million which is not payable in cash but represents the value of 1.5 million shares that will become issuable to Advent for achievement of the one-time milestone for submission of application to MHRA for product approval. Such shares were not issued as of December 31, 2023, and the total value, previously recognized as stock compensation expense, was reclassified from Additional Paid-in-Capital to Accounts payable and accrued expenses to related parties and affiliates.

10. Preferred Stock

Series C Convertible Preferred Stock

On July 20, 2022, the Company filed a Certificate of Elimination with the Secretary of State of the State of Delaware with respect to the Company's Series A Preferred Stock and Series B Preferred Stock pursuant to which both series were eliminated and returned to the status of authorized and unissued preferred shares of the Company, as there are no longer any Series A or Series B Preferred shares outstanding.

Also on July 20, 2022, the Company filed the Certificate of Designations for Series C Preferred Stock (the "Series C Certificate of Designations") with the Secretary of State of the State of Delaware, setting forth the terms of the Series C Preferred Stock. The Series C Certificate of Designations, effective as of July 20, 2022, that was created out of the authorized and unissued shares of preferred stock of the Company, provides for 10,000,000 shares, par value $0.001 per share, and establishes the rights, preferences and privileges of the Series C.

The Company determined that the Series C Shares contain contingent redemption provisions allowing redemption by the holder upon certain defined events ("deemed liquidation events"). As the event that may trigger the redemption of the Series C Shares is not solely within the Company's control, the Series C Shares are classified as mezzanine equity (temporary equity) in the Company's consolidated balance sheets.

2023 Activities

During the year ended December 31, 2023, the Company entered into various Subscription Agreements (the "Series C Subscription Agreements") with certain investors (the "Series C Investors"). Pursuant to the Series C Subscription Agreements, the Company issued the Series C Investors an aggregate of 1.0 million shares of the Company's Series C convertible preferred stock, par value $0.001 per share (the "Series C Shares"), at a weighted purchase price of $14.01 per share for proceeds of approximately $13.3 million.

During the year ended December, 2023, the Company issued approximately 56,000 Series C Shares with a fair value of $1.0 million to certain lenders in lieu of cash payments of $0.9 million in debt, including $0.1 million accrued interest. The Company recognized an approximately $0.1 million debt extinguishment loss.

During the year ended December, 2023, approximately 1.2 million Series C Shares with a book value of $18.9 million were converted into 30.8 million common shares at a ratio of 1:25.

2022 Activities

During the year ended December 31, 2022, the Company entered into various Subscription Agreements (the "Series C Subscription Agreements") with certain investors (the "Series C Investors"). Pursuant to the Series C Subscription Agreements, the Company issued the Series C Investors an aggregate of 1.4 million shares of the Company's Series C convertible preferred stock, par value $0.001 per share (the "Series C Shares"), at a weighted purchase price of $16.15 per share for gross proceeds of approximately $22.0 million.

Pursuant to some of the Series C Subscription Agreements, certain Series C investors chose to purchase the Series C Shares by debt redemption. During the year ended December 31, 2022, the Company extinguished approximately $3.4 million debt, including $0.4 million of accrued interest in lieu of partial consideration received for issuance the Series C Shares. The Company received approximately $18.7 million net proceeds from issuance of the Series C Shares. Additionally, as a partial consideration for certain Series C investors, the Company agreed to amend the terms of the warrants that are currently held by them.

On August 12, 2022, an unrelated investor exercised existing warrants to purchase 1.4 million common shares at a weighted average exercise price of $0.24 per share and a total purchase price of approximately $329,000. The warrant holder agreed to receive Series C Preferred Shares instead of common shares and agreed that these Series C shares could not be converted for a period of three months. Since Series C Preferred shares are convertible into common shares at a ratio of 1:25, the number of Series C Shares issued to the warrant holder was 1/25 of the 1.4 million common shares for which the warrants were exercisable, or 54,847 Series C Preferred Shares.

Each of the Series C Shares which were sold for prices between $15.00 and $21.25 per share will be convertible into 25 shares of common stock (equivalent to prices of $0.60 to $0.85 per share of common stock) at the option of the holder three months after the effective date of purchase.

