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# NORTHWEST BIOTHERAPEUTICS INC

## FORM 10-K

(Annual Report)

Filed 02/28/23 for the Period Ending 12/31/22

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|---|---|
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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, 2022**

☐ 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 $30,474,000 on June 30, 2022.

As of February 24, 2023, the registrant had1,072,879,079 shares of common stock outstanding.

**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). 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.

On May 10, 2022, top line data from the Phase III trial of DCVax-L were presented in a scientific conference at the New York Academy of Sciences by one of the investigators in the trial. The presentation was made available publicly on a third-party site. On November 17, 2022, the Phase III trial results were reported in a peer reviewed publication in JAMA Oncology, a top scientific and medical journal.

The Company is now working on preparations for an application for regulatory approval of DCVax-L. The Company is working with teams of specialized consultants on pre-requisites for the application, and on portions of the application package itself. One of the pre-requisites — obtaining regulatory approval of a Pediatric Investigation Plan (PIP) — was completed during 2022 on an accelerated basis, including regulatory approval to use the same trial design with external controls as was used in the Company's Phase 3 trial. Additionally, substantial progress was made with the contract research organization (CRO) and specialized consultants on preparing the Trial Master File to be inspection-ready for regulators.

Post-COVID difficulties continue to impact the Company's programs and operations, due to backlogs in the supply chain, at clinical trial sites, and at regulators. The supply chain backlogs include 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 clinical trial site backlogs involve delays for various clinical trial follow-up matters, such as queries and additional documentation. With regulators, committee processes and regulatory processes were focused on COVID matters during the pandemic, and a substantial backlog of non-COVID matters accumulated. The Company is hopeful that the various backlog circumstances will improve in 2023.

**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, UK. Prior to 2022, our production of dendritic cell vaccine products in the UK was taking place in a GMP (clean room) facility in London, with a capacity of about four to six patients per month. 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 substantial support space for process development, Quality Control testing, quarantined storage, cryostorage and other functions are anticipated to have potential capacity to produce dendritic cell vaccines for up to 40 to 45 patients per month, or approximately 450 to 500 patients annually. The buildout of Phase 1A of the Sawston facility was previously completed, and the buildout of Phase 1B has been under way in 2022 and Q1 of 2023. Our buildout of the Sawston facility is designed to proceed in phases, as modules, both for efficiency in the timing of capital costs and to allow flexibility in operations and usage.

During 2021, initial licenses were obtained for operations in the Sawston facility, after technology transfer from the London facility, recruitment of technical personnel, development of some 1,000 regulatory documents, and buildout of Phase 1A of the facility. The initial licenses included a license from the Human Tissue Authority (HTA) for collection and processing of human cells and tissues, and licenses from the Medicines and Healthcare Products Regulatory Agency (MHRA) for manufacturing for clinical trials and compassionate use.

GMP production of DCVax-L products for compassionate use began in the Sawston facility in February 2022, after the licenses were obtained in Q4 2021, and continued throughout 2022. In parallel, extensive activities were conducted throughout 2022 to further develop the operations, personnel, regulatory documents and data necessary to apply for a commercial manufacturing license for the Sawston facility. The application package was submitted at the end of June, and reviewed by the regulatory authorities over the following months. An initial onsite inspection by regulatory authorities took place in October for the commercial license application, and also served as the annual review/renewal inspection for the prior licenses for compassionate use and clinical trial manufacturing. Further submissions and interactions with the regulator took place between October and February, and a follow-up inspection took place in early February 2023. The Company is now awaiting any further requirements or communications from regulators.

In parallel, production of DCVax-L products for compassionate use continued in the London facility. In the US, the Company entered into contract discussions for resumption of manufacturing capacity there.

The Company also continued process and infrastructure improvements that will be needed for scale-up. These include work towards development of a system designed to avoid or reduce bottlenecks in quality control testing and product "release," and equipping the facility to establish capacity for controlled cryostorage of millions of doses.

The initial production capacity in the Sawston facility occupies only a small fraction of the total space there. 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, as previously reported we entered into a sublease on December 31, 2021 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 for the Sawston facility, and the manufacturing at the Sawston facility, have been carried out or managed by Advent BioServices, who is the contract operator of the facility.

In parallel with our activities in the Sawston facility, development work on the Flaskworks system continued throughout 2022. As previously reported, the Flaskworks system is designed to close and automate the manufacturing of cell therapy products such as DCVax®. The Flaskworks company was previously owned by its technical founders and Corning Inc, and following our acquisition in 2020 it became a wholly owned subsidiary of our Company. We anticipate that the Flaskworks system will enable substantial scale-up of production volumes of DCVax products and potentially substantial reduction of production costs (including potential reduction of indirect costs related to capital-intensive facility costs). We anticipate that implementation of the Flaskworks system will enable certain phases of the Sawston buildout to be simplified and streamlined. For further details on the financial aspects of the Flaskworks acquisition, please see Item 8 Note 5 below.

**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, 2022, we have 103 issued patents and 64 pending patent applications worldwide, grouped into 9 patent families. Of these, 98 issued patents and 43 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 59 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 2022, four new patents were issued to us as part of our worldwide patent portfolio. The European patent was validated as 16 national patents. 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 that may be potential future markets for related DCVax products and a potential method for determining the immunopotency of dendritic cells produced by our manufacturing processes.

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.

During 2020, three 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 that may be potential future markets for related DCVax products.

The expiration dates of the issued US patents involved in our current business range from 2023 to 2036, and pending applications may involve longer time periods. The expiration dates of the issued European patents involved in our current business range from 2023 to 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.

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 (including Kite, Juno, Sotio, AiVita, Mendus, Medicenna and many others). In addition, many big pharma companies (including BMS, Merck, Pfizer, Astra Zeneca, Roche and others) are rapidly commercializing checkpoint inhibitor drugs to “take the brakes off” patients’ immune responses to cancer. Other novel technologies for cancer are also under development or approved, such as the Optune electro-therapy device developed by NovoCure, various biologics that Medicenna is developing, 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 specialized expertise. The Company began the year with 20 full-time employees (FTEs) and ended the year on December 31, 2022 with 22 FTEs. The Company's internal workforce is approximately gender equal. As in the past, the Company relied upon external 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. At 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, 2022, 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, 2022 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 to perform such control activities and other factors.***

In connection with the preparation of our financial statements for the year ended December 31, 2019, and prior years, our management and our independent auditor identified certain internal control deficiencies that, in the aggregate, represented material weaknesses. Although we have remediated the past material weaknesses and we have no material weakness noted for the years ended December 31, 2022, 2021, and 2020, 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 other factors. We may not be able to attract or retain sufficient numbers of qualified personnel.

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, 2022, we had a total of 22 full-time employees: 20 full-time employees in the US, and 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 regulator, 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.

***Changes in manufacturing methods for DCVax-L could require us to conduct equivalency studies and/or additional clinical trials.***

With biologics products, in some cases "the process is the product": i.e., the manufacturing process is considered to be as integral to the product as is the composition of the product itself. If any changes are made in the manufacturing process, and such changes are considered material by the regulatory authorities, the company sponsor may be required to conduct equivalency studies to show that the product is equivalent under the changed manufacturing processes as under the original manufacturing processes, and/or the company sponsor may be required to conduct additional clinical trials. In addition, if there are multiple manufacturing locations, equivalency studies may be required to show that the products produced in the respective facilities are substantially the same. Our manufacturing processes have undergone some changes during or since the early clinical trials, and we have multiple manufacturing locations. Accordingly, we may be required to conduct equivalency studies, and/or additional clinical trials, before we can obtain product approval, unless the regulatory authorities are satisfied that the changes in processes do not affect the quality, efficacy or safety of the product, and satisfied that the products made in each manufacturing location are substantially the same.

***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, 2022, we had 103 issued patents and 64 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 2023 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. 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, 2022, 1,068.4 million shares of our common stock are issued and outstanding. In addition, as of December 31, 2022, 3.8 million shares of our common stock are issuable upon exercise of outstanding warrants, and 45.7 million shares of our common stock are issuable upon exercise of outstanding options.

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

From time to time, we may be subject to a variety of claims and lawsuits or counterclaims. In the past, we were engaged in several shareholder litigations. We believed 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. We are currently involved in shareholder derivative litigation and a lawsuit initiated by us with respect to market activity that we believe constitutes manipulation in violation of applicable securities laws. Litigation and claims or counterclaims are expensive, time consuming and 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 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.

The Company also owns a 17-acre parcel of land near the Sawston facility which was part of the Company’s original acquisition of the Sawston property and was not part of the subsequent sale of the Sawston property to Huawei.

**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: Canaccord Genuity LLC, Citadel Securities LLC, G1 Execution Services LLC, GTS Securities LLC, Instinet LLC, Lime Trading Corp., Susquehanna International Group LLP, and Virtu Americas LLC (*Northwest Biotherapeutics Inc. v. Canaccord, et al.,* No. 1:22-cv-10185-GHW-GWG). 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 January 13, 2023, the defendants notified the court that they plan to file a Motion to Dismiss the Complaint. The Company plans to pursue the case vigorously.

In February and March, 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 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) through its Say on Pay vote, and the director awards are subject to shareholder approval. 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”).

The Company believes these cases are baseless and intends to vigorously contest the Derivative Action. On February 22, 2023, the Company filed a Motion to Dismiss the case.

**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 February 15, 2023, there were approximately 45,152 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.

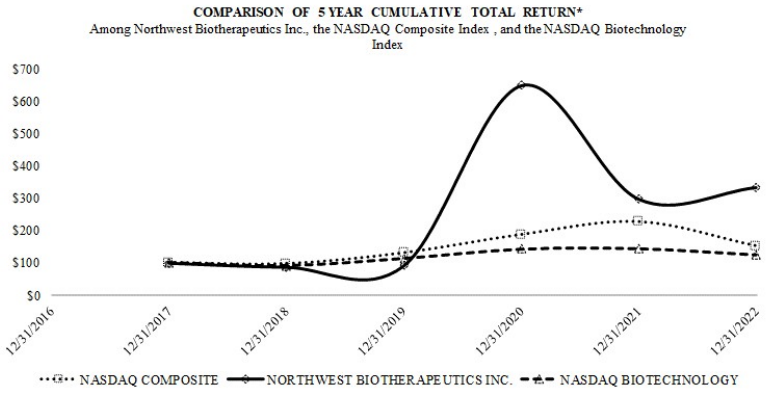
**Dividend Policy**

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, 2017 in stock or index, including reinvestment of dividends.

| | 12/31/2017 | 12/31/2018 | 12/31/2019 | 12/31/2020 | 12/31/2021 | 12/31/2022 |
|---|---|---|---|---|---|---|
| Northwest Biotherapeutics Inc. | 100.00 | 87.37 | 91.37 | 648.38 | 297.62 | 333.55 |
| NASDAQ Composite | 100.00 | 96.12 | 129.97 | 186.69 | 226.63 | 151.61 |
| NASDAQ Biotechnology | 100.00 | 90.47 | 113.28 | 142.73 | 144.09 | 124.36 |

**Recent Sales of Unregistered Securities**

During the year ended December 31, 2022, 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, 2022, the Company issued an aggregate of 1.4 million shares of Series C convertible preferred stock (the “Series C Shares”) to accredited investors for gross proceeds of approximately $22.0 million. During the year ended December 31, 2022, the Company extinguished approximately $3.4 million outstanding debt 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. 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.

During the year ended December 31, 2022, the Company issued an aggregate of 13.1 million shares of common stock to accredited investors for $9.5 million cash.

During the year ended December 31, 2022, the Company issued an aggregate of 74.3 million shares of common stock to accredited investors for $11.1 million cash from the exercise of warrants issued in the past with an exercise price between $0.18 and $0.85.

During the year ended December 31, 2022, the Company issued an aggregate of 18.1 million shares of common stock to accredited investors in lieu of cash payments on $11.3 million outstanding debt.

During the year ended December 31, 2022, the Company issued an aggregate of 7.5 million shares of common stock at fair value of $5.9 million to Advent BioServices for services provided to the Company. This payment covers 8 milestones: 6 workstreams (Comparability, Stability, Potency, Product Profile, Fill/Finish, Mechanism of Action), and 2 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).

During the year ended December 31, 2022, the Company issued an aggregate of 1.0 million shares of common stock at fair value of $1.6 million to third-party consultants for professional services rendered.

During the year ended December 31, 2022, the Company issued an aggregate of 5.2 million shares of common stock to accredited investors from exercise of stock options with an exercise price between $0.23 and $0.34.

During the year ended December 31, 2021, the Company issued an aggregate of 6.3 million shares of common stock to accredited investors for $4.1 million cash.

During the year ended December 31, 2021, the Company issued an aggregate of 107.3 million shares of common stock to accredited investors for $20.0 million cash from the exercise of warrants and stock options issued in the past with an exercise price between $0.175 and $0.52.

**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, 2022 as compared to the year ended December 31, 2021. The discussion of the Company's financial condition and results of operations for the year ended December 31, 2021 compared to the same period in 2020 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, 2022.*

**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 brain cancer (GBM). As previously reported, the data collection and confirmation process was conducted by the independent contract research organization (CRO) who managed the trial and by other independent service firms, and the data were analyzed by independent statisticians.

On May 10, 2022, top line data from the Phase III trial of DCVax-L were presented in a scientific conference at the New York Academy of Sciences by one of the investigators in the trial. The presentation was made available publicly on a third-party site. On November 17, 2022, the Phase III trial results were reported in a peer reviewed publication in JAMA Oncology, a top scientific and medical journal.

The Company is now working on preparations for an application for regulatory approval of DCVax-L. The Company is working with teams of specialized consultants on pre-requisites for the application, and on portions of the application package itself. One of the pre-requisites — obtaining regulatory approval of a Pediatric Investigation Plan (PIP) — was completed during 2022 on an accelerated basis, including regulatory approval to use the same trial design with external controls as was used in the Company's Phase 3 trial.

Additionally, substantial progress was made with the CRO and specialized consultants on preparing the Trial Master File to be inspection-ready for regulators.

Post-COVID difficulties continue to impact the Company's programs and operations, due to backlogs in the supply chain, at clinical trial sites, and at regulators. The supply chain backlogs include 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 clinical trial site backlogs involve delays for various clinical trial follow-up matters, such as queries and additional documentation. With regulators, committee processes and regulatory processes were focused on COVID matters during the pandemic, and a substantial backlog of non-COVID matters accumulated. The Company is hopeful that the various backlog circumstances will improve in 2023.

In the future, we plan to conduct clinical trials of DCVax-L for other types of solid tumor cancers, beyond brain cancer, 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.

**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, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing coronavirus pandemic ("COVID-19") and the COVID-19 control responses.

***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, 2022 and 2021, the undiscounted net future cash flows of the U.K. property were greater than the carrying value. Therefore, no impairment loss was considered necessary.

***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.

The estimated 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 Adopted Accounting Standards**

*Income Taxes*

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. On January 1, 2021, we adopted this standard without any material impact on our consolidated financial statements and related disclosures.

*Debt*

In August 2020, the FASB issued ASU No. 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This ASU is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption was permitted, but no earlier than fiscal years beginning after December 15, 2020. This update permits the use of either the modified retrospective or fully

retrospective method of transition. We adopted the new standard as of January 1, 2021, we adopted this standard without any material impact on our consolidated financial statements and related disclosures.

*Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. On January 1, 2022, we adopted this standard without any material impact on the Company's consolidated financial statements or disclosures.

**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 are still evaluating the impact of this pronouncement on the consolidated financial statements.

**Results of Operations**

***Operating costs:***

Our operating costs and expenses consist primarily of research and development (R&D) expenses. Such R&D expenses include clinical trial expenses while we are conducting trials, and additional costs related to completion of a trial, including substantial one-time expenses such as for final site visits, query resolutions, additional data collection and documentation, and related matters. There are also increased costs after completion of a Phase III trial, such as for statistical analyses and preparations 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 planned Phase II clinical trials. 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 subsidiary in the Netherlands.

