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NORTHWEST BIOTHERAPEUTICS INC

FORM 10-K

(Annual Report)

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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, 2021

☐ 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)

N/A
(Former Name, Former Address and Former Fiscal Year, if changed since last report)

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 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, or 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. ☒

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 $ 1,212,762,000 on June 30, 2021.

As of February 25, 2022, the registrant had 960,022,117 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2022.

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). 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. On October 5, 2020, the Company announced that Data Lock for the Phase III trial had been reached, and that a series of steps and processes would follow. These processes included data validation, analyses of the data by independent statisticians, preparations by the statisticians of summaries of the Trial results for review by the Company, the Principal Investigator, the Steering Committee of the Trial, the Scientific Advisory Board, and a panel of independent brain cancer experts, in preparation for publication in a scientific journal and public announcement. This series of processes is under way. It is anticipated that public announcement will follow these processes.

As also previously reported, coronavirus-related difficulties have impacted most aspects of the process, especially with the successive waves of COVID cases in many areas. The independent service firms have had limited capacity, and restrictions on operations. Key experts at certain specialized service providers have been unavailable for periods of time. Other experts have gone on extended leave. Clinical trial site personnel have been unavailable due to being reassigned for COVID, and the limited site personnel have had to work under restrictions. Committee processes and regulatory processes have been similarly focused on COVID matters and delayed on other matters. Firms such as the ones storing the Phase III trial tissue samples that are needed for certain analyses, and the firms conducting the analyses, continue to have only limited operations. Even logistical matters such as the shipping of materials have been, and continue to be, subjected to substantial difficulties and delays.

On August 28, 2020, we 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®. We acquired 100% of the ownership, and Flaskworks became a wholly-owned subsidiary of the Company. Flaskworks was previously owned by its technical founders and Corning Inc. The technical team from Flaskworks joined us as part of the Acquisition. It is anticipated that the Flaskworks system will enable substantial scale-up of production volumes of DCVax products and substantial reduction of production costs. Our buildout of the Sawston, UK facility has been designed to proceed in phases, as modules, both for efficiency in the timing of capital costs and to allow flexibility in operations and usage. We anticipate that implementation of the Flaskworks system will enable certain phases of the buildout to be simplified and streamlined. For further details on the financial aspects of the acquisition, please see Item 8 Note 5 below.

Our second product, DCVax®-Direct, is designed to treat inoperable solid tumors. A 40-patient Phase I trial has been completed, and included treatment of a diverse range of more than a dozen types of cancers. We plan to work on preparations for Phase II trials of DCVax-Direct as resources permit.

The 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 8 days for DCVax-L, and 7 days for DCVax-Direct, followed by quality control and release testing (including a sterility test that may take a couple of weeks).

As previously reported, we have been developing a manufacturing facility in Sawston, U.K. To date, our production of dendritic cell vaccine products in the UK has been taking place in a GMP (clean room) facility in London, with a capacity of about 4 - 6 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 some additional support and storage space, have anticipated potential capacity to produce dendritic cell vaccines for about 40 to 45 patients per month, or approximately 450 to 500 patients annually. The buildout of Phase 1A of the facility was completed in Q4 2020.

During 2021, work continued for technology transfer from the London facility to the Sawston facility, recruitment of contract technical personnel for Sawston, development of some 1,000 regulatory documents for operations in the Sawston facility, and applications to both the Human Tissue Authority (HTA) and the MHRA for inspections of the Sawston facility and its operations, and issuance of licenses for manufacturing in the facility. These applications and inspections were successfully completed. The HTA license was issued in October 2021 and the MHRA license was issued in December 2021. Following some required validation work after the licenses were issued, production of DCVax-L began this month.