11. Stockholders' Deficit

Common Stock

On January 9, 2023, the Company filed a Certificate of Amendment of its Seventh Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of the State of Delaware, which effected an increase in the Company's authorized shares of common stock, from 1.2 billion to 1.7 billion, par value $0.001 per share.

2023 Activities

During the year ended December 31, 2023, the Company received $2.9 million from the exercise of outstanding warrants and options with an exercise price between $0.153 and $2.00, of which $1.2 million was received in December 2022 as investor advances. The Company issued approximately 12.8 million shares of common stock upon these warrant exercises.

During the year ended December 31, 2023, certain options and warrants holders elected to exercise some of their options and warrants pursuant to cashless exercise formulas. The Company issued approximately 21.3 million shares of common stock upon exercise of 22.9 million warrants at exercise prices between $0.17 and $0.22 per share, and 3.9 million options at exercise prices between $0.23 and $0.55 per share.

During the year ended December 31, 2023, the Company issued approximately 37.0 million shares of common stock with a fair value of $24.7 million to certain lenders in lieu of cash payments of $19.0 million of debt, including $1.8 million of accrued interest, and settled $1.1 million true-up provision (see Note 7).

2022 Activities

During the year ended December 31, 2022, the Company received $9.5 million from issuance of 13.1 million shares of common stock to various investors.

During the year ended December 31, 2022, the Company received $11.1 million from the exercise of warrants issued in the past with an exercise price between $0.18 and $0.85. The Company issued approximately 45.3 million shares of common stock and 0.3 million Series C convertible preferred stock in lieu of common stock upon these warrant exercises.

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During the year ended December 31, 2022, certain warrant holders elected to exercise some of their warrants pursuant to cashless exercise formulas. The Company issued approximately 29.0 million shares of common stock for exercise of 36.0 million warrants at exercise prices between $0.18 and $0.52.

During the year ended December 31, 2022, certain options holders elected to exercise some of their options pursuant to cashless exercise formulas. The Company issued approximately 5.2 million shares of common stock for exercise of 8.2 million options at exercise prices between $0.23 and $0.34.

During the year ended December 31, 2022, the Company issued approximately 18.1 million shares of common stock to certain lenders in lieu of cash payments on $11.3 million outstanding debt, including $1.8 million interest.

2021 Activities

During the year ended December 31, 2021, the Company received $4.1 million from issuance of 6.3 million shares of common stock to various investors. The Company also received $0.3 million partial proceeds pursuant to one security purchase agreement. Accordingly, such amounts are included in Investor advances in the accompanying consolidated balance sheet as of December 31, 2021.

During the year ended December 31, 2021, the Company received $20.0 million from the exercise of warrants and stock options issued in the past with an exercise price between $0.175 and $0.40. The Company issued approximately 86.9 million shares of common stock upon these warrant and stock option exercises.

The Company also entered into certain warrant exercise agreements which contain a conditional right to purchase shares directly from the Company in a future raise of capital (the “Piggy-back Right”). In exchange for these exercises, the Company agreed that if the Company (i) publicly releases top line data from the Phase III trial of its DCVax®-L vaccine (such eventuality, the “Release”) and (ii) consummates the first offering of its common stock following such Release (the “Next Offering”) then Holder shall have the conditional right, at its sole option exercisable typically within seven days following the Next Offering, to independently purchase from the Company up to a number of shares equal in value to 50% of the Total Exercise Amount provided that: the price per share paid by Holder shall be equal to the Next Offering price per share less 12%. This Piggy-back Right was granted to the warrant holders in connection with their early exercise of warrants prior to the Release. The Company recognized approximately $0.6 million inducement expense during the year ended December 31, 2021.

During the year ended December 31, 2021, certain warrant and stock option holders elected to exercise some of their warrants and stock options pursuant to cashless exercise formulas. The Company issued approximately 20.4 million shares of common stock for exercise of 24.5 million warrants and stock options. The exercise prices were between $0.20 and $0.52.