***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 pre-revenue company, we do not allocate R&D 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, 2022, 2021 and 2020**

We recognized a net loss of $105 million, a net income of $179.1 million and a net loss of $529.8 million for the years ended December 31, 2022, 2021 and 2020, 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. The net loss of $105 million and a loss of $529.8 million for the year ended December 31, 2022 and 2020 included a non-cash loss of $25.8 million and $435.4 million from the change in fair value derivative liabilities, respectively.

Net cash used in operations was $52.8 million, $38.3 million and $32.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. The increase in cash used in operating activities in 2022 compared to 2021 was mainly due to an increase in R&D expenses.

*Research and development expense*

For the years ended December 31, 2022, 2021 and 2020, research and development expense was $35.5 million, $20.3 million and $33.6 million, respectively. The R&D expenses in 2022 were similar to the level of such expenses in 2020, when the Phase 3 trial was reaching completion and undergoing final data collection, query resolution and other requirements to reach Data Lock. The decrease in 2021 compared to 2020 was mainly related to a decrease of $12.0 million stock-based compensation that represented the vesting of a portion of previously granted equity-based awards, and that was recognized in research and development expense.

The R&D expenses in 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 6 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 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 10 key one-time milestones for pre-requisites and preparations for an application for product approval. These included 3 milestones for obtaining the 3 licenses required for the Sawston facility, 6 milestones for the 6 product workstreams, and 1 milestone related to preparing key portions of an application for regulatory approval of the DCVax-L product. We paid $3.0 million for the cash component of 7 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 8 milestones, and we accrued $3.6 million for the stock component of future milestones.

*General and Administrative Expense*

General and administrative expenses were $33.4 million, $33.4 million and $54.3 million for the years ended December 31, 2022, 2021 and 2020, respectively. 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.

The decrease in 2021 compared to 2020 was mainly related to a decrease of $24.2 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 $3.3 million related to consulting expenses.

*Change in fair value of derivatives*

We recognized a non-cash loss of $25.8 million, a non-cash gain of $239.3 million and a non-cash loss of $435.4 million for the years ended December 31, 2022, 2021 and 2020, 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, 2022, 2021 and 2020 were as follows:

| December 31, 2022 | December 31, 2021 | December 31, 2020 |
|---|---|---|
| $ 0.78 | $ 0.70 | $ 1.53 |

*Debt Extinguishment*

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.

During the year ended December 31, 2020, we converted debt of approximately $12.7 million principal and $1.2 million accrued interest into approximately 58.4 million shares of common stock and 6.2 million warrants. We also extinguished $6.6 million embedded derivative liabilities, wrote off $0.9 million unamortized debt discount and made some debt amendment upon the conversion. We recorded an approximate $1.6 million debt extinguishment loss from the conversion.

Our PPP Loan forgiveness application for Round 1 was approved on December 7, 2020. We recorded approximately $0.4 million debt extinguishment gain from the forgiveness of PPP Loan during the year ended December 31, 2020.

*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, 2022, 2021 and 2020, we recorded interest expense of $6.1 million, $5.0 million and $8.5 million, respectively.

*Foreign currency transaction (loss) gain*

During the years ended December 31, 2022, 2021, and 2020, we recognized foreign currency transaction loss of $3.3 million, loss of $1.7 million and gain of $2.3 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. The fluctuation of the exchange rates was larger in 2022 compared to the same period in 2021.

**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, 2022 (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 | $ 242 | $ 242 | $ — | $ — |
| Short term notes payable (2) | | | | |
| 8% unsecured | 14,998 | 14,998 | — | — |
| 9% unsecured | 884 | 884 | — | — |
| 12% unsecured | 844 | 844 | — | — |
| Long term notes payable (3) | | | | |
| 8% unsecured | 6,053 | — | 6,053 | — |
| 6% secured | 1,004 | 54 | 28 | 922 |
| Operating leases (4) | 3,813 | 981 | 863 | 1,969 |
| Minimum commitment obligation (5) | 5,298 | — | 5,298 | — |
| **Total** | **$ 33,136** | **$ 18,003** | **$ 12,242** | **$ 2,891** |

(1) The obligations related to short-term convertible notes were approximately $0.2 million as of December 31, 2022, which included remaining contractual unpaid interest of $0.1 million.

(2) The obligations related to short-term notes were approximately $3.3 million as of December 31, 2022, which included unpaid interest of $0.8 million.

(3) The obligations related to long-term notes were approximately $7.1 million as of December 31, 2022, which included unpaid interest for the next five years of approximately $0.6 million.

(4) The operating lease obligations during the next two years included approximately $0.5 million for our offices in Maryland and U.K. Approximately £2.5 million ($3.0 million) in lease obligations for the next five years related to the Vision Centre in the U.K. that we leased back in December 2018.

(5) 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 £4.4 million ($5.3 million).

**Operating Activities**

We used $52.8 million, $38.3 million and $32.1 million in cash for operating activities during the years ended December 31, 2022, 2021 and 2020, 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 $2.9 million, $6.0 million and $6.6 million in cash for purchase of additional equipment in the UK and our build out in Sawston, UK during the years ended December 31, 2022, 2021 and 2020, respectively.

We spent approximately $1.5 million related to the Flaskworks acquisition during the year ended December 31, 2020.

**Financing Activities**

We received approximately $18.7 million cash from issuance of 1.2 million shares of Series C convertible preferred stock during the year ended December 31, 2022.

We received approximately $9.5 million, $4.1 million and $26.8 million in cash proceeds from issuance of common stock and warrants, in both public and private offerings during the years ended December 31, 2022, 2021 and 2020, respectively.

We received approximately $11.1 million, $20.0 million and $13.9 million cash proceeds from the exercise of warrants and options during the years ended December 31, 2022, 2021 and 2020, respectively.

We received approximately $5.6 million, $29.7 million and $13.7 million in cash proceeds from the issuance of multiple notes payable during the years ended December 31, 2022, 2021 and 2020, respectively.

We received approximately $0.3 million in cash proceeds from issuances of debt with a related party during the year ended December 31, 2020.

We made aggregate debt payments of $5.5 million and $5.8 million and $2.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

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

We are exposed to market risks in the ordinary course of our business primarily related to interest rate sensitivities and the volatility of our common stock price.

**Interest Rate Risk**

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of December 31, 2022 would have no material impact on our consolidated financial statements.

**Foreign Currency Exchange Rate Risk**

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk.

**Common Stock Price Volatility**

Our common stock has experienced periods of high trading volatility. We negotiate the settlement of debt payment obligations in exchange for equity securities of the Company, which can create a non-cash charge upon extinguishment of debt as the price of our common stock fluctuates. If we continue to enter into these settlements, the increased levels of volatility in our common stock trading price will result in increased dilution and extinguishment gains or losses.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The full text of our audited consolidated financial statements as of December 31, 2022 and 2021 and for the fiscal years ended December 31, 2022, 2021 and 2020, 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**

Not applicable.

**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, 2022. 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”).

Our management concluded that as of December 31, 2022, our disclosure controls and procedures were effective.

**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, 2021. Based on this assessment, we determined that we have

effectively designed and implemented, consistently performed, and tested the functioning of these controls. Accordingly, we concluded that the Company's internal control over financial reporting was effective as of December 31, 2022.

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, 2022. 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**

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

**ITEM 9B. OTHER INFORMATION**

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.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

**DIRECTORS**

| Name | Age | Position |
|---|---|---|
| Linda F. Powers | 67 | Class III Director, Chairperson, President and Chief Executive Officer, Chief Financial and Accounting Officer |
| J. Cofer Black | 73 | Class I Director |
| Dr. Alton L. Boynton | 78 | Class I Director, Chief Scientific Officer |
| Jerry Jasinowski | 83 | Class II Director |
| Dr. Navid Malik | 54 | Class III Director |

**Director Biographies**

*Linda F. Powers.* Ms. Powers has served as the Chairperson of our Board of Directors since her appointment on May 17, 2007, Chief Executive Officer and President since June 8, 2011 and Chief Financial and Accounting Officer since June 8, 2020. Ms. Powers served as a managing director of Toucan Capital Fund II from 2001 to 2010, and Toucan Capital Fund III from 2010 to 2018. She also has over 16 years' experience in corporate finance and restructurings, mergers and acquisitions, joint ventures and intellectual property licensing. Ms. Powers is or was previously a Board member of the Rosalind Franklin Society, M2GEN (an affiliate of Moffitt Cancer Center) and the Chinese Biopharmaceutical Association. She was the Chair of the Maryland Stem Cell Research Commission for the first two years of the state's stem cell funding program, and has served an additional thirteen years on the Commission. Ms. Powers served for several years on a Steering Committee of the National Academy of Sciences, evaluating government research funding, and was appointed to three Governors' commissions created to determine how to build the respective states' biotech and other high-tech industries. For more than six years, Ms. Powers taught an annual internal course at the National Institutes of Health for the bench scientists and technology transfer personnel on the development and commercialization of medical products. Ms. Powers serves on the boards of several private biotechnology companies. Ms. Powers holds a B.A. from Princeton University, where she graduated magna cum laude and Phi Beta Kappa. She also earned a J.D., magna cum laude, from Harvard Law School. We believe Ms. Powers' background and experience make her well qualified to serve as a Director.

*Dr. Navid Malik.* Dr. Malik was appointed to the Board of Directors in April 2012. Dr. Malik is currently Head of Research and an Executive Director at The Life Sciences Division, a UK Investment Bank (since 2018). From January 2012 to December 2015, Dr. Malik was previously the Head of Life Sciences Research at Cenkos Securities Plc. in the U.K., an institutional stockbroking securities firm. From September 2011 through January 2012, Dr. Malik was the Head of Life Sciences Research at Sanlam (Merchant Securities), a global financial services firm. Dr. Malik was Partner and Head of Life Sciences at Matrix Investment Banking Division, Matrix Group, a financial services firm in London, from December 2008 through September 2011. Dr. Malik was a Senior Pharmaceuticals and Biotechnology Analyst at Wimmer Financial LLP from September 2008 through December 2008, and was the Senior Life Sciences Analyst at Collins Stewart Plc from January 2005 through September 2008. In 2011, Dr. Malik was awarded two StarMine Awards (awarded each year by Thomson Reuters and the Financial Times): Number One Stock Picker in the European Pharmaceutical Sector, and Number Two Stock Picker in the U.K. and Ireland Healthcare Sector. Dr. Malik holds a Ph.D. in Drug Delivery within Pharmaceutical Sciences, as well as degrees in Biomedical Sciences Research (M.Sc.) and Biochemistry and Physiology (B.Sc., joint honors). Dr. Malik also holds an MBA in finance from the City University Business School, London. We believe that Dr. Malik's extensive experience in the life sciences fields and investment banking sector make him well qualified to serve as a Director.

*J. Cofer Black.* Ambassador Black was appointed to the Board of Directors in January 2016. Ambassador Black is an internationally renowned U.S. government leader and expert in cybersecurity, counterterrorism and national security. In addition to serving on company and bank boards, he presently serves as an independent consultant. Between 2009 and 2016, he served as Vice President for Global Operations at Blackbird Raytheon Technologies, a division of Raytheon Company, a NYSE-listed security company. From 2004 until 2008, he provided strategic guidance and business development as Vice Chairman of Blackwater Worldwide and as Chairman of Total Intelligence Solutions. During 2002 – 2005, he was appointed by the President of the United States to serve as the Ambassador, Coordinator for Counterterrorism, reporting directly to the Secretary of State for developing, coordinating and implementing American counterterrorism policy. Prior to his role as Ambassador, he served a 28-year career in the Central Intelligence Agency, reaching Senior Intelligence Service (SIS-4) level as Director, Counterterrorist Center (D/CTC), where he managed 1,300 professional personnel and an annual operational budget of more than one billion dollars. Ambassador Black is experienced representing the United States at the Head of State level, managing media as a diplomatic spokesperson and in public speaking as keynote speaker both as a senior U.S. Government official and business leader. Ambassador Black has received numerous awards and recognitions throughout his career, including the Distinguished Intelligence Medal (the CIA's highest award for achievement). Ambassador Black received a B.A. in International Affairs from the University of Southern California in 1973 and an M.A. in International Affairs from the University of Southern California in 1974. We believe Ambassador Black's background and experience in business management and information technology make him well qualified to serve as a Director.

*Alton L. Boynton, Ph.D.* Dr. Boynton co-founded our Company, has served as our Chief Scientific Officer and a Director since our inception in 1998, was appointed our Chief Operating Officer in August 2001, was appointed President in May 2003, and served as Chief Executive Officer from June 2007 to June 2011. Prior to founding our Company, Dr. Boynton headed the Molecular Oncology research lab at the Pacific Northwest Research Foundation (the original foundation of Bill Hutchinson, from which the Fred Hutchinson Cancer Center was spun off). Dr. Boynton also served as Director of the Department of Molecular Medicine of Northwest Hospital from 1995 to 2003 where he coordinated the establishment of a program centered on carcinogenesis. Prior to joining Northwest Hospital, Dr. Boynton was Associate Director of the Cancer Research Center of Hawaii, The University of Hawaii, where he also held the positions of Director of Molecular Oncology of the Cancer Research Center and Professor of Genetics and Molecular Biology. Dr. Boynton received his Ph.D. in Radiation Biology from the University of Iowa in 1972. We believe Dr. Boynton's background and experience make him well qualified to serve as a Director.

*Jerry Jasinowski.* Mr. Jasinowski was appointed to the Board of Directors in April 2012. Mr. Jasinowski retired in 2007. Mr. Jasinowski currently serves on the boards of directors of Procurian and the Washington Tennis and Education Foundation and has held directorships in several other companies since 1990. From 2004 through 2007, Mr. Jasinowski served as the President of the Manufacturing Institute, an organization dedicated to improving and expanding manufacturing in the United States, of which he was a founder. Mr. Jasinowski was also the President and CEO of the National Association of Manufacturers, a trade association with 13,000 corporate members from 1990 to 2004. Mr. Jasinowski holds an A.B. in Economics from Indiana University and an M.A. in Economics from Columbia University. We believe that Mr. Jasinowski's extensive experience across a wide range of manufacturing, technology, and financial firms, including Fortune 1000 and Fortune 500 companies, make him well qualified to serve as a Director.

## EXECUTIVE OFFICERS

The following table sets forth information regarding the Company's current executive officers.

| Name | Age | Position |
|---|---|---|
| Linda F. Powers | 67 | Class III Director, Chairperson, President and Chief Executive Officer, Chief Financial and Accounting Officer |
| Dr. Alton L. Boynton | 78 | Class I Director, Chief Scientific Officer |
| Leslie J. Goldman | 77 | Senior Vice President, General Counsel |
| Dr. Marnix L. Bosch | 63 | Chief Technical Officer |

*Linda F. Powers.* Please see "*Director Biographies*" above.

*Alton L. Boynton, Ph.D.* Please see "*Director Biographies*" above.

*Leslie J. Goldman.* Mr. Goldman joined us in June 2011, and serves as Senior Vice President and General Counsel. In this capacity, Mr. Goldman has responsibility for legal matters, investor relations and financing activities. Prior to joining us, Mr. Goldman was a partner at the law firm of Skadden, Arps for over 30 years, specializing in a wide array of advanced technologies and their commercialization. Mr. Goldman also serves as an advisor to a number of other technology companies. In addition, for eight years, Mr. Goldman served as Chairman of the Board of a group of TV stations in four mid-size cities across the country. Mr. Goldman received a B.A. from the University of Michigan in 1967 and a J.D. from the University of Michigan in 1970.