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

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

Intellectual Property and Orphan Drug Designation

We have an integrated strategy for protection of our technology through both patents and other mechanisms, such as Orphan Drug status. As of December 31, 2021, we have 204 issued patents and 59 pending patent applications worldwide, grouped into 11 patent families. Of these, 200 issued patents and 47 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 and quality control. For example, in the United States, we have seven issued and five pending patent applications that relate to the composition and/or use of our DCVax products. We also have other U.S patents and applications that cover, among other things, quality control for DCVax 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 seven patents issued by and eight 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 and quality control, and the automated system. In Japan, we have nine issued patents and three 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 2021, seven 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.

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 U.S. patents involved in our current business range from 2022 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 2022 to 2024, 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 U.S. 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 Juno, Kite, Bellicum, Agenus, Asterias, Immunicum, Sotio, AiVita 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 have recently been 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 various expertise. The Company began the year with 19 full-time employees (FTEs) and ended the year on December 31, 2021 with 20 FTEs. With the acquisition of Flaskworks during FY2020, the Company gained additional experienced technical scientific management (1) and scientists (2). The Company's internal workforce is approximately gender equal. As in the past, the Company relied upon specialists in the areas of manufacturing, construction and construction management, clinical trial management, data validation and analysis, scientific advisory, regulatory advisory, legal, financial accounting and tax, and Information Technology. 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, 2021, 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, 2021 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, 2021, and December 31, 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, 2021, we had a total of 20 full time employees: 18 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.

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 results from the small early stage clinical trials of DCVax-L for newly diagnosed GBM were quite positive, those results may not be achieved in our later stage clinical trials, such as the 331-patient Phase III trial for GBM that is nearing completion, and our product candidates may not ultimately be found to be effective. Similarly, although we believe the interim blinded data from the Phase III trial that we have collected and reported to date are encouraging, the results of this trial when the data are unblinded may not be as encouraging or may not be positive at all. Further, although the safety profile of our DCVax-L product was excellent in the early stage clinical trials, toxicity may be seen as we treat larger numbers of patients in late stage clinical trials. 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 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 Bellicum, Agenus, Asterias, Dandrit, Immunicum, Sotio, AiVita 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 complete our Phase III trial and analysis of its results, or 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 plan to 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, 2021, we had 200 issued patents and 47 pending patent applications worldwide relating to our product candidates and related matters such as manufacturing processes. The issued patents expire at various dates from 2022 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 may not be sufficiently broad 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 situationsif the core DCVax technology is not effective or is toxic or is not commercially viable, our business could fail. We do not currently have other technologies that could provide alternative support for us.

Risks Related to our Common Stock

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

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

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

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

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

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

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

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

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

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

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

- provide the Board of Directors with the ability to alter the bylaws without stockholder approval;
- establish staggered terms for board members;
- place limitations on the removal of directors; and
- provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

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

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

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act. As of December 31, 2021, 948.4 million shares of our common stock are issued and outstanding. In addition, as of December 31, 2021, 123 million shares of our common stock are issuable upon exercise of outstanding warrants, and 42.6 million shares of our common stock are issuable upon exercise of outstanding options.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

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

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

ITEM 3. LEGAL PROCEEDINGS

Not Applicable.

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, 2022, there were approximately 41,900 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.

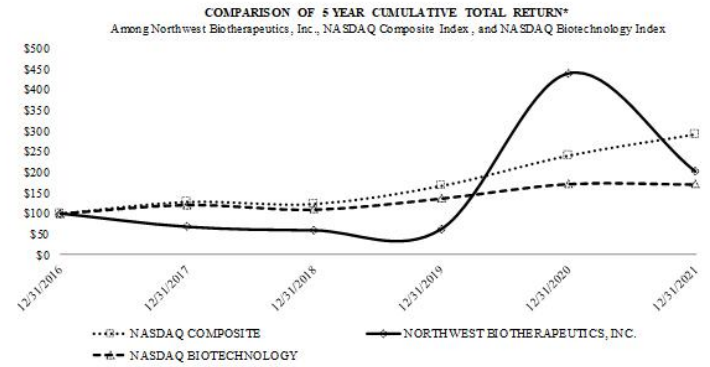
Dividend Policy

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, 2016 in stock or index.