Stock Purchase Warrants

The following is a summary of warrant activity for the years ended December 31, 2023, 2022 and 2021 (in thousands, except per share data):

	Number of Warrants	Weighted Average Exercise Price	Remaining Contractual Term
Outstanding as of January 1, 2021	**331,753**	**$ 0.28**	**1.61**
Warrants granted	1,209	1.39	
Warrants exercised for cash	(86,726)	0.23	
Cashless warrants exercise	(19,743)	0.22	
Warrants expired and cancellation	(1,024)	2.95	
Outstanding as of December 31, 2021	**225,469**	**$ 0.30**	**0.96**
Warrants exercised for cash	(46,671)	0.25	
Cashless warrants exercise	(35,951)	0.23	
Warrants expired and cancellation	(1,799)	1.58	
Outstanding as of December 31, 2022	**141,048**	**$ 0.31**	**1.46**
Warrants exercised for cash	(12,650)	0.23	
Cashless warrants exercise	(22,907)	0.20	
Warrants expired and cancellation	(250)	1.36	
Outstanding as of December 31, 2023	**105,241**	**$ 0.31**	**1.83**

The options and warrants held by Ms. Powers and Mr. Goldman are subject to an ongoing suspension on a rolling basis pursuant to the Blocker Letter. In addition, other executive officers and directors extended their suspensions to various dates until at least April 30, 2024.

At December 31, 2023, of the 105 million total outstanding warrants listed above, approximately 94 million warrants were under block or suspension agreements.

Warrant Modifications

Between January 10, 2023 and December 31, 2023, the Company amended multiple warrants whereby the maturity dates of certain warrants were extended for an additional approximately 3 months. The value of these modifications were calculated using the Black-Scholes-Merton option pricing model based on the following weighted average assumptions.

	Post-modification	Pre-modification
Exercise price	$ 0.30	$ 0.31
Expected term (in years)	2.1	1.9
Volatility	73 %	82 %
Risk-free interest rate	4.7 %	4.7 %
Dividend yield	0 %	0 %

The incremental fair value attributable to the modified awards compared to the original awards immediately prior to the modification was calculated at $2.5 million, of which $0.7 million was associated with debt financing and was recognized as an additional debt discount and interest expense (see Note 7), and the remaining $1.8 million was treated as a deemed dividend and is reflected as “Deemed dividend related to warrant modifications” in the accompanying consolidated statement of operations and comprehensive loss.

12. Commitments and Contingencies

Operating Lease- Lessee Arrangements

Company has operating leases for corporate offices in the U.S. and U.K., and for manufacturing facilities in the U.K. The Leases with an initial term of 12 months or less are not recorded in the balance sheet. The Company has elected the practical expedient to account for each separate lease component of a contract and its associated non-lease components as a single lease component, thus causing all fixed payments to be capitalized. The Company also elected the package of practical expedients permitted within the new standard, which among other things, allows the Company to carry forward historical lease classification. The lease renewal options have not been included in the calculation of the lease liabilities and right-of-use ("ROU") assets as the Company has not yet determined whether to exercise the options. Variable lease payment amounts that cannot be determined at the commencement of the lease such as increases in lease payments based on changes in index rates or usage, are not included in the ROU assets or liabilities. These are expensed as incurred and recorded as variable lease expense.

At December 31, 2023, the Company had operating lease liabilities of approximately $4.8 million for both the 20-year lease of the building for the manufacturing facility in Sawston, U.K., and the current office lease in the U.S. and ROU assets of approximately $4.2 million for the Sawston lease and U.S. office lease are included in the consolidated balance sheet.

Operating Lease- Lessor Arrangements

On December 31, 2021, the Company entered into a Sub-lease Agreement (the "Agreement") with Advent, a related party as discussed in Note 8. The Agreement permits use by Advent of a portion of the space in the Sawston facility which is leased by the Company under a separate head lease with a different counterparty that commenced on December 14, 2018. The Company subleased approximately 14,459 square feet of 88,000 square foot building interior space, plus corresponding exterior support space and parking located in Sawston, UK. Lease payments under the Agreement are two times the £5.75 (approximate $7.32 per square foot based on exchange rate as of December 31, 2023) rate per square foot payable under the head lease, subject to a cap of $10 per square foot. Accordingly, the lease payments under the Sublease are set at $145,000 per year. The total lease payments paid by the Company for the overall building, exterior space and parking under the head lease were £500,000 (approximate $637,000), and were increased to £520,000 (approximate $662,000) per year effective December 25, 2023. The term of the Agreement shall end on the same date as the head lease term ends.