*Marnix L. Bosch, Ph.D.* Dr. Bosch joined us in 2000, and serves as our Chief Technical Officer. In this capacity, Dr. Bosch plays a key role in the preparation and submission of our regulatory applications, as well as ongoing development of our product lines, and ongoing development and/or acquisition of new technologies. Dr. Bosch led the process of designing the protocols, and managed the successful preparation and submission of our Investigational New Drug (IND) applications for FDA approval to conduct clinical trials for prostate cancer, brain cancer, ovarian cancer and multiple other cancers. He also led the processes for other regulatory submissions in both the U.S. and abroad (including the successful applications for orphan drug status in both the U.S. and Europe for DCVax-L for brain cancer). He spearheaded the development of our manufacturing and quality control processes. Prior to joining us in 2000, Dr. Bosch worked at the Dutch National Institutes of Health (RIVM) as head of the Department of Molecular Biology, as well as in academia as a professor of Pathobiology. He has authored more than 40 peer-reviewed research publications in immunology and virology, and is an inventor on several patent applications on dendritic cell product manufacturing.

## CORPORATE GOVERNANCE

### Board Leadership Structure

The Board believes that Ms. Powers' service as both Chairperson of the Board and Chief Executive Officer is in the Company's and our stockholders' best interests. Ms. Powers possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing us, and is thus, we believe, best positioned to develop Company strategies, business plans and priorities, and corresponding Board agendas that ensure that the Board's time and attention are focused on the most critical matters. The Company has multiple major programs under way, with operations and infrastructure on two continents, which require heightened efficiency and involvement between the Board and management. Ms. Powers' combined role enables decisive leadership, and, we believe, facilitates this efficiency and involvement. Our lead independent director is Mr. Jerry Jasinowski.

### Board of Directors' Role in Risk Oversight

The Board plays an active role in risk oversight of our Company. The Board does not have a formal risk management committee, but administers this oversight function through various standing committees of the Board of Directors and/or through the full Board. The Audit Committee maintains responsibility for oversight of financial reporting-related risks, including those related to our accounting, auditing and financial reporting practices. The Audit Committee also reviews reports and considers any material allegations regarding potential violations of our Company's Code of Conduct. The Compensation Committee oversees risks arising from our compensation

policies and programs and has responsibility for evaluating and approving our executive compensation and benefit plans, policies and programs. The Company also performed an enterprise-wide risk assessment as well as an enterprise-wide fraud risk assessment during 2021 and will continue to update such assessments on an annual basis.

**Director Independence**

Our Board of Directors has undertaken a review of the independence of our directors and has determined that a majority of the Board consists of members who are currently "independent" as that term is defined within the meaning of Section 5605(a)(2) of the Nasdaq Stock Market Rules. The Board of Directors has determined each of Messrs. Malik and Jasinowski, and Ambassador Black to be independent.

**Audit Committee**

The Audit Committee has responsibility for recommending the appointment of our independent accountants, supervising our finance function (which includes, among other matters, our investment activities), reviewing our internal accounting control policies and procedures, and providing the Board such additional information and materials as it may deem necessary to make the Board aware of significant financial matters which require the attention of the Board. The Audit Committee discusses the financial statements with management, approves filings made with the SEC and maintains the necessary discussions with the Company's independent accountants. The Audit Committee acts under a written charter, which is posted on our website at www.nwbio.com/board-committee-charters/.

The Audit Committee currently consists of Messrs. Malik and Jasinowski. Our Board of Directors has determined that Jerry Jasinowski, the Chairman of the Audit Committee, qualifies as an "audit committee financial expert" as defined by the SEC. Our Board has determined that each member of the Audit Committee is "independent" within the meaning of Section 5605(a)(2) of the Nasdaq Stock Market Rules as well as pursuant to the additional test for independence for audit committee members imposed by SEC regulation and Section 5605(c)(2)(A) of the Nasdaq Stock Market Rules. The Audit Committee is established in accordance with Section 3(a)(58)(A) of the Exchange Act.

**Compensation Committee**

The Compensation Committee is responsible for determining the overall compensation levels of our executive officers and administering our equity compensation plans. The Compensation Committee currently consists of Messrs. Malik and Jasinowski. Our Board of Directors has determined that each member of the Compensation Committee is "independent" under the current listing standards of Nasdaq. The Compensation Committee acts under a written charter, which is posted on our website at *www.nwbio.com/board-committee-charters/.*

**Conflicts Committee**

The Conflicts Committee is responsible for review and evaluation of related party matters including related party transactions. The Conflicts Committee currently consists of Ambassador Black, Mr. Jasinowski and Dr. Malik. Our Board of Directors has determined that each member of the Conflicts Committee is "independent" within the meaning of Section 5605(a)(2) of the Nasdaq Stock Market Rules. The Conflicts Committee acts under a written charter, which is posted on our website at *www.nwbio.com/board-committee-charters/.* The Conflicts Committee does not delegate its authority pursuant to its written charter.

**Nominations Committee**

The Nominations Committee is responsible for assisting the Board of Directors in, among other things, effecting Board organization, membership and function, including: identifying qualified Board nominees; and effecting the organization, membership and function of Board committees, including composition and recommendation of qualified candidates and reviewing the Company's Corporate Governance Guidelines. The Nominations Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the Board of Directors based on the criteria, skills and qualifications that have been recognized by the Nominations Committee. While our nomination policy does not prescribe specific diversity standards, the Nominations Committee and its independent members seek to identify nominees who have a variety of perspectives, professional experience, education, difference in viewpoints and skills, and personal qualities that will result in a well-rounded Board of Directors. The Nominations Committee operates under a written charter, which is posted on our website at *www.nwbio.com/board-committee-charters/.*

The Nominations Committee currently consists of Messrs. Malik and Jasinowski. The Board of Directors has determined that each member of the Nominations Committee is "independent" under the current listing standards of Nasdaq. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Nominations Committee.

**Information Regarding Meetings of the Board and Committees**

The business of our Company is under the general oversight of our Board, as provided by the laws of Delaware and our bylaws. During 2022, the Board held 22 meetings and also conducted business by written consent. During 2022, the Audit Committee held 4 meetings, the Conflicts Committee held 6 meetings, and the Compensation Committee held 2 meetings. The Nominations Committee did not hold any meetings. Each person who was a director during 2022 attended at least 75% of the 22 Board meetings. We do not have a formal written policy with respect to Board members' attendance at our annual meeting of stockholders. All five of our directors attended our last annual meeting of stockholders.

**Code of Conduct**

We have an established Code of Conduct applicable to all Board members, executive officers, employees and contractors. Our Code of Conduct is posted on our website at www.nwbio.com.

**ITEM 11. EXECUTIVE COMPENSATION**

**EXECUTIVE COMPENSATION**

**Compensation Discussion and Analysis**

***Overview***

This Compensation Discussion and Analysis describes the compensation program for the Company's principal executive and principal financial officer, and our three most highly compensated executive officers other than our principal executive and financial officer who were serving as executive officers as of December 31, 2022. We refer to these individuals as our "named executive officers" or "NEOs."

For purposes of this executive compensation discussion, the names and positions of our named executive officers for the 2022 fiscal year were:

- Linda F. Powers, President and Chief Executive Officer, Chief Financial and Accounting Officer;
- Leslie Goldman, Senior Vice President and General Counsel;
- Marnix L. Bosch, Ph.D., Chief Technical Officer; and
- Alton L. Boynton, Ph.D., Chief Scientific Officer and Secretary.

***Philosophy and Objectives***

Our success is highly dependent on our ability to attract, engage and retain executive officers who possess the skills, competencies and passion that are consistent with our vision. To this end, our compensation program has been developed with the following overarching principles in mind:

- the pay of our NEOs should balance incentivizing performance, ensuring retention and maximizing stockholder value and should be linked to performance evaluated against key milestones.
- our executive compensation program should enable us to recruit, develop, motivate and retain top talent.

Periodically, the Compensation Committee reviews the objectives and components of our executive compensation program to assess whether they continue to align with these philosophies. To establish compensation parameters for our named executive officers, our

Compensation Committee evaluated each element of compensation separately and the total compensation for each named executive officer, as well as the compensation levels at similarly situated companies. Based on this review and analysis, our Compensation Committee determined that our process for determining executive compensation is aligned with stockholder interests.

***Risk Management and Mitigation***

In reviewing our compensation structure in 2022, the Compensation Committee also considered whether our compensation policies and practices could affect our risk profile and whether such compensation policies and practices could potentially encourage excessive risk taking by our employees. In considering these issues, the Compensation Committee did not find that our compensation policies and other policies generally raised undue risks for the Company or potentially could encourage excessive risk taking by our employees.

***Elements of 2022 Compensation***

Our 2022 executive compensation program consisted of two primary elements:

- Base salary;
- Annual bonus.

*Base Salary*

Base salary is the fixed portion of an executive's annual compensation. Base salaries for our NEOs are established based on the individual's scope of responsibilities, experience, and market factors. The Compensation Committee typically reviews base salaries on an annual basis, referencing salary levels at similarly situated companies to understand the marketplace for individuals in similar positions. The Committee annually reviews the base salary of our CEO in executive session and recommends her base salary to the independent members of the Board for approval, based on the criteria described above.

The Compensation Committee does not use a formulaic approach when setting an executive officer's base salary. However, taking into account the recommendations of our CEO, the Compensation Committee considers the following factors when determining (or, in the case of the CEO, recommending to the Board) individual base salary levels:

- the nature and responsibility of the executive's position,
- market trends for individuals in similar positions at comparable companies,
- the executive's expertise, tenure, responsibilities and performance, and
- competitiveness of the market for the executive's services.

In April, May and November 2022, our Compensation Committee reviewed the compensation of each of our NEOs. The Compensation Committee and Board considered the factors described above, and determined to leave Ms. Powers', Mr. Goldman's, Dr. Bosch's and Dr. Boynton's salaries unchanged.

*Annual Bonus Awards*

Our NEOs are eligible to receive an annual bonus in respect of their individual performance and the performance of the Company. The Company determines Annual Bonus Awards based upon progress achieved in the Company's programs (including clinical development, manufacturing, intellectual property and finances) and progress toward potential eventual commercialization, as well as the individual's roles and contributions toward the progress.

*Restricted Stock Awards*

The Company did not make any restricted stock or option awards to the NEOs in 2022. The Company also made no restricted stock or option awards in 2021. The Company has made no equity awards in nearly three years. However, the equity pool established under the Company's Equity Compensation Plan remains in place.

Additional information regarding the stock options granted to NEOs in 2020 is set forth below in the "Summary Compensation Table" and the "Outstanding Equity Awards at 2022 Fiscal-Year End" table.

*Other Compensation Plans*

401(k) Plan. The NEOs are eligible to participate in employee benefit plans and programs, including long-term disability, to the same extent as the Company's other full-time employees, subject to the terms and eligibility requirements of those plans. The NEOs also participate in our 401(k) plan, subject to limits imposed by the Internal Revenue Code, to the same extent as the Company's other full-time employees.

Other Benefits. We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans.

Limited Perquisites. Perquisites or other personal benefits are not a significant component of the compensation to our NEOs. We provide only limited perquisites to our NEOs, such as coverage of phone and internet costs.

Employment Agreements, The Company entered into employment agreements with each of Ms. Powers, Mr. Goldman, Dr. Bosch and Dr. Boynton in 2011. The 2011 agreements have expired. The Company entered into a new employment agreement with Dr. Bosch, which is currently in effect. The Company plans to enter into new employment agreements with Ms. Powers, Mr. Goldman and Dr. Boynton in due course.

***Process for Setting Executive Compensation***

*Compensation Committee Review*

Our Compensation Committee reviews the elements of our NEOs' total compensation throughout the year, to evaluate whether each element remains competitive. In making compensation decisions, the Committee relies on its own judgment after reviewing external data about similarly situated companies, and also considers the following factors:

- the executive's scope of responsibilities, as well as leadership, management and technical expertise, growth potential, and position in our reporting structure;
- overall Company and individual performance;
- retention needs; and
- the recommendations of our CEO (except with respect to her own compensation)..

Each year, the Compensation Committee expects to evaluate all elements of executive officer compensation, after reviewing the prior year's results and the achievement of Company operational and financial objectives. The purpose of this annual evaluation is to determine whether any changes in an officer's compensation may be appropriate. The CEO does not participate in the Committee's deliberations regarding her own compensation. At the Committee's request, the CEO may review with the Committee the performance of the other executive officers. Our Compensation Committee gives substantial weight to the CEO's evaluations and recommendations because she is particularly able to assess the other executive officers' performance and contributions.

*Independent Compensation Consultant*

The Compensation Committee does currently not retain an independent compensation consultant.

***Tax Considerations***

Section 162(m) of the Internal Revenue Code limits the amount of compensation that may be deducted per covered employee, including each of our NEOs, to $1 million per taxable year. Thus, it is expected that compensation deductions for any covered individual will be subject to a $1 million annual deduction limitation. However, the Company does not currently have significant taxable income and hence this issue is not currently a significant consideration. If the tax deductibility of compensation becomes a significant consideration to be evaluated by our Compensation Committee, the Committee may still conclude that the lost deduction on compensation for our NEOs is outweighed by the benefit of being able to attract and retain talented management. Accordingly, the Committee may continue to approve executive compensation that it believes is best for the Company without regard to whether the compensation is fully deductible.

**Compensation Committee Report**

The compensation committee has reviewed and discussed the compensation discussion and analysis included in this Annual Report on Form 10-K with management and, based on such review and discussions, the compensation committee recommended to our board of directors that the compensation discussion and analysis be included in this Annual Report on Form 10-K.

The foregoing report has been furnished by the Compensation Committee.
Dr. Navid Malik (Chairperson)
Jerry Jasinowski

**Summary Compensation Table**

The following table sets forth certain information concerning compensation paid to or accrued for our executive officers, referred to as our Named Executive Officers, during the years ended December 31, 2022, 2021 and 2020.

**The dollar values listed in the table below for option awards are a non-cash accounting measure** (based on the Black Scholes formula, under which high volatility of share price contributes to high valuations) **and do not constitute intrinsic value or exercise value for the options. The options had no intrinsic or exercise value when they were awarded.**

The options awarded in 2020, listed in the table below, were granted for employee performance during 2018, 2019 and 2020. The options were awarded at prices that were generally at or above the market price or the price paid by unrelated investors for the Company's shares at the time of the award.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Option Awards ($) | Total ($) |
|---|---|---|---|---|---|
| Linda F. Powers | 2022 | $ 700,000 | $ 400,000 [1] | $ — | $ 1,100,000 |
| Chairperson, President | 2021 | $ 700,000 | $ 300,000 [2] | $ — | $ 1,000,000 |
| & Chief Executive Officer | 2020 | $ 700,000 | $ — | $ 17,317,000 [3] | $ 18,017,000 |
| Leslie Goldman | 2022 | $ 525,000 | $ 300,000 [1] | $ — | $ 825,000 |
| Senior Vice President and | 2021 | $ 525,000 | $ 200,000 [2] | $ — | $ 725,000 |
| General Counsel | 2020 | $ 525,000 | $ — | $ 10,548,000 [3] | $ 11,073,000 |
| Marnix L. Bosch, Ph.D. [4] | 2022 | $ 397,500 | $ 200,000 [1] | $ — | $ 597,500 |
| Chief Technical Officer | 2021 | $ 442,500 | $ 125,000 [2] | $ — | $ 567,500 |
| | 2020 | $ 427,500 | $ — | $ 7,494,000 [3] | $ 7,921,500 |
| Alton L. Boynton, Ph.D. | 2022 | $ 350,000 | $ 100,000 [1] | $ — | $ 450,000 |
| Chief Scientific Officer | 2021 | $ 350,000 | $ 75,000 [2] | $ — | $ 425,000 |
| and Corporate Secretary | 2020 | $ 350,000 | $ — | $ 5,152,000 [3] | $ 5,542,000 |

(1) These bonuses were for employees' performance during 2022, and were approved in 2023 but have not been paid. These bonuses will not be paid until the Company feels it is financially feasible.