	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Northwest Biotherapeutics, Inc.	100.00	67.57	59.03	61.74	438.09	201.09
NASDAQ Composite	100.00	128.24	123.26	166.68	239.42	290.63
NASDAQ Biotechnology	100.00	121.06	109.77	136.56	171.64	170.55

Recent Sales of Unregistered Securities

During the year ended December 31, 2021, the Company issued certain equity securities as set forth in Note 11 (Stockholders' Deficit) to our financial statements, for the consideration described in such footnote, which disclosure is incorporated into this Item 5. Such securities were issued by the Company 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.

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, 2021 as compared to the year ended December 31, 2020. The discussion of the Company's financial condition and results of operations for the year ended December 31, 2020 compared to the same period in 2019 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, 2020.

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). 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. On October 5, 2020, the Company announced that Data Lock for the Phase III trial had been reached, and that a series of steps and processes would follow. These processes included data validation, analyses of the data by independent statisticians, preparations by the statisticians of summaries of the Trial results for review by the Company, the Principal Investigator, the Steering Committee of the Trial, the Scientific Advisory Board, and a panel of independent brain cancer experts, in preparation for publication in a scientific journal and public announcement. This series of processes is under way. It is anticipated that public announcement will follow these processes.

As also previously reported, coronavirus-related difficulties have impacted most aspects of the process, especially with the waves of COVID cases in many areas. The independent service firms have had limited capacity, and restrictions on operations. Key experts at certain specialized service providers have been unavailable for periods of time. Other experts have gone on extended leave. Clinical trial site personnel have been unavailable due to being reassigned for COVID, and the limited site personnel have had to work under restrictions. Committee processes and regulatory processes have been similarly focused on COVID matters and delayed on other matters. Firms such as the ones storing the Phase III trial tissue samples that are needed for certain analyses, and the firms conducting the analyses, continue to have only limited operations. Even logistical matters such as the shipping of materials have been, and continue to be, subjected to substantial difficulties and delays.

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 acquired 100% of the ownership, and Flaskworks became a wholly-owned subsidiary of the Company. Flaskworks was previously owned by its technical founders and Corning Inc. The technical team from Flaskworks joined the Company as part of the Acquisition. It is anticipated that the Flaskworks system will enable substantial scale-up of production volumes of DCVax products and substantial reduction of production costs. The Company's buildout of the Sawston, UK facility has been designed to proceed in phases, as modules, both for efficiency in the timing of capital costs and to allow flexibility in operations and usage. The Company anticipates that implementation of the Flaskworks system will enable certain phases of the buildout to be simplified and streamlined. For further details on the financial aspects of the acquisition, please see Item 8 Note 5 below.

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. The Company plans 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, 2021 and 2020, 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.

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

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

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

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

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

We recognize forfeitures when they occur.

Recently 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.

Recently Issued Accounting Standards Not Yet Adopted

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. The adoption of ASU 2021-04 is not expected to have a material impact on our financial statements or disclosures.

Results of Operations

Operating costs:

Operating costs and expenses consist primarily of research and development expenses, including clinical trial expenses, which increase when we are actively participating in clinical trials and especially when we are in a large ongoing international phase III trial or we are completing such a large international trial, and undertaking substantial one-time expenses such as for final site visits, query resolutions, statistical work for the Statistical Analysis Plan, preparations for data analyses and other activities related to completion and assessment of the trial and its results. The operating costs also include administrative expenses associated with trials, and increase as such operating activities grow.

In addition to clinical trial related costs, our operating costs may include ongoing work relating to our DCVax products, including R&D, product characterization, and related matters. Going forward, we are also incurring large amounts of costs to carry out and complete statistical analyses, validation work, data reports and other work associated with analyzing the trial results and proceeding.