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The following summarizes quantitative information about the Company's operating leases (in thousands):

	For the year ended December 31, 2023		
	U.K	U.S	Total
Lease cost			
Operating lease cost	$ 595	$ 255	$ 850
Short-term lease cost	74	—	74
Variable lease cost	—	15	15
Sub-lease income	(145)	—	(144)
Total	$ 524	$ 270	$ 794
Other information			
Operating cash flows from operating leases	$ (622)	$ (224)	$ (846)
Weighted-average remaining lease term – operating leases	8.0	0.7	
Weighted-average discount rate – operating leases	12 %	12 %	

	For the year ended December 31, 2022		
	U.K	U.S	Total
Lease cost			
Operating lease cost	$ 588	$ 260	$ 848
Short-term lease cost	79	—	79
Variable lease cost	—	13	13
Sub-lease income	(145)	—	(145)
Total	$ 522	$ 273	$ 795
Other information			
Operating cash flows from operating leases	$ (619)	$ (290)	$ (909)
Weighted-average remaining lease term – operating leases	8.5	1.3	
Weighted-average discount rate – operating leases	12 %	12 %	

	For the Year ended December 31, 2021		
	U.K	U.S	Total
Lease cost			
Operating lease cost	$ 653	$ 277	$ 930
Short-term lease cost	51	—	51
Variable lease cost	48	5	53
Total	$ 752	$ 282	$ 1,034
Other information			
Operating cash flows from operating leases	$ (688)	$ (178)	$ (866)
Weighted-average remaining lease term – operating leases	9.0	1.8	
Weighted-average discount rate – operating leases	12 %	12 %	

The Company recorded lease costs as a component of general and administrative expense during the years ended December 31, 2023, 2022 and 2021.

Maturities of our operating leases, excluding short-term leases and sublease agreement, are as follows:

Year ended December 31, 2024	$	867
Year ended December 31, 2025		662
Year ended December 31, 2026		662
Year ended December 31, 2027		662
Year ended December 31, 2028		662
Thereafter		6,600
Total		10,115
Less present value discount		(5,347)
Operating lease liabilities included in the Consolidated Balance Sheet at December 31, 2023	$	4,768

Maturities of our operating leases under the sublease agreement, are as follows:

Year ended December 31, 2024	$	145
Year ended December 31, 2025		145
Year ended December 31, 2026		145
Year ended December 31, 2027		145
Year ended December 31, 2028		145
Thereafter		1,450
Total	$	2,175

Manufacturing Services Agreements

Advent BioServices

On May 14, 2018, the Company entered into a DCVax®-L Manufacturing and Services Agreement (“MSA”) with Advent BioServices, a related party which was formerly part of Cognate BioServices and was spun off separately as part of an institutional financing of Cognate. The MSA provides for manufacturing of DCVax-L products at an existing facility in London. The MSA is structured in the same manner as the Company’s prior agreements with Cognate BioServices. The MSA provides for certain payments for achievement of milestones and, as was the case under the prior agreement with Cognate BioServices, the Company is required to pay certain fees for dedicated production capacity in the London facility reserved exclusively for DCVax production and pay for manufacturing of DCVax-L products for a certain minimum number of patients, whether or not the Company fully utilizes the dedicated capacity and number of patients. The MSA remains in force until five years after the first commercial sales of DCVax-L products pursuant to a marketing authorization, accelerated approval or other commercial approval, unless cancelled. Either party may terminate the MSA on twelve months’ notice, to allow for transition arrangements by both parties. During the notice period services would still be provided. Minimum required payments for this notice period are anticipated to total approximately £4.5 million ($5.7 million).

The Company entered into SOW 6 with Advent, which was incorporated into the Ancillary Services Agreement, on April 1, 2022, and amended it on September 26, 2022 and again on September 26, 2023. The milestone incentives involve a combination of cash and stock and are not paid until they are achieved and earned, as described in Note 9.