(2) These bonuses were for employees' performance during 2021, and were approved in 2022 but have not been paid. These bonuses will not be paid until the Company feels it is financially feasible.

(3) Represents the aggregate grant date fair value of stock options for service during 2018, 2019 and 2020, granted during the 2020 fiscal year. This is a non-cash accounting measure, calculated in accordance with Accounting Standards Codification, 718, Compensation-Stock Compensation, and does not constitute intrinsic value or exercise value for the options. Certain assumptions used to calculate the valuation of the awards are set forth in Management's Discussion and Analysis in our 2020 Annual Report.

(4) Dr. Bosch was relocated to our subsidiary in Netherlands effective August 1, 2019. His annual salary is 375,000 euros, which is equivalent to approximately $0.4 million. Dr. Bosch's compensation is paid in Euros and therefore varies based on the exchange rate. The compensation amounts paid to Dr. Bosch presented in the table above are determined by multiplying the amount of euros paid by the average exchange rate of $1.06 per euro for fiscal 2022, of $1.18 per euro for fiscal 2021, and of $1.14 per euro for fiscal 2020.

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

The following table shows outstanding stock option awards classified as exercisable and un-exercisable as of December 31, 2022:

| | Securities Underlying Unexercised Option Awards | | | |
|---|---|---|---|---|
| **Name and Principal Position** | **Number of Unexercised Options (#) Exercisable [1]** | **Number of Unexercised Options (#) Unexercisable** | **Option Exercise Price ($)** | **Option Expiration Date** |
| Linda F. Powers | 39,200,000 [2] | — | $ 0.23 | 5/28/2028 |
| Chairperson, President & Chief Executive Officer, | 10,770,429 [3] | — | $ 0.35 | 7/2/2030 |
| Chief Financial and Accounting Officer | 32,558,724 [3] | — | $ 0.35 | 12/1/2030 |
| | 11,789,879 [4] | — | $ 0.55 | 9/2/2030 |
| | | | | |
| Leslie Goldman | 24,500,000 [5] | — | $ 0.23 | 5/28/2028 |
| Senior Vice President and General Counsel | 6,731,518 [6] | | $ 0.35 | 7/2/2030 |
| | 21,822,937 [6] | — | $ 0.35 | 12/1/2030 |
| | 5,894,939 [7] | — | $ 0.55 | 9/2/2030 |
| | | | | |
| Marnix Bosch | 7,940,182 [8] | — | $ 0.25 | 6/13/2027 |
| Chief Technical Officer | 10,798,729 [9] | — | $ 0.35 | 7/2/2030 |
| | 16,630,726 [10] | — | $ 0.35 | 12/1/2030 |
| | | | | |
| Alton L. Boynton, Ph.D. | 2,967,065 [11] | — | $ 0.23 | 8/31/2028 |
| Chief Scientific Officer and Secretary | 3,096,498 [12] | — | $ 0.35 | 7/2/2030 |
| | 3,697,693 [13] | — | $ 0.35 | 12/1/2030 |

(1) Ms. Powers and Mr. Goldman are subject to a voluntary blocking agreement under which they cannot exercise any options, warrants or other derivative securities unless they provide the Company at least 61 days' advance notice.

(2) On May 28, 2018, we granted 39,200,000 stock options to Ms. Powers for service during part of 2018 and a number of preceding years. The options are exercisable at a price of $0.23 per share, and have a 10-year exercise period. 50% of the options vested on the grant date, and 50% vested over a 24-month period in equal monthly installments. Following entry into previous securities suspension agreements in 2021, Ms. Powers entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Ms. Powers cannot exercise or convert any options, warrants or other derivative securities unless Ms. Powers provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Ms. Powers received no consideration for entry into such arrangement.

(3) On July 2, 2020, we granted 10,770,429 stock options to Ms. Powers for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. Following entry into previous securities suspension agreements, in 2021 Ms. Powers entered into a voluntary blocking agreement with the Company under which Ms. Powers cannot exercise or convert any options, warrants or other derivative securities, unless Ms. Powers provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Ms. Powers received no consideration for entry into such arrangement.

On July 2, 2020, we granted 32,558,724 stock options to Ms. Powers for service during 2018, 2019 and 2020. These options were subject to certain vesting requirements which have been fulfilled. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. Following entry into previous securities suspension agreements, in 2021, Ms. Powers entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Ms. Powers cannot exercise or convert any options, warrants or other derivative securities, unless Ms. Powers provides the Company at least 61 days' advance notice. As

a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Ms. Powers received no consideration for entry into such arrangement.

(4) On September 2, 2020, we granted 11,789,879 stock options to Ms. Powers for service during 2018, 2019 and 2020. These options were subject to certain vesting requirements, which have been fulfilled. The options are exercisable at a price of $0.55 per share, and have a 10-year exercise period. Following entry into previous securities suspension agreements, in 2021, Ms. Powers entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Ms. Powers cannot exercise or convert any options, warrants or other derivative securities, unless Ms. Powers provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Ms. Powers received no consideration for entry into such arrangement.

(5) On May 28, 2018, we granted 24,500,000 stock options to Mr. Goldman. The options are exercisable at a price of $0.23 per share, and have a 10-year exercise period. 50% of the options vested on the grant date, and 50% vested over a 24-month period in equal monthly installments thereafter. Following entry into previous securities suspension agreements, in 2021, Mr. Goldman entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Mr. Goldman cannot exercise or convert any options, warrants or other derivative securities, unless Mr. Goldman provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Mr. Goldman received no consideration for entry into such arrangement.

(6) On July 2, 2020, we granted 6,731,518 stock options to Mr. Goldman for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. These options were fully vested upon grant. Following entry into previous securities suspension agreements, in 2021 Mr. Goldman entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Mr. Goldman cannot exercise or convert any options, warrants or other derivative securities, unless Mr. Goldman provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Mr. Goldman received no consideration for entry into such arrangement.

On July 2, 2020, we granted 21,822,937 stock options to Mr. Goldman for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. These options are subject to certain vesting requirements. Following entry into previous securities suspension agreements, in 2021 Mr. Goldman entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Mr. Goldman cannot exercise or convert any options, warrants or other derivative securities, as applicable, to acquire shares of the Company's common stock, unless Mr. Goldman provides the Company at least 61 days' advance notice. As a result, such derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended. Mr. Goldman received no consideration for entry into such arrangement.

On January 14, 2021, Mr. Goldman assigned 20,000,000 options that were granted on July 2, 2020 to The Goldman NWBIO GRAT Trust for no consideration. On April 28, 2022, Sue Goldman, Trustee of The Goldman NWBIO GRAT Trust transferred 12,709,287 options to Mr. Goldman in satisfaction of the first annuity amount due to Mr. Goldman. As of December 31, 2022, 7,290,713 options were remaining in The Goldman NWBIO GRAT Trust.

(7) On September 2, 2020, we granted 5,894,939 stock options to Mr. Goldman for service during 2018, 2019 and 2020. These options were subject to certain vesting requirements, which have been fulfilled. The options are exercisable at a price of $0.55 per share, and have a 10-year exercise period. Following entry into previous securities suspension agreements, in 2021 Mr. Goldman entered into a voluntary blocking agreement on an ongoing rolling basis with the Company under which Mr. Goldman cannot exercise or convert any options, warrants or other derivative securities, unless Mr. Goldman provides the Company at least 61 days' advance notice. Mr. Goldman received no consideration for entry into such arrangement.

(8) On June 13, 2017, we awarded 7,940,182 options to Dr. Bosch under the 2007 Stock Plan. The options are exercisable at a price of $0.25 per share, and had a 5-year exercise period. 50% of the options vested on the grant date, and 50% vested over a 24-month period in equal monthly installments. On January 14, 2018, we extended the exercise period of the options from 5-year to 10-year. In 2021, Dr. Bosch entered into a securities suspension agreement with the Company that (i) suspended the exercisability of the vested options and (ii) made no changes to the other terms of such securities. The suspension has continued on a monthly basis since then, with respect to 20,429,456 options. The suspension agreement expired on January 12, 2023. Dr. Bosch received no consideration for entry into such arrangement.

(9) On July 2, 2020, we granted 10,798,729 stock options to Dr. Bosch for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. These options were fully vested upon grant. Dr. Bosch entered into a securities suspension agreement with the Company that (i) suspended the exercisability of the vested options and (ii) made no changes to the other terms of such securities. The suspension agreement expired on January 12, 2023. Dr. Bosch received no consideration for entry into such arrangement.

10) On July 2, 2020, we granted 16,630,726 stock options to Dr. Bosch for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. 50% of these options were vested on the grant date, with the remainder vesting in monthly installments over one year. Dr. Bosch entered into a securities suspension agreement with the Company that (i) suspended the exercisability of 13,165,992 of the vested options and (ii) made no changes to the other terms of such securities. The suspension agreement expired on January 12, 2023. Dr. Bosch received no consideration for entry into such arrangement.

11) On August 31, 2018, we granted 2,967,065 stock options to Dr. Boynton. The options are exercisable at a price of $0.23 per share, and have a 10-year exercise period. 50% of the options vested on the grant date, and 50% vested over a 24-month period in equal monthly installments thereafter. Dr. Boynton entered into a securities suspension agreement with the Company that (i) suspended the exercisability of the vested options and (ii) made no changes to the other terms of such securities. The suspension agreement expired on January 12, 2023. Dr. Boynton received no consideration for entry into such arrangement.

12) On July 2, 2020, we granted 3,096,498 stock options to Dr. Boynton for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. These options were fully vested upon grant. Dr. Boynton entered into a securities suspension agreement with the Company that (i) suspended the exercisability of the vested options and (ii) made no changes to the other terms of such securities. The suspension agreement expired on January 12, 2023. Dr. Boynton received no consideration for entry into such arrangement.

13) On July 2, 2020, we granted 15,697,693 stock options to Dr. Boynton for service during 2018, 2019 and 2020. The options are exercisable at a price of $0.35 per share, and have a 10-year exercise period. 50% of these options were vested on the grant date, with the remainder vesting in monthly installments over one year. Dr. Bosch entered into a securities suspension agreement with the Company that (i) suspended the exercisability of the vested options and (ii) made no changes to the other terms of such securities. The suspension agreement expired on January 12, 2023. Dr. Boynton received no consideration for entry into such arrangement.

On July 27, 2022, Dr. Boynton assigned 3,000,000 options to his relatives for no consideration. On December 6, 2022, Dr. Boynton assigned 9,000,000 options to his relatives for no consideration.

**Non-qualified Defined Contribution and Other Non-qualified Deferred Compensation Plans**

We do not maintain either a non-qualified defined contribution or non-qualified deferred compensation plan.

**Potential Payments on Termination or Change in Control**

The Company does not currently have any arrangements that would trigger payments upon termination of a NEO or upon a change in control of the Company. However, the Company plans to enter into employment agreements with Ms. Powers, Mr. Goldman and Dr. Boynton in due course, which may contain such arrangements.

**CEO Pay Ratio Disclosure**

We are providing the following information about the relationship of the annual total compensation of our employees and the annual total compensation of our CEO. Based on the information for fiscal year 2022, we reasonably estimate that the ratio of our CEO's annual total compensation to the annual total compensation of our median employee was 4:1. Our pay ratio estimate has been calculated in a manner consistent with Item 402(u) of Regulation S-K using the data and assumptions summarized below.

We identified the median employee by examining the 2022 annual base salary compensation for all individuals, excluding our CEO. We identified our median compensation employee by examining total compensation paid for fiscal year 2022 to all individuals, excluding Ms. Powers, who were employed by us on December 31, 2022, the last day of our fiscal year based on payroll records. No assumptions, adjustments or estimates were made in respect of total compensation, except that we annualized the compensation of any

employee that was not employed with us for all of fiscal year 2022.We excluded independent contractors retained on an as needed basis, whose compensation is determined by an unaffiliated third party, and who are therefore are not considered our employees for purposes of the pay ratio calculation.

Once we identified our median employee, we calculated such employee's annual total compensation for 2022 in accordance with the requirements of Item 402(c)(2)(x) of Regulation S-K, resulting in that employee's annual total compensation of $161,000. The median employee's annual total compensation includes annualized base salary, annualized bonus during the fiscal year ended December 31, 2022.

With respect to the CEO, we used the amount reported as total compensation in the Summary Compensation Table included in this annual report on Form 10-K. Any estimates and assumptions used to calculate total annual compensation are described in footnotes to the Summary Compensation Table.

**Compensation Committee Interlocks and Insider Participation**

None of our officers currently serves, or in the past year has served, as a member of the compensation committee of any entity that has one or more officers serving on our board of directors.

## DIRECTOR COMPENSATION

The following table sets forth certain information concerning compensation paid or accrued to our non-executive directors during the years ended December 31, 2022.

**The dollar values listed in the table for option awards are a non-cash accounting measure** (based on the Black Scholes formula, under which high volatility of share price contributes to high valuations) **and do not constitute intrinsic or exercise value for the options. The options had no intrinsic or exercise value when they were awarded.**

The options were awarded at prices that were at the market price of the Company's shares at the time of the award (at $0.34 per share).

| Name | Year | Fees Earned or Paid in Cash ($) [2] | Option Awards ($) [1] | Total ($) |
|---|---|---|---|---|
| Dr. Navid Malik | 2022 | $ 150,000 | $ — | $ 150,000 |
| | 2021 | $ 150,000 | $ — | $ 150,000 |
| | 2020 | $ 150,000 | $ 4,123,000 | $ 4,273,000 |
| Jerry Jasinowski | 2022 | $ 150,000 | $ — | $ 150,000 |
| | 2021 | $ 150,000 | $ — | $ 150,000 |
| | 2020 | $ 150,000 | $ 1,497,000 | $ 1,647,000 |
| J. Cofer Black | 2022 | $ 150,000 | $ — | $ 150,000 |
| | 2021 | $ 150,000 | $ — | $ 150,000 |
| | 2020 | $ 150,000 | $ 1,250,000 | $ 1,400,000 |

(1) All of the options awarded to Directors in 2020 were conditional upon shareholder approval when the awards were made, and all were approved by shareholders at the 2022 annual meeting. The options awarded to Dr. Malik included approximately $1.8 million for regular Board service and $2.3 million for special Board service.

(2) The non-executive independent directors were compensated on a monthly basis $12,500 ($150,000 annually) for their consistent availability on short notice, participation in the frequent meetings of the board of directors, leadership of at least one board committee, participation on multiple committees of the Board, commitment to corporate governance initiatives, and frequent consultations with management on operational matters. The Company has not yet paid Mr. Jasinowski's Director fees for many years of service. In December 2022, the Company made partial payment of $600,000 to Mr. Jasinowski towards his outstanding unpaid director fees. The Company still owed Mr. Jasinowski $375,000 as of December 31, 2022.

(3) Ms. Powers and Dr. Boynton are executives of the Company and do not receive separate compensation for their services as a Director

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

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table presents information regarding the beneficial ownership of our common stock as of January 31, 2023 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of any class of our equity securities;
- our directors and nominees for director;
- each of our Named Executive Officers, as defined in Item 402(a)(3) of Regulation S-K; and
- our directors and executive officers as a group.

Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assume the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 31, 2022. Shares issuable pursuant to the exercise of stock options and warrants exercisable on or prior to the date 60 days after March 31, 2022 are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and the entities named in the table have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws, if any. The table below is based upon the information supplied by our transfer agent, Computershare Trust Company, N.A., the Company's records and from Schedules 13D and 13G filed with the SEC.