Following our acquisition of Flaskworks, our operating costs now include the costs for its ongoing operations and its intellectual property filings.

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. Additional substantial costs relate to the maintenance and substantial expansion of manufacturing capacity, in both the US and Europe.

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

Research and development:

Discovery and preclinical research and development 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 research and development costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

General and administrative:

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

For the Years Ended December 31, 2021, 2020 and 2019

We recognized a net income of $179.1 million, a net loss of $529.8 million and a net loss of $20.8 million for the years ended December 31, 2021, 2020 and 2019, 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 $529.8 million for the year ended December 31, 2020 included a non-cash loss of $435.4 millionfrom change in fair value derivative liabilities.

Net cash used in operations was $38.3 million, $32.1 million and $31.9 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Research and development expense

For the years ended December 31, 2021, 2020 and 2019, research and development expense was $20.3 million, $33.6 million and $14.1 million, respectively. Research and development expenses included activities and involvement of external consultants as the Phase 3 trial moved through final data collection and query resolution, independent data validation, and other preparations for Data Lock and analyses. The decrease in 2021 compared to 2020 was mainly related to a decrease of $12 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.

We incurred approximately $7.4 million, $7.5 million and $5.7 million in expenses from related parties during the years ended December 31, 2021, 2020 and 2019, respectively.

General and Administrative Expense

General and administrative expenses were $33.4 million, $54.3 million and $16.3 million for the years ended December 31, 2021, 2020 and 2019, respectively. 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 gain of $239.3 million, a non-cash loss of $435.4 million and a non-cash gain of $11.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. The non-cash gain was primarily due to the decrease of our stock price as of December 31, 2021 ($0.70 per share) compared to December 31, 2020 ($1.53 per share). The non-cash loss was primarily due to the increase of our stock price as of December 31, 2020 ($1.53 per share) compared to December 31, 2019 ($0.21 per share).

Debt Extinguishment

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 approximate $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, 2021, 2020 and 2019, we recorded interest expense of $5 million, $8.5 million and $3 million, respectively.

Foreign currency transaction gain

During the years ended December 31, 2021, 2020, and 2019, we recognized foreign currency transaction loss of $1.7 million, gain of $2.3 million and $0.3 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.

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, 2021 (amount 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	$ 234	$ 234	$ —	$ —
Short term notes payable (2)				
8% unsecured	2,333	2,333	—	—
9% unsecured	4,453	4,453	—	—
12% unsecured	1,026	1,026	—	—
Long term notes payable (3)				
1% unsecured	436	—	—	436
8% unsecured	28,030	—	28,030	—
6% secured	1,669	91	61	1,517
Operating leases (4)	9,633	—	7,224	2,409
Purchase obligation (5)				
Total	**$ 47,814**	**$ 8,137**	**$ 35,315**	**$ 4,362**

(1) The obligations related to short-term convertible notes were approximately $0.2 million as of December 31, 2021, which included remaining contractual unpaid interest of $0.1 million.

(2) The obligations related to short-term notes were approximately $7.8 million as of December 31, 2021, which included unpaid interest of $0.6 million.

(3) The obligations related to long-term notes were approximately $30.1 million as of December 31, 2021, which included unpaid interest for the next 5 years of approximately $2.1 million.

(4) The operating lease obligations during the next 2 years included approximately $0.6 million for our offices in Maryland and U.K, and approximately $0.2 million for our office in Maryland for the next 3-4 years. Approximately £1 million ($1.4 million) in lease obligations during the next 2 years and approximately £1.5 million ($2 million) for the next 3 to 5 years related to the Vision Centre in the U.K. that we leased back in December 2018. We also included approximately $5.1 million of anticipated payments to Advent BioServices, which represents the next year's obligation under the current Manufacturing Services Agreement. The remaining contract term as of December 31, 2021 was approximately 1 year under the Manufacturing Services Agreement with Advent.