German Tax Matter

The German tax authorities have audited our wholly owned subsidiary, NW Bio GmbH, for 2013-2015. The NW Bio GmbH submitted substantial documentation to refute certain aspects of the assessments and the German tax authorities agreed in principle with the Company's proposed revised approach and settlement offer. A final settlement bill was received from the German Tax Authority confirming that only a portion of the original bill was owed, €277,000 (approximately $306,000), for corporate taxes, interest, and reduced penalty for the period under audit, which the Company paid on September 2, 2021. The Company also received and paid the final settlement bill from the local authority for trade taxes for the audit period in the amount of €231,000 (approximately $255,000). On November 4, 2021, the Company received a letter from the local tax authorities asking for additional late fees of €513,000 (now approximately $566,000) on reimbursable withholding taxes that had been waived during the settlement process. On December 8, 2021, the Company appealed the assessment of additional late fees. Additionally, the Company requested that NW Bio GmbH be deregistered from the trade register, as it no longer had current operations. The deregistration was granted effective December 31, 2021. Between January 2022 and July 2022, the Company received tax bills for the corporate and trade taxes for the 2016-2020 tax years that totaled approximately €222,000 (approximately $245,000). On July 27, 2022, the Company was informed that the German Tax Authorities were prepared to waive €135,000 (approximately $149,000) of the penalties. The Company offered to pay this reduced penalty if an extended payment plan was approved. A response was received dated November 14, 2022 indicating that the tax authority would not be able to grant a further deferral of payment of these penalties. In a letter dated December 27, 2022, the Leipzig tax authority sent letters to the former and current managing directors of NW Bio GmbH giving 30 days to respond to a tax liability questionnaire. Based on the responses to the liability questionnaires the tax authorities have currently not directed any further measures against former and current managing directors of NW Bio GmbH with respect to tax liability proceedings.

As of December 31, 2023, the Company accrued for the current amounts owed for these penalties of €188,000 (approximately $207,000) after a partial payment of €189,000 (approximately $208,000) on October 12, 2023. Subsequently on January 17, 2024, the Company fully paid the remaining €189,000 (approximately $207,000). As of December 31, 2023, the Company accrued for trade tax liability of €155,000 (approximately $171,000) and corporation tax of €98,000 (approximately $108,000). Based on the Company's current operating state in Germany and the negotiations, the Company believes, based on its evaluation under ASC 740, that the resolution of these tax matters will not likely result in a net material charge to the Company.

Other Contingent Payment Obligation

During the year ended December 31, 2023, the Company entered into certain non-dilutive funding agreements with multiple investors, pursuant to which the Company received funding of $5.0 million related to a gain contingency. These agreements are accounted for under ASC 470 and are recognized as contingent payment obligations on the Company's consolidated balance sheet. The Company's payment obligations only apply when such are received by the Company.

13. Income Taxes

No provision was made for U.S. taxes on undistributed foreign earning as such earnings are considered to be permanently reinvested. It is not practicable to determine the amount of additional tax, if any that might be payable on those earnings if repatriated.

The tax effects of temporary differences and tax loss and credit carry forwards that give rise to significant portions of deferred tax assets and liabilities at December 31, 2023 and 2022 are comprised of the following (in thousands):

	As of December 31, 2023	As of December 31, 2022
Deferred tax asset		
Net operating loss carryforward	$ 211,533	$ 202,525
Research and development credit carryforwards	18,377	17,989
Stock based compensation and other	15,712	18,021
Capitalized research and experimental expenses	15,823	9,144
Total deferred tax assets	261,445	247,679
Valuation Allowance	(261,445)	(247,679)
Deferred tax asset, net of allowance	$ —	$ —

The Company has identified the United States, Maryland, Germany and United Kingdom as significant tax jurisdictions.