Except as otherwise noted, the address of the individuals in the following table is c/o Northwest Biotherapeutics, Inc., 4800 Montgomery Lane, Suite 800, Bethesda, MD 20814.

| Name of Beneficial Owner | Number of Shares or Options Beneficially Owned | Percentage[(1)] |
|---|---|---|
| **Directors and Officers:** | | |
| Alton L. Boynton, Ph.D. | 9,773,445 | * % |
| Marnix L. Bosch, Ph.D., M.B.A. | 35,379,439 | 3.3 % |
| Linda F. Powers(2) | 29,411,759 | 2.8 % |
| Leslie J. Goldman(3) | 172,742 | * % |
| Dr. Navid Malik | 24,807,288 | 2.3 % |
| Jerry Jasinowski | 13,943,095 | 1.3 % |
| J. Cofer Black | 6,484,433 | * % |
| **All executive officers and directors as a group (seven persons)** | 119,972,201 | **10.3 %** |

* Less than 1%

(1) Percentage represents beneficial ownership percentage of common stock calculated in accordance with SEC rules and does not equate to voting percentages. Based upon 1,072,659,109 shares of Common Stock issued and outstanding as of January 31, 2023. Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares of common stock beneficially owned and the percentage of ownership of such person, we deemed to be outstanding all shares of Common Stock subject to options and warrants currently exercisable or convertible, or exercisable or convertible within 60 days of January 31,

2023. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

(2) Consists of 29,411,759 shares of common stock held by Ms. Powers. Ms. Powers also holds 56,992,773 warrants (the majority acquired from a third party, and the rest acquired in past years, as previously reported, from the Company in connection with loans by Ms. Powers to the Company when such loans were needed to help the Company to survive). Ms. Powers holds 39,200,000 options awarded in 2018 for service during part of that year and a number of preceding years, and 55,119,032 options awarded in 2020 for service during 2018, 2019 and 2020. In 2021, Ms. Powers entered into a voluntary blocking agreement with the Company pursuant to which Ms. Powers cannot exercise or convert any options, warrants or other derivative securities, as applicable, unless Ms. Powers provides the Company at least 61 days' advance notice. As a result, such options, warrants and other derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended.

(3) Consists of 172,742 shares of common stock held by Mr. Goldman. Mr. Goldman also holds 643,043 warrants acquired in past years, as previously reported, from the Company in connection with loans by Mr. Goldman to the Company when such loans were needed to help the Company to survive. Mr. Goldman holds 24,500,000 options awarded in 2018 for service during part of that year and a number of preceding years, and 34,449,394 options awarded in 2020 for service during 2018, 2019, and 2020. In 2021, Mr. Goldman entered into a voluntary blocking agreement with the Company under which Mr. Goldman cannot exercise or convert of any options, warrants or other derivative securities, as applicable, to acquire shares of the Company's common stock, unless Mr. Goldman provides the Company at least 61 days' advance notice. As a result, such options, warrants and other derivative securities are not considered "beneficially owned" within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended.

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

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

**Advent BioServices, Ltd.**

Advent BioServices, Ltd. ("Advent") is a related party based in the U.K. and owned by Toucan Holdings, which is controlled by our Chairperson and Chief Executive Officer, Linda F. Powers. Advent was previously the U.K. branch of Cognate until it was spun off from Cognate in late 2016. Since then, Advent has operated independently of Cognate, providing manufacturing and related services for production of DCVax-L products.

The Company had three operational programs with Advent during 2022: (a) an ongoing manufacturing program at the existing GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston facility, and (c) a one-time program for specialized work, organized into 10 sets of one-time milestones, for the following:

- Qualifying for and obtaining 3 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;
- 6 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 of key portions of the application for product approval itself.

On November 8, 2019, the Company entered into an Ancillary Services Agreement with an initial eight-month term for the U.K. Facility Development Activities and Compassionate Use Program Activities, which is described in Note 10 of the financial statements included in the Company's 2019 Annual Report. The total amount paid by the Company to Advent during 2022 was approximately $12.7 million, which included $3.1 million for services rendered and invoiced in 2021 but not paid by the Company until 2022, and $9.6 million for services in 2022. In addition, during the year ended December 31, 2022, the Company paid, for 8 one-time milestones, an aggregate of $3.0 million in cash and 7.5 million shares at fair value of approximately $5.9 million. On December 31, 2021, the Company entered into a Sub-lease Agreement with Advent for 14,459 of the 88,000 square foot space in the Sawston facility which is leased by the Company under a separate head lease with a different counterparty.

**Related-Party Transaction Approval Policy**

Under SEC rules, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment or board membership. Any transactions with any person who is, or at any time since the beginning of the Company's fiscal year was, a director or executive officer or a nominee to become a director of the Company, any person who is known to be the beneficial owner of more than 5% of any class of the Company's voting securities, any immediate family member or person sharing the household of any of the foregoing persons, any firm, corporation or other entity in which any of the foregoing persons is a partner or principal, is subject to approval or ratification in accordance with the procedures of the Company's Related-Party Transaction Policy.

**Conflicts Committee**

The Conflicts Committee of the Board reviews and approves all related-party matters and transactions for potential conflicts of interests and reasonableness, as described in the Corporate Governance Matters section above. The Conflicts Committee's one-time review and approval of any series of similar related-party transactions (such as a series of transactions governed by a single contract) suffices to satisfy this policy with respect to each and every transaction in the series.

**DIRECTOR INDEPENDENCE**

Our Board of Directors has undertaken a review of the independence of our directors and has determined that a majority of the Board consists of members who are currently "independent" as that term is defined within the meaning of Section 5605(a)(2) of the Nasdaq Stock Market Rules. The Board of Directors has determined each of Messrs. Malik and Jasinowski, and Ambassador Black to be independent.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Fees Paid to Independent Public Accountants**

Cherry Bekaert was engaged in January 2021 to serve as our independent public accounting firm beginning with the fiscal year ended December 31, 2020. Marcum served as our independent public accounting firm for the fiscal years ended December 31, 2017, 2018 and 2019, and was engaged to serve in such capacity for 2020.

**Audit Fees**

The aggregate fees billed for the fiscal years ended December 31, 2022 for professional services rendered by Cherry Bekaert for the audit of our annual financial statements for 2022, an independent audit of the Company's internal controls for 2022, and the review our financial statements included in our quarterly reports on Form 10-Q for 2022 was $550,000. The fees billed in connection with the fiscal year ended December 31, 2021 for consultation and consents from Marcum for the audit of our annual financial statement for 2021 was approximately $31,000.

The aggregate fees billed in connection with the fiscal year ended December 31, 2020 for professional services rendered by Cherry Bekaert for the audit of our annual financial statement for 2020, including the review of the financial statement information included in our Quarterly Reports on Form 10-Q during 2020, was $300,000.

**Audit-Related Fees**

There were no fees billed in the fiscal years ended December 31, 2022 and 2021 for assurance and related services rendered by Cherry Bekaert or Marcum related to the performance of the audit or review of our financial statements.

**Tax and Other Non-Audit Professional Services**

There were no fees billed in the fiscal years ended December 31, 2022 and 2021 for professional services rendered by Cherry Bekaert or Marcum for tax related services or other non-audit professional services fees.

**Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services**

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee pre-approved all of the services provided by our principal accountants during the fiscal years ended December 31, 2022 and 2021.

**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") (incorporated by reference to Exhibit 10.87 filed with the Registrant's Annual Report on Form 10-K on March 1, 2022). |
| 10.88 | Loan Agreement, dated September 26, 2022, 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: February 28, 2023

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<br>Linda F. Powers | President and Chief Executive Officer<br>Principal Executive Officer<br>Principal Financial and Accounting Officer | February 28, 2023 |
| /s/ Alton L. Boynton<br>Alton L. Boynton | Director | February 28, 2023 |
| /s/ Navid Malik<br>Dr. Navid Malik | Director | February 28, 2023 |
| /s/ Jerry Jasinowski<br>Jerry Jasinowski | Director | February 28, 2023 |
| /s/ J. Cofer Black<br>J. Cofer Black | Director | February 28, 2023 |

**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 consolidated balance sheets of Northwest Biotherapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

**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 Management's Report on Internal Control over Financial Reporting included in Item 9A—*Controls and Procedures* in the Company's 2022 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. 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 Matter – Debt and Equity Accounting Considerations**

The critical audit matters communicated below are matters arising from the current period audit of the consolidated 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 consolidated 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 consolidated 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 related party and non-related party stock-based compensation, 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 related party and non-related party stock-based compensation, processes.
- We obtained a listing of all debt, derivative liabilities, mezzanine equity and equity transactions, including related party and non-related party stock-based compensation, 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 related party and non-related party stock-based compensation, to ensure these were disclosed in accordance with the relevant accounting guidance.

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

/s/ Cherry Bekaert LLP

Cherry Bekaert LLP
Tampa, Florida
February 28, 2023

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 6,965 | $ 15,169 |
| Prepaid expenses and other current assets | 2,460 | 2,121 |
| Total current assets | 9,425 | 17,290 |
| Non-current assets: | | |
| Property, plant and equipment, net | 13,418 | 15,027 |
| Construction in progress | 2,028 | — |
| Right-of-use asset, net | 4,189 | 4,889 |
| Indefinite-lived intangible asset | 1,292 | 1,292 |
| Goodwill | 626 | 626 |
| Other assets | 345 | 1,036 |
| Total non-current assets | 21,898 | 22,870 |
| **TOTAL ASSETS** | **$ 31,323** | **$ 40,160** |
| **LIABILITIES, MEZZANINE EQUITY, AND STOCKHOLDERS' DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 10,687 | $ 6,976 |
| Accounts payable and accrued expenses to related parties and affiliates | 6,955 | 3,971 |
| Convertible notes, net | 135 | 135 |
| Notes payable, net | 15,403 | 7,104 |
| Contingent payable derivative liability | 8,668 | 8,232 |
| Warrant liability | 80,559 | 106,784 |
| Investor advances | 2,566 | 250 |
| Share liability | 678 | — |
| Lease liabilities | 354 | 317 |
| Total current liabilities | 126,005 | 133,769 |
| Non-current liabilities: | | |
| Notes payable, net of current portion, net | 5,991 | 25,156 |
| Lease liabilities, net of current portion | 4,370 | 5,226 |
| Total non-current liabilities | 10,361 | 30,382 |
| Total liabilities | 136,366 | 164,151 |
| **COMMITMENTS AND CONTINGENCIES (Note 12)** | | |
| Mezzanine equity: | | |
| Series C Convertible Preferred Stock, 10,000,000 shares designated; 1.4 million and 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively; aggregate liquidation preference of $22.3 million | 23,060 | — |
| Stockholders' deficit: | | |
| Preferred stock ($0.001 par value); 100,000,000 shares authorized as of December 31, 2022 and 2021, respectively | — | — |
| Common stock ($0.001 par value); 1,200,000,000 shares authorized; 1,068.4 million and 948.4 million shares issued and outstanding as of December 31, 2022 and 2021, respectively | 1,068 | 948 |
| Additional paid-in capital | 1,164,885 | 1,066,873 |
| Stock subscription receivable | (79) | (79) |
| Accumulated deficit | (1,297,122) | (1,192,090) |
| Accumulated other comprehensive income | 3,145 | 357 |
| Total stockholders' deficit | (128,103) | (123,991) |
| **TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT** | **$ 31,323** | **$ 40,160** |

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, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Revenues:** | | | |
| Research and other | $ 1,683 | $ 1,005 | $ 1,291 |
| Total revenues | 1,683 | 1,005 | 1,291 |
| **Operating costs and expenses:** | | | |
| Research and development | 35,511 | 20,308 | 33,637 |
| General and administrative | 33,353 | 33,399 | 54,259 |
| Total operating costs and expenses | 68,864 | 53,707 | 87,896 |
| Loss from operations | (67,181) | (52,702) | (86,605) |
| **Other income (expense):** | | | |
| Change in fair value of derivative liabilities | (25,821) | 239,347 | (435,351) |
| Change in fair value of share liabilities | 33 | — | — |
| Loss from extinguishment of debt | (2,691) | (165) | (1,582) |
| Interest expense | (6,068) | (5,011) | (8,544) |
| Inducement expense | — | (647) | — |
| Foreign currency transaction (loss) gain | (3,304) | (1,696) | 2,261 |
| Total other (loss) income | (37,851) | 231,828 | (443,216) |
| **Net (loss) income** | $ (105,032) | $ 179,126 | $ (529,821) |
| | | | |
| Other comprehensive income (loss) | | | |
| Foreign currency translation adjustment | 2,788 | 1,505 | (1,984) |
| Total comprehensive (loss) income | $ (102,244) | $ 180,631 | $ (531,805) |
| | | | |
| Net (loss) earnings per share applicable to common stockholders | | | |
| Basic | $ (0.10) | $ 0.21 | $ (0.73) |
| Diluted | $ (0.10) | $ (0.06) | $ (0.73) |
| | | | |
| Weighted average shares used in computing basic (loss) earnings per share | 1,015,852 | 873,517 | 725,129 |
| Weighted average shares used in computing diluted (loss) earnings per share | 1,015,852 | 1,007,869 | 725,129 |

See accompanying notes to the consolidated financial statements

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

| | Mezzanine equity Series C Convertible Preferred Stock | | Common Stock | | Additional Paid-in | Subscription | Accumulated | Accumulated Other Comprehensive | Total Stockholde |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Par value | Capital | Receivable | Deficit | Income | Deficit |
| **Balances at January 1, 2020** | — | $ — | 614,292 | $ 614 | $ 794,900 | $ (10) | $ (841,395) | $ 836 | $ (45,0 |
| Issuance of common stock and warrants for cash in a registered direct offering (net of $10.3 million warrant liability and $ 0.6 million cash offering cost) | — | — | 97,981 | 98 | 16,462 | (69) | — | — | 16,4 |
| Issuance of common stock and warrants for conversion of debt and accrued interest | — | — | 58,368 | 58 | 19,591 | — | — | — | 19,6 |
| Warrants exercised for cash | — | — | 47,511 | 48 | 13,867 | — | — | — | 13,9 |
| Reclassification of warrant liabilities related to warrants exercised for cash | — | — | — | — | 22,701 | — | — | — | 22,7 |
| Cashless warrants exercise | — | — | 7,086 | 7 | (7) | — | — | — | |
| Cashless option exercise | — | — | 71 | — | — | — | — | — | |
| Reclassification of warrant liabilities related to cashless warrants exercise | — | — | — | — | 9,478 | — | — | — | 9,4 |
| Beneficial conversion feature related to amended convertible note | — | — | — | — | 44 | — | — | — | |
| Issuance of common stock in connection with Flaskworks acquisition | — | — | 655 | 1 | 1,132 | — | — | — | 1,1 |
| Stock-based compensation | — | — | 3,667 | 4 | 52,205 | — | — | — | 52,2 |
| Reclassification of warrant liabilities related to sequencing policy | — | — | — | — | 78,292 | — | — | — | 78,2 |
| Net loss | — | — | — | — | — | — | (529,821) | — | (529,8 |
| Cumulative translation adjustment | — | — | — | — | — | — | — | (1,984) | (1,9 |
| **Balances at December 31, 2020** | — | — | 829,631 | 830 | 1,008,665 | (79) | (1,371,216) | (1,148) | (362,9 |
| Issuance of common stock for cash | — | — | 6,272 | 6 | 4,064 | — | — | — | 4,0 |
| Issuance of common stock and warrants for conversion of debt and accrued interest | — | — | 5,145 | 5 | 7,495 | — | — | — | 7,5 |
| Warrants and stock options exercised for cash | — | — | 86,910 | 87 | 19,888 | — | — | — | 19,9 |
| Reclassification of warrant liabilities related to warrants exercised for cash | — | — | — | — | 68,692 | — | — | — | 68,6 |
| Cashless warrants and stock options exercise | — | — | 20,439 | 20 | (20) | — | — | — | |
| Reclassification of warrant liabilities related to cashless warrants exercise | — | — | — | — | 2,369 | — | — | — | 2,3 |
| Stock-based compensation | — | — | 48 | — | 15,571 | — | — | — | 15,5 |
| Reclassification of warrant liabilities based on authorized shares | — | — | — | — | (59,851) | — | — | — | (59,8 |
| Net income | — | — | — | — | — | — | 179,126 | — | 179,1 |
| Cumulative translation adjustment | — | — | — | — | — | — | — | 1,505 | 1,5 |
| **Balances at December 31, 2021** | — | — | 948,445 | 948 | 1,066,873 | (79) | (1,192,090) | 357 | (123,9 |
| 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 | — | — | — | 9,6 |
| Warrants exercised for cash | — | — | 45,298 | 45 | 11,060 | — | — | — | 11,1 |
| Reclassification of warrant liabilities related to warrants exercised for cash | — | 535 | — | — | 24,434 | — | — | — | 24,4 |
| Cashless warrants and stock options exercise | — | — | 34,224 | 34 | (34) | — | — | — | |
| Reclassification of warrant liabilities related to cashless warrants exercise | — | — | — | — | 26,800 | — | — | — | 26,8 |
| Issuance of common stock for conversion of debt and accrued interest | — | — | 18,139 | 19 | 13,787 | — | — | — | 13,8 |
| Stock-based compensation | — | — | 9,141 | 9 | 12,289 | — | — | — | 12,2 |
| Net loss | — | — | — | — | — | — | (105,032) | — | (105,0 |
| Cumulative translation adjustment | — | — | — | — | — | — | — | 2,788 | 2,7 |
| **Balances at December 31, 2022** | 1,415 | $ 23,060 | 1,068,394 | $ 1,068 | $1,164,885 | $ (79) | $(1,297,122) | $ 3,145 | $ (128,1 |