(5) We have possible contingent obligations to pay certain fees to contract manufacturers if we shut down or suspend programs.

For a shut down or suspension of the DCVax-L program at Advent, the Company must give 12 months' advance notice. During the notice period services would still be provided. Minimum required payments for this notice period total approximately £3.8 million ($5.1 million).

As of December 31, 2021, no shut-down or suspension fees were triggered.

Operating Activities

We used $38.3 million, $32.1 million and $31.9 million in cash for operating activities during the years ended December 31, 2021, 2020 and 2019, 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 $6 million, $6.6 million and $0.4 million in cash for purchase of additional equipment in the UK and our build out in Sawston, UK during the years ended December 31, 2021, 2020 and 2019, respectively.

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

Financing Activities

We received approximately $4.1 million, $26.8 million and $6.9 million in cash proceeds from issuance of common stock and warrants, in both public and private offerings during the years ended December 31, 2021, 2020 and 2019, respectively.

We received approximately $20.0 million, $13.9 million and $2.2 million cash proceeds from the exercise of warrants and options during the years ended December 31, 2021, 2020 and 2019, respectively.

We received approximately $29.7 million, $13.7 million and $7.0 million in cash proceeds from the issuance of multiple notes payable during the years ended December 31, 2021, 2020 and 2019, 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 $5.8 million and $2.0 million and $6.1 million during the years ended December 31, 2021, 2020 and 2019, respectively.

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

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The full text of our audited consolidated financial statements as of December 31, 2021 and 2020 and for the fiscal years ended December 31, 2021, 2020 and 2019, begins on page F-1 of this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

As required by Rule 13a-15 under the Exchange Act, our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2021. 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, 2021, 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, 2021.

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, 2021. 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, 2021 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

The information required by Item 10 is hereby incorporated by reference from our 2022 Proxy Statement under the captions “Election of Directors” and “Code of Ethics.” To the extent that we do not file the 2022 Proxy Statement prior to the end of the 120-day period following December 31, 2021, we will amend this Annual Report on Form 10-K to provide the required information.

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

EXHIBIT INDEX

Exhibit Number	Description
3.1	Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant’s Amendment No. 1 to the Registration Statement on Form S-1(File No. 333-134320) on July 17, 2006).
3.2	Third Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 filed with the Registrant’s Current Report on Form 8-K on June 22, 2007).
3.3	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 filed with the Registrant’s Current Report on Form 8-K on June 22, 2007).
3.5	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant’s Quarterly Report on Form 10-Q on May 21, 2012).
3.6	Amendment to Seventh Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with the Registrant’s Current Report on Form 8-K on September 26, 2012).

3.7	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).
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.
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").
21.1	Subsidiaries of the Registrant.
23.1	Independent Registered Public Accounting Firm's Consent.
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Schema Document.
101.CAL	Inline XBRL Calculation Linkbase Document.
101.DEF	Inline XBRL Definition Linkbase Document.
101.LAB	Inline XBRL Label Linkbase Document.
101.PRE	Inline XBRL Presentation Linkbase Document.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

NORTHWEST BIOTHERAPEUTICS, INC.
(Registrant)

Date: March 1, 2022

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

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

Signature	Title	Date
/s/ Linda F. Powers Linda F. Powers	President and Chief Executive Officer Principal Executive Officer Principal Financial and Accounting Officer	March 1, 2022
/s/ Alton L. Boynton Alton L. Boynton	Director	March 1, 2022
/s/ Navid Malik Dr. Navid Malik	Director	March 1, 2022
/s/ Jerry Jasinowski Jerry Jasinowski	Director	March 1, 2022
/s/ J. Cofer Black J. Cofer Black	Director	March 1, 2022

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, 2021 and 2020, and the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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, 2021, 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 that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over financial reporting, 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 2021 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 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 matter communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the 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 it relates.