The Company's U.S. net operating loss ("NOL") carryforwards for tax purposes as of December 31, 2023, are approximately $739.7 million. Unused NOL carryforwards from years prior to 2018 of $519.5 million will begin to expire in 2021 through 2037. NOL incurred in 2018 and later amount to $220.2 million and shall carryforward indefinitely. NOL carryforwards are generally available to offset future taxable income. However, an Internal Revenue Code Section 382 analysis has not been performed to determine availability of NOL to offset future taxable income, and the utilization of NOL may be limited under the Internal Revenue Code Section 382 as a result of changes in ownership of the Company's stock over the loss periods and prior to utilization of the carryforwards. The Company also has approximately $18.4 million in research and development tax credits available to offset federal income tax in future periods. If unused, these credits expire through 2037. The Company's NOL carryforwards for foreign tax purposes as of December 31, 2023 are $39.3 million. NOL in the United Kingdom and Germany of $22.3 million and $16.7 million respectively do not expire over time. NOL in the Netherlands of $0.4 million will begin to expire in 2025 through 2033. The Company's tax years are still open under statute from 2018 to present, although NOL carryovers from prior tax years are subject to examination and adjustments to the extent utilized in future years.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and taxing strategies in making this assessment. In case the deferred tax assets will not be realized in future periods, the Company has provided a valuation allowance for the full amount of the deferred tax assets at December 31, 2023 and 2022.

The expected tax expense (benefit) based on the U.S. federal statutory rate is reconciled with actual tax expense (benefit) as follow
(dollars in thousands):

	As of December 31, 2023	As of December 31, 2022
Statutory federal income tax rate	21.0 %	21.0 %
State taxes, net of federal tax benefit	5.8 %	4.6 %
Tax rate differential on foreign income	0.0 %	(0.2)%
Derivative gain or loss	1.2 %	(5.2)%
Expiration of net operating losses	(3.5)%	(2.6)%
Other permanent items and true ups	(4.6)%	(6.0)%
R&D Credit	0.6 %	0.0 %
Change in rate	1.5 %	0.1 %
Change in valuation allowance	(22.0)%	(11.7)%
Income tax provision (benefit)	0.0 %	0.0 %

	As of December 31, 2023	As of December 31, 2022
Federal		
Current	$ —	$ —
Deferred	(9,859)	(8,868)
State		
Current	—	—
Deferred	(3,927)	(3,097)
Foreign		
Current		
Deferred	19	(489)
Change in valuation allowance	13,767	12,454
Income tax provision (benefit)	$ —	$ —

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ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. As of December 31, 2023 and 2022, there were no uncertain tax positions. The Company's policy for recording interest and penalties associated with uncertain tax positions is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest during the year ended December 31, 2023, 2022 and 2021. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

14. Revision to Prior Period Financial Statements

As described in Item 9A, during the three and nine months ended September 30, 2023, the Company recorded the valuation of a number of its convertible notes, that it had entered into during the third quarter of 2023, at a fair value under the market approach using the price actually paid. In preparing the annual report on Form 10-K for the years ended December 31, 2023, 2022 and 2021, the Company determined that its application of the market approach for calculating the fair value based on the price actually paid was incorrect. The Company engaged a third-party valuation expert to prepare a modified Monte Carlo simulation under the income approach to determine fair value of the convertible notes as of December 31, 2023. In order to properly reflect the same valuation methodology of these notes for the third quarter of 2023, the Company is revising its prior period financial statements. This resulted in a non-cash adjustment to the convertible notes at fair value of $4.9 million as of September 30, 2023, and a non-cash adjustment to the change in fair value of convertible notes for both the three and nine months ended September 30, 2023 of $4.9 million.

The effect of the revisions to the unaudited condensed consolidated financial statements is as follows (amount in thousands):

Condensed Consolidated Balance Sheet (Unaudited)

	As of September 30, 2023		
	As Previously Reported	Adjustments	As Revised
Convertible notes at fair value	$ 10,250	$ 4,942	$ 15,192
Total current liabilities	49,223	4,942	54,165
Total liabilities	$ 68,945	$ 4,942	$ 73,887
Accumulated deficit	$(1,340,802)	$ (4,942)	$(1,345,744)
Total stockholders' deficit	(65,119)	(4,942)	(70,061)
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	$ 31,492	$ —	$ 31,492

Condensed Consolidated Statement of Operations (Unaudited)