See accompanying notes to the consolidated financial statements

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

| | For the years ended December 31, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Cash Flows from Operating Activities:** | | | |
| **Net (loss) income** | $ (105,032) | $ 179,126 | $ (529,821) |
| **Reconciliation of net (loss) income to net cash used in operating activities:** | | | |
| Depreciation and amortization | 1,252 | 324 | 87 |
| Amortization of debt discount | 2,771 | 2,301 | 3,013 |
| Change in fair value of derivatives | 25,821 | (239,347) | 435,351 |
| Change in fair value of contingent liability | — | — | 913 |
| Change in fair value of share liability | (33) | — | — |
| Loss from extinguishment of debt | 2,691 | 165 | 1,582 |
| Inducement expense | — | 647 | — |
| Amortization of operating lease right-of-use asset | 248 | 262 | 338 |
| Stock-based compensation for services | 12,298 | 15,498 | 52,209 |
| Non-cash interest expense | — | — | 4,270 |
| Subtotal of non-cash charges | 45,048 | (220,150) | 497,763 |
| **Changes in operating assets and liabilities:** | | | |
| Prepaid expenses and other current assets | (397) | 3,475 | (2,350) |
| Other non-current assets | 625 | (179) | (31) |
| Accounts payable and accrued expenses | 3,492 | 77 | 1,702 |
| Related party accounts payable and accrued expenses | 3,354 | (674) | 431 |
| Lease liabilities | 135 | 26 | 213 |
| Net cash used in operating activities | (52,775) | (38,299) | (32,093) |
| **Cash Flows from Investing Activities:** | | | |
| Purchase of equipment and construction in progress | (2,902) | (6,015) | (6,610) |
| Acquisition of Flaskworks, net of cash | — | — | (1,532) |
| Net cash used in investing activities | (2,902) | (6,015) | (8,142) |
| **Cash Flows from Financing Activities:** | | | |
| Proceeds from issuance of Series C convertible preferred stock | 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, net | 9,465 | 4,070 | 26,814 |
| Proceeds from exercise of warrants and stock options | 11,105 | 19,975 | 13,915 |
| Proceeds from issuance of notes payable, net | 5,600 | 29,665 | 8,557 |
| Proceeds from warrants modification | — | — | 4 |
| Proceeds from issuance of convertible notes payable, net | — | — | 5,115 |
| Proceeds from issuance of convertible notes payable to related party | — | — | 315 |
| Investor advances | 2,566 | 250 | — |
| Repayment of notes payable | (5,489) | (5,828) | (1,556) |
| Repayment of notes payable to related parties | — | — | (379) |
| Repayment of convertible notes payable | — | — | (89) |
| Net cash provided by financing activities | 41,968 | 48,132 | 52,696 |
| Effect of exchange rate changes on cash and cash equivalents | 5,505 | 1,368 | (2,850) |
| Net (decrease) increase in cash and cash equivalents | (8,204) | 5,186 | 9,611 |
| | | | |
| Cash and cash equivalents, beginning of the period | 15,169 | 9,983 | 372 |
| **Cash and cash equivalents, end of the period** | $ 6,965 | $ 15,169 | $ 9,983 |
| | | | |
| **Supplemental disclosure of cash flow information** | | | |
| Interest payments on notes payable | $ (912) | $ (1,730) | $ — |
| Interest payments on notes payable to related party | $ — | $ — | $ (9) |
| Interest payments on convertible notes payable | $ — | $ — | $ (11) |
| Interest payments on convertible notes payable to related party | $ — | $ — | $ (19) |

See accompanying notes to the consolidated financial statements

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

| | For the years ended December 31, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Supplemental schedule of non-cash investing and financing activities:** | | | |
| Issuance of common stock as consideration related to Flaskworks acquisition | — | — | 220 |
| Cashless warrants and stock options exercise | $ 34 | $ 20 | $ 7 |
| Reclassification of warrant liabilities related to warrants exercised for cash | $ 24,969 | $ 68,692 | $ 22,701 |
| Reclassification of warrant liabilities related to cashless warrants exercise | $ 26,800 | $ 2,369 | $ 9,478 |
| Reclassification of warrant liabilities based on authorized shares | $ — | $ 59,851 | $ 78,292 |
| Issuance of common stock and warrants for conversion of debt and accrued interest | $ 11,541 | $ 7,487 | $ 8,230 |
| Offering cost related to warrant liability | $ — | $ — | $ 4,876 |
| Issuance of Series C convertible preferred stock in lieu of debt redemption | $ 3,408 | $ — | $ — |
| Exercise common stock warrants by debt redemption | $ 277 | $ — | $ — |
| Reclassification between shares payable and equity | $ 250 | $ — | $ — |
| Capital expenditures included in accounts payable | $ 699 | $ 33 | $ 1,088 |
| 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 | $ — |
| Issuance of warrants in conjunction with convertible note payable | $ — | $ — | $ 153 |
| Issuance of warrants in connection with debt modification | $ — | $ — | $ 395 |
| Warrant modification in connection with debt amendment | $ — | $ — | $ 91 |
| Beneficial conversion feature related to amended convertible note | $ — | $ — | $ 44 |

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, 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, in the U.K. and in the Netherlands.

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.

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®.

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 is working on prerequisites and preparations for filing an application for regulatory approval of the product.

**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 $105.0 million for the year ended December 31, 2022. The Company used approximately $52.8 million of cash in its operating activities during the year ended December 31, 2022.

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.

As previously reported, coronavirus-related difficulties have impacted the Company's programs, especially with the successive waves of COVID-19 cases in many areas. Although the impact was reduced as the pandemic abated during 2022, the impacts from prior periods continued to affect the Company's programs. There were supply chain difficulties in regard to certain necessary supplies and reagents. The independent service firms on which the Company relies for a variety of functions had limited capacity, and restrictions on operations. Key experts at certain specialized service providers were unavailable for periods of time due to illness in their family. Other experts went on extended leave due to restrictions on operations. Clinical trial sites did not allow personnel from the contract research organization (CRO) managing the trial, or other service providers, to visit the sites for trial matters such as data monitoring and collection activities. Clinical trial site personnel were unavailable due to being reassigned for COVID-19, and the limited site personnel had to work under restrictions. Committee processes and regulatory processes were focused on COVID-19 matters and delayed on other matters. Firms such as the ones storing the Phase III trial tissue samples that were needed for certain analyses, and the firms conducting such analyses had limited operations. Even logistical matters such as the shipping of materials were subjected to substantial restrictions and delays.

**NORTHWEST BIOTHERAPEUTICS, INC.**
**Notes to the Consolidated Financial Statements**

**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, 2022 and 2021, 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, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing coronavirus pandemic ("COVID-19") and the COVID-19 control responses.

**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, 2022, of the total $7.0 million in cash and cash equivalents, $0.4 million was held by foreign subsidiaries. As of December 31, 2021, of the total $15.2 million in cash and cash equivalents, $0.5 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 clinical 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. During 2022, the Company the Company commenced the next phase of the Sawston facility buildout: Phase 1B. The Company incurred additional construction works related to Phase 1B build out during the year ended December 31, 2022. Phase 1B is expected to be completed and placed in use by approximately the end of Q2 2023. Those costs were classified as construction in progress on the consolidated balance sheet as of December 31, 2022.

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, 2022 and 2021.

**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.

**NORTHWEST BIOTHERAPEUTICS, INC.**
**Notes to the Consolidated Financial Statements**

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).

**Embedded Conversion Features**

The Company evaluates embedded conversion features within convertible debt instruments to determine whether the embedded conversion feature(s) should be bifurcated from the host instrument and accounted for as a derivative at fair value with changes in fair value recorded in the Statement of Operations. If the conversion feature does not require recognition of a bifurcated derivative, the convertible debt instrument is evaluated for consideration of any beneficial conversion feature ("BCF") requiring separate recognition. When the Company records a BCF, the intrinsic value of the BCF is recorded as a debt discount against the face amount of the respective debt instrument (offset to additional paid-in capital) and amortized to interest expense over the life of the debt.

**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.

**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 has 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 or 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 these 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.

**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 Adopted Accounting Standards**

*Income Taxes*

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. On January 1, 2021, the Company adopted this standard without any material impact on its consolidated financial statements and related disclosures.

*Debt*

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This ASU is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption was permitted, but no earlier than fiscal years beginning after December 15, 2020. This update permits the use of either the modified retrospective or fully retrospective method of transition. The Company has adopted the new standard as of January 1, 2021 without any material impact on its consolidated financial statements and related disclosures.

*Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. On January 1, 2022, the Company adopted this standard without any material impact on the Company's consolidated financial statements or disclosures.

**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 is still evaluating the impact of this pronouncement on the 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 outstanding warrants, certain embedded conversion feature associated with convertible debt and contingent payable to Cognate BioServices on a recurring basis to determine the fair value of the liability.

| | | 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 |

| | | Fair value measured at December 31, 2021 | | |
|---|---|---|---|---|
| | Fair value at December 31, 2021 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Warrant liability | $ 106,784 | $ — | $ — | $ 106,784 |
| Embedded redemption option | 988 | — | — | 988 |
| Contingent payable derivative liability | 8,232 | — | — | 8,232 |
| Total fair value | $ 116,004 | $ — | $ — | $ 116,004 |

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2022 and 2021.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2022 and 2021. 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 | Total |
|---|---|---|---|---|---|
| **Balance - January 1, 2021** | **$ 354,972** | **$ 2,507** | **$ 8,275** | **$ —** | **$ 365,754** |
| Additional warrant liability | 1,785 | — | — | — | 1,785 |
| Additional embedded redemption option | — | 947 | — | — | 947 |
| Reclassification of warrant liabilities | (11,210) | — | — | — | (11,210) |
| Debt conversion | — | (1,925) | — | — | (1,925) |
| Change in fair value | (238,763) | (541) | (43) | — | (239,347) |
| **Balance – December 31, 2021** | **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** |

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, 2022 and 2021 is as follows:

| | 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 % |

| | As of December 31, 2021 | |
|---|---|---|
| | Warrant Liability | Contingent Payable Derivative Liability |
| Strike price | $ 0.30 | $ 0.70 * |
| Contractual term (years) | 1.0 | 1.6 |
| Volatility (annual) | 90 % | 72 % |
| Risk-free rate | 0.1 % | 0.6 % |
| Dividend yield (per share) | 0 % | 0 % |

* Contingent payable derivative liability based on stock price as of December 31, 2022 and 2021.

**5. Stock-Based Compensation**

The following table summarizes total stock-based compensation expense recognized for the years ended December 31, 2022, 2021 and 2020 (in thousands).

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Research and development | $ 1,918 | $ 7,607 | $ 19,792 |
| Research and development - Advent | | | |
| Milestones achieved [1] | 5,870 | — | — |
| Future milestones [2] | 3,573 | — | — |
| General and administrative | 937 | 7,964 | 32,163 |
| **Total stock-based compensation expense** | **$ 12,298** | **$ 15,571** | **$ 51,955** |

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, 2022, for 8 one-time milestones that were earned, the Company recognized and expensed approximately $5.9 million for 7.5 million shares.

(2) For 2 further one-time milestones that are anticipated to be achieved and earned in the future, the Company recognized and expensed (but did not issue shares for) the pro-rata portion on the remaining potential milestone stock awards during the year ended December 31, 2022, of $3.5 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, 2022, 2021 and 2020:

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Exercise price | $ 0.65 | $ 0.92 | $ 0.26 |
| Expected term (years) | 3.9 | 5.3 | 5.2 |
| Expected stock price volatility | 99 % | 97 % | 98 % |
| Risk-free rate | 3.3 % | 1 % | 0 % |
| Dividend yield (per share) | 0 % | 0 % | 0 % |

The total unrecognized compensation cost was approximately $1.6 million as of December 31, 2022 and will be recognized over the next 1.3 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 still 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 for 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.

**NORTHWEST BIOTHERAPEUTICS, INC.**
**Notes to the Consolidated Financial Statements**

The following table summarizes stock option activity under the Company's option plans (including awards to key external consultants and vendors in addition to internal parties) during the years ended December 31, 2022, 2021 and 2020 (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, 2020 | 104,659 | $ 0.24 | 8.4 | $ — |
| Granted (Approved 2018-2020) [1] | 208,525 | 0.37 [2] | 10.0 | — |
| Cashless exercise | (94) | 0.34 | — | — |
| Forfeited/expired | (4,250) | 0.22 | — | — |
| Outstanding as of December 31, 2020 | 308,840 | 0.33 | 8.9 | 372,219 |
| Granted | 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 [3] | 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 |
| Options vested [4] | 282,271 | $ 0.33 | 7.0 | $ 127,951 |

(1) The options granted during the year ended December 31, 2020 included options already approved at various times during the three years 2018 - 2020 but not issued until Q3 2020, and also included options that will vest for performance and milestones going forward over the next two years. The options included awards to key external consultants and vendors in addition to internal parties.

(2) The weighted average exercise price of the Q3 2020 options was initially $0.25. However subsequently, the exercise price was amended to a weighted average exercise price of $0.36.

(3) Awards granted to Flaskworks employees and consultants.

(4) Approximately 83.3 million options were not exercisable until January 12, 2023, and 153.3 million options are not exercisable until at least April 30, 2023.

The existing options and warrants held by Ms. Linda Powers, the Company's Chief Executive Officer, and Mr. Leslie Goldman, the Company's Senior Vice President, General Counsel are subject to a voluntary blocking agreement under which they cannot be exercised except upon at least 61 days' prior notice to the Company.