	For the Three Months Ended September 30, 2023			For the Nine Months Ended September 30, 2023		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Change in fair value of convertible notes	$ —	$ 4,942	$ 4,942	$ —	$ 4,942	$ 4,942
Total other loss	(4,755)	(4,942)	(9,697)	(3,314)	(4,942)	(8,256)
Net loss	(18,580)	(4,942)	(23,522)	(43,680)	(4,942)	(48,622)
Net loss attributable to common stockholders	$ (19,099)	$ (4,942)	$ (24,041)	$ (45,113)	$ (4,942)	$ (50,055)
Total comprehensive loss	$ (17,702)	$ (4,942)	$ (22,644)	$ (44,968)	$ (4,942)	$ (49,910)
Net loss per share applicable to common stockholders						
Basic	$ (0.02)	$ —	$ (0.02)	$ (0.04)	$ (0.01)	$ (0.05)
Diluted	$ (0.02)	$ —	$ (0.02)	$ (0.04)	$ (0.01)	$ (0.05)

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Condensed Consolidated Statement of Stockholders' Deficit (Unaudited)

	For the Three Months Ended September 30, 2023		For the Nine Months Ended September 30, 2023	
	Accumulated Deficit	Total Stockholders' Deficit	Accumulated Deficit	Total Stockholders' Deficit
As Previously Reported				
Net loss	$ (18,580)	$ (18,580)	$ (43,680)	$ (43,680)
Balance at September 30, 2023	$(1,340,802)	$ (65,119)	$(1,340,802)	$ (65,119)
Adjustments	$ (4,942)	$ (4,942)	$ (4,942)	$ (4,942)
As Revised				
Net loss	$ (23,522)	$ (23,522)	$ (48,622)	$ (48,622)
Balance at September 30, 2023	$(1,345,744)	$ (70,061)	$(1,345,744)	$ (70,061)

Condensed Consolidated Statement of Cash Flows (Unaudited)

	For the Nine Months Ended September 30, 2023		
	As Previously Reported	Adjustments	As Revised
Cash Flows from Operating Activities:			
Net loss	$ (43,680)	$ (4,942)	$ (48,622)
Reconciliation of net loss to net cash used in operating activities:			
Change in fair value of convertible notes	—	4,942	4,942
Subtotal of non-cash charges	5,677	4,942	10,619
Net cash used in operating activities	$ (36,679)	$ —	$ (36,679)

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15. Subsequent Events

Between January 1, 2024 and February 28, 2024, the Company received $5.5 million in funding from the sale of preferred shares, proceeds from warrant exercise, proceeds of debt arrangements.

Between January 1, 2024 and February 28, 2024, the Company issued approximately 0.2 million shares of Series C preferred stock for proceeds of $1.9 million.

Between January 1, 2024 and February 28, 2024, the Company received $1.3 million from the exercise of 5.7 million outstanding warrants.

Between January 1, 2024 and February 28, 2024, approximately 0.2 million Series C Shares with a book value of $2.3 million were converted into 4.3 million common shares in accordance with their terms at a ratio of 1:25.

Between January 1, 2024 and February 28, 2024, the Company issued approximately 2.8 million shares of common stock to certain lenders in lieu of cash payments of $1.4 million of debt, including $0.2 million of accrued interest. The Company also issued 1.0 million shares of common stock to extinguish $0.6 million outstanding share liability.

On January 8, 2024, certain warrants holders elected to exercise some of their warrants pursuant to cashless exercise formulas. The Company issued approximately 0.7 million shares of common stock upon exercise of 1.3 million warrants at exercise prices at $0.34 per share.

On February 22, 2024, the Company received a $0.8 million prepayment for the purchase of securities for which the terms are in the process of being finalized.

On February 27, 2024, the Company entered into a one-year convertible note (the “Note”) with an individual investor (the “Holder”) for principal amount of $1.5 million. The Note bears interest at 11% per annum and is convertible into Series C preferred shares at $11.50 per share at the Holder’s sole option. The Series C preferred shares are convertible into common stock 30 days after the debt conversion date. Each Series C preferred share is convertible into 25 shares of common stock. In addition, the Holder has an alternative option to convert the Note into a non-dilutive financial instrument, which has the same terms at those in the non-dilutive funding agreements as described in Note 12.