Stock Options Modification

On April 30, 2020, the Company's CEO, Linda Powers agreed to not exercise approximately 39.2 million existing options held by her for six months, until November 1, 2020 and correspondingly extended the contractual term for six months. The Company recognized approximately $78,000 of incremental stock-based compensation for this modification during the year ended December 31, 2020, based on the following weighted average assumptions:

| | Post Modification | Pre Modification |
|---|---|---|
| Exercise price | $ 0.23 | $ 0.23 |
| Expected term (years) | 4.3 | 4.0 |
| Expected stock price volatility | 97 % | 97 % |
| Risk-free rate of interest | 0 % | 0 % |

For another former officer, on August 5, 2020, the Company cancelled 1.75 million options which were originally issued in December 2019 and issued 3.0 million options (the "Replacement Options") with an exercise price of $0.22 and vesting of 1/3 immediately and the remaining 2/3 vesting ratably over the following 24 months from the grant date. The incremental stock-based compensation for this modification was approximately $0.3 million based on the following weighted average assumptions, which will be amortized over the new vesting terms.

| | Post Modification | Pre Modification |
|---|---|---|
| Exercise price | $ 0.22 | $ 0.22 |
| Expected term (years) | 5.3 | 4.7 |
| Expected stock price volatility | 96 % | 97 % |
| Risk-free rate of interest | 0 % | 0 % |

*Flaskworks*

On August 28, 2020, the Company entered into a Unit Purchase Agreement (the "Agreement") to acquire Flaskworks. Included in the consideration pursuant to the Agreement was Stock Consideration in the amount of approximately $2.0 million. This Stock Consideration is issued in the form of Rights to receive such value in shares issued pursuant to and subject to the vesting criteria set forth in a Rights Issuance Agreement entered into in connection with the closing of Flaskworks Acquisition. Because the Rights were subject to future employment and performance conditions, the Stock Consideration was not included in consideration payable for the Flaskworks Acquisition but rather was recorded as contingent consideration payable to employees for accounting purposes. The Company anticipates that the treatment of this Stock Consideration for tax purposes may be different than for accounting purposes and will reflect the fact that this Stock Consideration was payment for acquisition of the ownership interests of certain shareholders of Flaskworks.

On December 1, 2020, the Company issued 1.5 million shares of common stock based upon the Flaskworks team having completed a significant milestone, in accordance with the Rights Issuance Agreement entered on August 28, 2020. During the year ended December 31, 2022, the Company reversed approximately $1.2 million stock-based compensation due to cancellation of certain unvested performance-based awards. Approximately $0.3 million was reversed from general and administrative and $0.9 million was reversed from research and development during the year ended December 31, 2022. During the years ended December 31, 2021 and 2020, the Company recognized approximately $0.7 million and $1.0 million stock-based compensation related to the Flaskworks Acquisition, respectively. Approximately $0.1 million was recognized in general and administrative and $0.5 million was recognized in research and development during the year ended December 31, 2021. Approximately $0.5 million was recognized in general and administrative and $0.5 million was recognized in research and development during the year ended December 31, 2020.

Restricted Stock Awards

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. The SOW provides for baseline costs and for 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. On September 26, 2022, the Company amended the SOW6 (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.) If all of the 10 one-time milestones are 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 application for product approval), the aggregate stock-based compensation under the Amended SOW 6 will be 13.5 million shares (including the shares already earned and issued for the milestones already achieved). As of December 31, 2022, the 13.5 million shares had an aggregate fair value of $10.1 million.

During the year ended December 31, 2022, the Company recognized and expensed (but only partly paid) approximately $4.0 million related to the cash component of seven one-time milestones that were completed and earned during the period. The seven completed milestones included five of the 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, as described below, but the cash portion of that eighth milestone was not yet earned).

For the cash components of three further one-time milestones under Amended SOW6 that are anticipated to be achieved and earned in the future, the Company recognized and expensed (but did not pay) during the year ended December 31, 2022, the pro-rata portion of $3.7 million.

For the stock component of the eight one-time milestones that were earned during the year ended December 31, 2022 (as also described above, in Stock Based Compensation), the Company recognized and expensed $5.9 million for the 7.5 million shares.

For two further one-time milestones that are anticipated to be achieved and earned in the future, the Company recognized and expensed (but did not issue) the pro-rata portion of the remaining potential milestone stock awards during the year ended December 31, 2022, of $3.5 million (as also described above, in Stock Based Compensation).

Other Service Agreement

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.

**6. Property, Plant and Equipment**

Property, plant and equipment consist of the following at December 31, 2022 and 2021 (in thousands):

| | December 31, 2022 | December 31, 2021 | Estimated Useful Life |
|---|---|---|---|
| Leasehold improvements | $ 13,070 | $ 13,910 | Lesser of lease term or estimated useful life |
| Office furniture and equipment | 300 | 310 | 3-5 years |
| Computer and manufacturing equipment and software | 2,238 | 1,799 | 3-5 years |
| Land in the United Kingdom | 82 | 92 | NA |
| | 15,690 | 16,111 | NA |
| Less: accumulated depreciation | (2,272) | (1,084) | |
| Total property, plant and equipment, net | $ 13,418 | $ 15,027 | |
| | | | |
| Construction in progress | $ 2,028 | $ — | |

Depreciation expense was approximately $1.3 million, $0.3 million and $87,000 for the years ended December 31, 2022, 2021 and 2020, respectively.

Construction in Progress

In connection with the Company's manufacturing facility in U.K, the Company has incurred and is incurring costs with certain vendors and contractors to design and build out certain stages of the facility. Additionally, the Company purchased certain manufacturing equipment that has been or will be installed in connection with the buildout. These costs were all capitalized and recorded as part of construction in progress at December 31, 2020. The Company received approval of an HTA license for collection and processing of human cells and tissues, and received an MHRA license for manufacture of cell therapy products for clinical trials and compassionate use at its Sawston, UK facility in December 2021. All costs associated with the facility buildout (Phase 1A) were reclassified from construction in progress to leasehold improvements effective December 2021 as a result of the receipt of the MHRA license, and are being amortized over the estimated useful life of the facility. During the year ended December 31, 2022, the Company started Phase 1B buildout to expand the operational portions of its UK facility. The additional costs related to the buildout were classified as construction in progress on the consolidated balance sheet as of December 31, 2022.

**7. Notes Payable**

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 to 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 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. 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. See Note 10.

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).

2021 Activities

The following tables summarize outstanding debt as of December 31, 2021 (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 | 2,320 | (118) | — | 2,202 |
| 9% unsecured | Various | 9 % | N/A | 4,232 | (80) | 47 | 4,199 |
| 12% unsecured | On Demand | 12 % | N/A | 703 | — | — | 703 |
| | | | | **7,255** | **(198)** | **47** | **7,104** |
| **Long term notes payable** | | | | | | | |
| 1% unsecured | Various | 1 % | N/A | 433 | — | — | 433 |
| 8% unsecured | 9/22/2023 | 8 % | N/A | 25,938 | (3,638) | 941 | 23,241 |
| 6% secured | 3/25/2025 | 6 % | N/A | 1,482 | — | — | 1,482 |
| | | | | **27,853** | **(3,638)** | **941** | **25,156** |
| **Ending balance as of December 31, 2021** | | | | **$ 35,243** | **$ (3,836)** | **$ 988** | **$ 32,395** |

On March 1, 2021, the Company entered into a Commercial Loan Agreement (the "Commercial Loan") with a commercial lender for an aggregate principal amount of $10.0 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 November 1, 2021. The Commercial Loan carries an original issue discount of $1.0 million.

**NORTHWEST BIOTHERAPEUTICS, INC.**
**Notes to the Consolidated Financial Statements**

In April 2021, the Company received two additional PPP loans ("2021 PPP Loans"). The 2021 PPP Loans were received on April 9, 2021 in the amount of $0.4 million total. The current term of the 2021 PPP Loans is five years with a maturity date of March 2026 and it contains a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the 2021 PPP Loans are deferred for the first 10 months of the term of the 2021 PPP Loans. The Company is using the loan to make payments for payroll, health and disability insurance and rent. On February 22, 2022, the 2021 PPP loans were approved for forgiveness.

Between June and December, 2021, the Company entered into multiple four-month note agreements (the "Notes") with various individual lenders (the "Holders") with an aggregate principal amount of $4.4 million for net proceeds of $4.2 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 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 and (b) exchange some or all of the outstanding loan amount for a variable number of shares (the "Contingent Rights"). Both (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) 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 (b) 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.

Between October and December 2021, the Company entered into multiple note extension agreements whereby the maturity date of the notes was extended for additional 2-4 months. The Company recognized $0.2 million debt extinguishment loss on the Consolidated Statement of Operations due to the extensions.

On November 22, 2021, the Company entered into a Commercial Loan Agreement (the "Loan") with a commercial lender for an aggregate principal amount of $16.5 million. The 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 Loan is amortized in 14 equal monthly installments of principal at 110% of the pro rata amount, plus accrued interest. The Loan carries an original issue discount of $1.5 million. The Loan allows pre-payment at any time at the Company's election. Upon announcement of the top line data ("TLD") from the Company's Phase III clinical trial of DCVax®-L for glioblastoma brain cancer, the Lender has a then-springing right to exchange the outstanding balance of the loan for common shares priced at the price of the first private placement transaction following TLD less a 12% discount and to purchase another 50% of that number of shares at the same price. This then-springing right expires 14 days after the post-TLD private placement.

During the year ended December 31, 2021, $5.6 million of debt and interest was independently exchanged by the lender into 5.1 million shares of common stock and 0.8 million warrants. The fair value of common stock and warrants for these conversions were approximately $7.5 million, extinguishing approximately $1.9 million in liability from the note conversions.

During the year ended December 31, 2021, the Company made aggregate cash payments of $5.8 million on notes payable.

**NORTHWEST BIOTHERAPEUTICS, INC.**
**Notes to the Consolidated Financial Statements**

**Interest Expenses Summary**

The following table summarizes total interest expenses related to outstanding debt for the years ended December 31, 2022, 2021 and 2020, respectively (in thousands):

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Interest expenses related to outstanding notes: | | | |
| Contractual interest | $ 2,890 | $ 2,347 | $ 1,231 |
| Amortization of debt discount | 2,771 | 2,301 | 2,891 |
| **Total interest expenses related to outstanding notes** | **5,661** | **4,648** | **4,122** |
| Interest expenses related to outstanding notes to related parties: | | | |
| Contractual interest | — | — | 20 |
| Amortization of debt discount | — | — | 122 |
| **Total interest expenses related to outstanding notes to related parties** | **—** | **—** | **142** |
| Interest expenses related to forbearance of debt to related parties | — | — | 4,270 |
| Interest expenses related to payables to Advent BioServices | — | 140 | — |
| Other interest expenses | 407 | 223 | 10 |
| **Total interest expense** | **$ 6,068** | **$ 5,011** | **$ 8,544** |

The following table summarizes the principal amounts of the Company's debt obligations as of December 31, 2022 (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 | $ — | $ — |
| Short term notes payable | | | | |
| 8% unsecured | 14,540 | 14,540 | — | — |
| 9% unsecured | 793 | 793 | | |
| 12% unsecured | 563 | 563 | — | — |
| Long term notes payable | | | | |
| 8% unsecured | 5,505 | — | 5,505 | — |
| 6% secured | 918 | — | — | 918 |
| **Total** | **$ 22,454** | **$ 16,031** | **$ 5,505** | **$ 918** |

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

Basic (loss) earnings per common share is computed by dividing net (loss) earnings by the weighted average number of common shares outstanding during the reporting period. Diluted earnings (loss) per common share is computed similar to basic (loss) earnings 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, 2022, 2021 and 2020 (in thousands):

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Net (loss) earnings - basic | $ (105,032) | $ 179,126 | $ (529,821) |
| Reversal of gain due to change in fair value of warrant liability | — | (239,347) | — |
| Net loss - diluted | (105,032) | $ (60,221) | $ (529,821) |
| | | | |
| Weighted average shares outstanding - basic | 1,015,852 | 873,517 | 725,129 |
| Diluted shares- Options | — | 38,496 | — |
| Diluted shares- Warrants | — | 95,780 | — |
| Convertible notes and interest | — | 76 | — |
| Weighted average shares outstanding - diluted | 1,015,852 | 1,007,869 | 725,129 |

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, | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Series C convertible preferred stock | 35,384 | — | — |
| Common stock options | 301,263 | 266,350 | 308,840 |
| Common stock warrants | 141,048 | 129,689 | 328,979 |
| Contingently issuable warrants | — | — | 2,774 |
| Convertible notes and accrued interest | 78 | — | 2,617 |
| **Potentially dilutive securities** | **477,773** | **396,039** | **643,210** |

**9. Related Party Transactions**

*Advent BioServices Services Agreements*

The Company had three operational programs with Advent during 2022: (a) an ongoing manufacturing program at the existing GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston facility, and (c) a one-time program for specialized work, organized into 10 sets of one-time milestones, for the following:

- Qualifying for and obtaining 3 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;
- 6 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 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, as previously reported. The development and manufacturing program at the Sawston facility is covered by an Ancillary Services Agreement entered into on November 18, 2019, as previously reported. The specialized work associated with the 10 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.

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 term of the Ancillary Services Agreement ends in July 2023.

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 3 licenses required for the Sawston facility, (b) successful completion of each of the 6 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, 2022, the Company paid an aggregate of $3.0 million in cash and 7.5 million shares at fair value of approximately $5.9 million combined for completion of 7 one-time milestones and partial completion of an 8th one-time milestone, and the Company also expensed (but did not pay) an aggregate of $3.7 million related to future cash milestone payments and $3.6 million related to fair value of future shares milestone payments that the Company anticipates will be achieved and earned over the course of the contract period.

The following table summarizes total research and development costs from Advent for the years ended December 31, 2022, 2021 and 2020, respectively (in thousands).

| | For the Year ended December 31, 2021 | | |
|---|---|---|---|
| | 2022 | 2021 | 2020 |
| Advent BioServices | | | |
| Manufacturing cost in London | $ 5,675 | $ 6,625 | $ 5,288 |
| Manufacturing cost at Sawston facility | 5,766 | 792 | 2,255 |
| SOW 6 one-time milestones - Shares | | | |
| Expensed and paid (milestone complete) (1) | 5,120 | — | — |
| Expensed and paid (partial milestone earned) (2) | 750 | — | — |
| Expensed but unpaid, not yet due (milestone not yet complete) (3) | 3,573 | — | — |
| SOW 6 one-time milestones - Cash | | | |
| Expensed and paid (milestone complete) (4) | 3,000 | — | — |
| Expensed and due, but unpaid (milestone complete) (5) | 1,000 | — | — |
| Expensed but unpaid, not yet due (milestone not yet complete) (6) | 3,700 | — | — |
| Total | $ 28,584 | $ 7,417 | $ 7,543 |

(1) This payment covers 7 one-time milestones: 5 workstreams (Comparability, Stability, Potency, Product Profile, Fill/Finish), and 2 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) This covers the one-time milestone workstream: Mechanism of Action.

(3) This 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) This payment covers 5 one-time milestones: 3 workstreams (Comparability, Potency, Fill/Finish ), and 2 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).

(5) This covers the 2 one-time milestone workstreams: Product Profile and Stability.

(6) This covers 3 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.

Additionally, the Company capitalized $28,000 and $3.2 million costs related to the Sawston buildout as of December 31, 2022 and 2021, respectively. The buildout contractors and process were overseen by Advent, and buildout costs were reviewed and invoiced by Advent.

*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 $6.96 per square foot based on exchange rate as of December 31, 2022) 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 based on $145,000 annually for 2022. The total lease payments paid by the Company to Huawei for the facility, exterior spaces and parking under the head lease are 500,000 pounds (approximately $600,000) per year. The term of the Agreement shall end on the same date as the head lease term ends.

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

*Related Party Accounts Payable*

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

As of December 31, 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. The 2021 balance also included certain expenses incurred in prior periods.*

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Advent BioServices - amount invoiced but unpaid | $ 1,844 | $ 3,046 |
| Advent BioServices - amount accrued and unpaid | 4,736 | — |
| Accounts payable and accrued expenses owed to Advent BioServices | $ 6,580 | $ 3,046 |

*Related Parties Loans*

*Loan from Advent BioServices*

Advent BioServices provided a short-term loan to the Company in the amount of $65,000 on September 26, 2018. The loan bore interest at 10% per annum, and is payable upon demand, with seven days' prior written notice to the Company.

During the year ended December 31, 2020, the Company made full repayment of $73,000 to Advent, including all outstanding interest.

*Loan from Leslie Goldman*

During the year ended December 31, 2020, the Company's Senior Vice President and General Counsel, Leslie Goldman, loaned the Company $0.3 million pursuant to various convertible notes (the "Notes"). The Notes bore interest rate at 10% per annum and 50% warrant coverage and were repayable upon 15 days' notice from the holder. The Notes were convertible, in whole or in part, into stock together with warrants.

During the year ended December 31, 2020, the Company made full repayment of $0.3 million to Mr. Goldman, including all outstanding interest.

*Warrants issued to Linda Powers*

On July 2, 2020, the Company issued approximately 15.2 million warrants (the "Forbearance Warrants") to Ms. Powers in consideration for Ms. Powers' previously reported forbearance and extension of loans of $5.4 million from Ms. Powers to the Company. These warrants were approved by the Board in November 2018 when the loans were long overdue, as previously reported, and the warrants were re-approved in January 2020, but were not issued until July 2, 2020.

The Forbearance Warrants have an exercise price of $0.21 per share with 5-year contractual term. The fair value of the Forbearance Warrants was approximately $4.3 million on the grant date, which was recognized as an additional interest expense.

**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.

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.

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.

**11. Stockholders' Deficit**

**2022 Activities**

*Common Stock*

Common Stock Issued for Cash

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.

Warrants Exercised for Cash

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.

Warrants and Options Cashless Exercise

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.

Debt Redemption

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**

Common stock Issued for Cash

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.

Warrants and Stock Options Exercised for Cash

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.

Warrants and Stock Options Cashless Exercise

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.

**2020 Activities**

Registered Direct Offering

Between January and February 2020, the Company issued an aggregate of 34.5 million shares of its common stock in a registered direct offering (the "Offering"). The net proceeds from the Offering were approximately $5.7 million, after deducting offering costs of $0.4 million paid by the Company.

In connection with the Offering, the Company also issued approximately 8.5 million 2-year term warrants with an exercise price of $0.25 per share to the investors and approximately 0.8 million 2-year term warrants with an exercise price between $0.17 and $0.21 per share to placement agent in this direct offering. The fair value of these new issued warrants was approximately $1.0 million. Additionally, the Company agreed to extend by twelve months the maturity date of certain existing warrants already held by some of those investors. The Company recorded an incremental change of approximately $2.5 million on the fair value of warrants due to the modifications, which was recorded as part of offering cost during the year ended December 31, 2020.

During April 2020, the Company issued an aggregate of 19.9 million shares of its common stock and 11.3 million new issued warrants in a registered direct offering (the "April Financing"). The common stock was offered at a price of $ 0.153 per share. The warrants are exercisable at $0.20 per share. The net proceeds from the April Financing were approximately $3.0 million, after deducting offering costs of $68,000 paid by the Company. An approximate $0.8 million of proceeds were allocated to warrant liabilities.

During May 2020, the Company issued an aggregate 14.2 million shares of its common stock and 5.6 million new issued warrants in a registered direct offering (the "May Financing"). The common stock was offered at a price between $ 0.17 and $0.225 per share. The warrants have an exercise price between $0.22 and $0.23 per share and an exercise period between 1.5-2.5 years. The Company received approximately $2.9 million from the May Financing. An approximate $0.9 million of proceeds were allocated to warrant liabilities.

All of the warrants issued in the May Financings were not exercisable until November 1, 2020. In addition, as part of these agreements, the investors who have existing outstanding warrants that had not already been suspended until November 1, suspended approximately 14.6 million existing warrants until November 1, 2020.

On August 5, 2020, the Company entered into financings totaling approximately $8.0 million (the "August Financing"). The financings were comprised of:

- Approximately $7.0 million from an offering at $0.32 per share of newly registered common stock of approximately 21.8 million shares with 20-35% warrants coverage. The warrants are exercisable at $0.34 per share for approximately 5.3 million shares, with an exercise period of 18 to 30 months. The fair value of these 5.3 million warrants was approximately $1.5 million.

- $1.0 million from a convertible note (the "August Note") which is convertible at $0.345 per share. The August Note carries no warrants unless it is converted. If, and only to the extent, the note is converted it will carry 35% warrants exercisable at $0.34 per share.

- All of the new warrants issued in the August Financing were suspended until December 15, 2020.

- In addition, as part of these agreements, the investors who have existing outstanding warrants that had not yet been suspended, suspended approximately 75.5 million additional existing warrant exercise shares until December 15, 2020. In consideration for the suspension of the 75.5 million existing warrant shares as part of the August Financing, the Company issued approximately 12.5 million warrants with an exercise price of $0.34 per share and an exercise period ranging from approximately 13.5 to 25.5 months following the termination of the suspensions. These suspension consideration warrants were also suspended until the same December date.

- Only the common stock sold directly or underlying the warrants and convertible note were registered in this transaction.

On October 12, 2020, the Company entered into financings totaling approximately $11.9 million (the "Offering"). The financings were comprised of:

- Approximately $10.0 million from an offering at $0.816 per share (based upon the average 10 day closing price ending on October 12, 2020) of newly registered common stock of approximately 12.2 million shares with 30% warrants coverage. The warrants are exercisable at an exercise price of $2.00 per share for approximately 3.6 million shares, with an exercise period of 12 months (following a 3-month suspension after issuance). The fair value of these 3.6 million warrants was approximately $1.2 million.

- Approximately $1.9 million from a convertible note which is convertible at $0.85 per share (the "Note"). The Note carries no warrants unless it is converted. If, and only to the extent, the Note is converted it will carry 30% warrants with an exercise price of $2.00 per share and an exercise period of 12 months (following a 3-month suspension after issuance).

- All of the new warrants issued in the Offering are suspended until January 15, 2021.

In addition, as part of these agreements, certain investors who have existing outstanding warrants that have not yet been suspended are now suspending approximately 3.5 million additional existing warrant exercise shares until January 15, 2021.

In consideration for the suspension of the 3.5 million existing warrant shares as part of the Offering, the Company issued approximately 261,000 warrants with an exercise price of $2.00 per share and an exercise period of 12 months (following a 3-month suspension after issuance). These suspension consideration warrants are also suspended until the same January date.

Warrants Exercised for Cash

During the year ended December 31, 2020, the Company issued 47.5 million shares of its common stock from warrants exercised for cash. The Company received $13.9 million in cash.

Cashless Warrants Exercise

During the year ended December 31, 2020, The Company issued approximately 7.1 million shares of common stock upon 8.6 million warrant cashless exercises with weighted average exercise price of $0.22.

Debt Conversion

During the year ended December 31, 2020, the Company converted approximately $13.9 million outstanding debt and interest into 58.4 million shares of common stock and 6.2 million warrants.

Flaskworks Shares Issuance

On December 1, 2020, the Company issued 1.5 million shares of common stock based upon the Flaskworks team having completed a significant milestone, in accordance with the Rights Issuance Agreement entered on August 28, 2020.

On December 25, 2020, upon the seller's election, the Company issued 0.7 million shares in equivalent of $0.2 million special consideration payment pursuant to the Unit Purchase Agreement. The $0.336 per share price was established by the Unit Purchase Agreement. The incremental change in fair value of the shares resulting from market price increase was approximately $0.9 million, which was recognized as additional general and administrative expense on the consolidated statement of operations.

***Stock Purchase Warrants***

The following is a summary of warrant activity for the years ended December 31, 2022, 2021 and 2020 (in thousands, except per share data):

| | Number of Warrants | Weighted Average Exercise Price | Remaining Contractual Term |
|---|---|---|---|
| **Outstanding as of January 1, 2020** | **359,473** | **$ 0.27** | **1.42** |
| Warrants granted | 88,658 | 0.22 | |
| Contingently issuable warrants (1) | 2,774 | 1.48 | |
| Warrants exercised for cash | (47,511) | 0.29 | |
| Cashless warrants exercise | (8,631) | 0.22 | |
| Warrants expired and cancellation | (63,010) | 0.32 | |
| **Outstanding as of December 31, 2020** | **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** |

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, 2023.

At December 31, 2022, of the 141 million total outstanding warrants listed above, approximately 137 million warrants were under block or suspension agreements.

The Company's total authorized shares for common stock were increased by 500 million shares as described in the Note 15. Subsequent events. As of February 28, 2023, approximately 59 million warrants are still under block or suspension agreements.

**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, 2022, the Company had operating lease liabilities of approximately $4.7 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 $6.96 per square foot based on exchange rate as of December 31, 2022) 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 are 500,000 pounds per year. The term of the Agreement shall end on the same date as the head lease term ends.

As the Agreement was effective on December 31, 2021, the Company started to recognize sub-lease income on January 1, 2022.

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

| | 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 % | |

| | For the Year ended December 31, 2020 | | |
|---|---|---|---|
| | U.K | U.S | Total |
| Lease cost | | | |
| Operating lease cost | $ 610 | $ 330 | $ 940 |
| Short-term lease cost | 44 | — | 44 |
| Variable lease cost | 45 | 20 | 65 |
| Total | $ 699 | $ 350 | $ 1,049 |
| | | | |
| Other information | | | |
| Operating cash flows from operating leases | $ (661) | $ (332) | $ (993) |
| Weighted-average remaining lease term – operating leases | 9.1 | 0.2 | |
| 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, 2022, 2021 and 2020.

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

| | |
|---|---|
| Year ended December 31, 2023 | $ 903 |
| Year ended December 31, 2024 | 809 |
| Year ended December 31, 2025 | 604 |
| Year ended December 31, 2026 | 604 |
| Year ended December 31, 2027 | 604 |
| Thereafter | 6,631 |
| Total | 10,155 |
| Less present value discount | (5,431) |
| Operating lease liabilities included in the Consolidated Balance Sheet at December 31, 2022 | $ 4,724 |

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

| | |
|---|---|
| Year ended December 31, 2023 | $ 145 |
| Year ended December 31, 2024 | 145 |
| Year ended December 31, 2025 | 145 |
| Year ended December 31, 2026 | 145 |
| Thereafter | 1,740 |
| Total | $ 2,320 |

*Advent BioServices Services Agreement*

The Company had three operational programs with Advent during 2022: (a) an ongoing manufacturing program at the existing GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston facility, and (c) a one-time program for specialized work, organized into 10 sets of one-time milestones, for the following:

- Qualifying for and obtaining 3 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;
- 6 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 of key portions of the application for product approval itself.

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 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 £4.4 million ($5.3 million).

On November 8, 2019, the Company and Advent entered into an Ancillary Services Agreement with an 8-month Term for U.K. Facility Development Activities and Compassionate Use Program Activities. The Ancillary Services Agreement establishes a structure under which Advent develops Statements of Work ("SOWs") for the U.K. Facility Development Activities and Compassionate Use Program Activities and delivers those SOWs to the Company for review and approval. After an SOW is 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 U.K. 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 Agreement also provides for Statements of Work (SOWs) with operational milestones and related payments. The Ancillary Services Agreement had an original term of eight months, which ended in July 2020. The Company and Advent have entered into a series of modifications which have expanded the milestones to be achieved and extended the term to September 2023.

The Company entered into SOW 6 with Advent, which was incorporated into the Ancillary Services Agreement on April 1, 2022 and amended on September 26, 2022. The amended SOW 6 provides for six workstreams that are prerequisites for an application for regulatory approval of DCVax-L, for drafting of key portions of the application, and for obtaining three required licenses for the Sawston facility. The SOW provides for baseline costs and provides for milestone incentives for completion of each of the workstreams, for obtaining regulatory approval of each of the three Sawston licenses, and for the completion of the key portions of an application for product approval. 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 $329,000), 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 $272,000). On November 4, 2021, the Company received a letter from the local tax authorities asking for additional late fees of €513,000 (now approximately $535,000) 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 $232,000). On July 27, 2022, the Company was informed that the German Tax Authorities were prepared to waive €135,000 (approximately $141,000) 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. The Company currently has accrued for the current amounts owed for these penalties of €377,000 (approximately $403,000) as well as for all unpaid taxes as of December 31, 2022. 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.

**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.

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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, 2022 and 2021 are comprised of the following (in thousands):

| | As of December 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Deferred tax asset | | |
| Net operating loss carryforward | $ 202,525 | $ 193,605 |
| Research and development credit carry forwards | 17,989 | 17,982 |
| Capitalized research and experimental expenditures | 9,144 | — |
| Stock based compensation and other | 18,021 | 23,637 |
| Total deferred tax assets | 247,679 | 235,224 |
| Valuation Allowance | (247,679) | (235,224) |
| 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, 2022, are approximately $709.9 million. Unused NOL carryforwards from years prior to 2018 of $527.4 million will begin to expire in 2021 through 2037. NOL incurred in 2018 and later amount to $182.5 million and shall carryforward indefinitely. NOL carryforwards are generally available to offset future taxable income; however, 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, and such limitation could be material. The Company also has approximately $18.0 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, 2022 are $39.7 million. NOL in the United Kingdom and Germany of $21.4 million and $17.9 million respectively do not expire over time. NOL in the Netherlands of $0.4 million will begin to expire in 2025 through 2032. The Company's tax years are still open under statute from 2017 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, 2022 and 2021.

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, 2022 | As of December 31, 2021 |
|---|---|---|
| Statutory federal income tax rate | 21.0 % | 21.0 % |
| State taxes, net of federal tax benefit | 4.6 % | (2.0)% |
| Tax rate differential on foreign income | (0.2)% | 0.1 % |
| Derivative gain or loss | (5.2)% | (28.0)% |
| Expiration of net operating losses | (2.6)% | 3.9 % |
| Other permanent items and true ups | (6.0)% | 0.1 % |
| R&D Credit | 0.0 % | 0.3 % |
| Change in rate | 0.1 % | 0.0 % |
| Change in valuation allowance | (11.7)% | 4.6 % |
| Income tax provision (benefit) | 0.0 % | 0.0 % |

| | As of December 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Federal | | |
| Current | $ — | $ — |
| Deferred | (8,868) | (5,765) |
| State | | |
| Current | — | — |
| Deferred | (3,097) | (1,975) |
| Foreign | | |
| Current | | |
| Deferred | (489) | (599) |
| Change in valuation allowance | 12,454 | 8,339 |
| Income tax provision (benefit) | $ — | $ — |

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, 2022, 2021, and 2020, 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, 2022, 2021 and 2020. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position

**14. Subsequent Events**

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 1,200,000,000 to 1,700,000,000, par value $0.001 per share.

During the period from January 1 to February 24, 2023, the Company received an additional $2.5 million through equity subscriptions and warrant exercises.

Between January and February 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 to the Series C Investors an aggregate of 146,948 shares of the Company's Series C Convertible Preferred Stock, par value $0.001 per share (the "Series C Shares") for proceeds of approximately $2.4 million. Each Series C Preferred share is convertible to 25 common shares at the option of the holder approximate 15 days after the effective date of purchase.

Between January and February 2023, 0.3 million shares of common stock were issued upon warrant exercises for proceeds of approximately $0.1 million.

During January 2023, the Company issued approximately 3.4 million shares of common stock to certain lenders in lieu of cash payments on $2.1 million outstanding debt, including $0.1 million interest.

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Between January and February 2023, the Company issued 43,401 share of Series C preferred stock in lieu of cash payments of $0.7 million of outstanding notes, including $0.1 million accrued interest.

During January 2023, certain options holders elected to exercise some of their options pursuant to cashless exercise formulas. The Company issued approximately 0.6 million shares of common stock for exercise of 1.1 million options at exercise prices between $0.34 and $0.35.

On February 15, 2023, the Company issued 150,000 shares of common stock upon conversion of 6,000 shares of Series C preferred stock.

During February 2023, the Company extended approximate 37.7 million warrants with maturity dates through March 15, 2023 in order to finalize ongoing financing transactions. The holders of these 37.7 million warrants had cash deposit of approximately $2.6 million in December 2022, which was recognized as a cash advance as of December 31, 2022 on the Company’s consolidated balance sheet.