Critical Audit Matter Description
As disclosed in Notes 4, 6, 8, and 11 to the consolidated financial statements, the Company had various debt, derivative, and equity transactions, including 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 subsequently have been 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, and equity transactions, including stock-based compensation, processes.
- We obtained a listing and of all debt, derivative liabilities, and equity transactions, including 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 complex 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 evidence obtained in other areas of the audit.

- We evaluated the disclosures surrounding debt, derivative liabilities, and equity transactions, including stock-based compensation, to ensure these were disclosed in accordance with the relevant accounting guidance.

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

/s/ Cherry Bekaert LLP
Tampa, Florida
March 1, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Northwest Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Northwest Biotherapeutics, Inc. and Subsidiaries (the “Company”) as of December 31, 2019, the related statements of operations and comprehensive loss, changes in stockholders’ deficit and cash flows for the year ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses and net operating cash flow deficits, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of the guidance in ASC Topic 842, Leases (“Topic 842”).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We served as the Company’s auditor from 2013 to 2021.

New York, NY
March 16, 2020

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,169	$ 9,983
Prepaid expenses and other current assets	2,121	5,528
Total current assets	17,290	15,511
Non-current assets:		
Property, plant and equipment, net	15,027	1,040
Construction in progress	—	9,074
Right-of-use asset, net	4,889	4,489
Indefinite-lived intangible asset	1,292	1,292
Goodwill	626	626
Other assets	1,036	867
Total non-current assets	22,870	17,388
TOTAL ASSETS	**$ 40,160**	**$ 32,899**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,976	$ 7,380
Accounts payable and accrued expenses to related parties and affiliates	3,971	5,363
Convertible notes, net	135	3,830
Notes payable, net	7,104	2,437
Contingent payable derivative liability	8,232	8,275
Warrant liability	106,784	354,972
Lease liabilities	317	167
Shares payable	250	—
Total current liabilities	133,769	382,424
Non-current liabilities:		
Notes payable, net of current portion, net	25,156	8,507
Lease liabilities, net of current portion	5,226	4,916
Total non-current liabilities	30,382	13,423
Total liabilities	164,151	395,847
COMMITMENTS AND CONTINGENCIES (Note 12)		
Stockholders' deficit:		
Preferred stock ($0.001 par value); 100,000,000 shares authorized as of December 31, 2021 and 2020, respectively	—	—
Common stock ($0.001 par value); 1,200,000,000 shares authorized; 948.4 million and 829.6 million shares issued and outstanding as of December 31, 2021 and 2020, respectively	948	830
Additional paid-in capital	1,066,873	1,008,665
Stock subscription receivable	(79)	(79)
Accumulated deficit	(1,192,090)	(1,371,216)
Accumulated other comprehensive income (loss)	357	(1,148)
Total stockholders' deficit	(123,991)	(362,948)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 40,160**	**$ 32,899**

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,		
	2021	**2020**	**2019**
Revenues:			
Research and other	$ 1,005	$ 1,291	$ 2,410
Total revenues	1,005	1,291	2,410
Operating costs and expenses:			
Research and development	20,308	33,637	14,106
General and administrative	33,399	54,259	16,283
Total operating costs and expenses	53,707	87,896	30,389
Loss from operations	(52,702)	(86,605)	(27,979)
Other income (expense):			
Change in fair value of derivative liabilities	239,347	(435,351)	11,828
Loss from extinguishment of debt	(165)	(1,582)	(1,941)
Interest expense	(5,011)	(8,544)	(2,975)
Inducement expense	(647)	—	—
Foreign currency transaction gain (loss)	(1,696)	2,261	255
Total other income (loss)	231,828	(443,216)	7,167
Net income (loss)	$ 179,126	$ (529,821)	$ (20,812)
Other comprehensive income (loss)			
Foreign currency translation adjustment	1,505	(1,984)	(164)
Total comprehensive income (loss)	$ 180,631	$ (531,805)	$ (20,976)
Net earnings (loss) per share applicable to common stockholders			
Basic	$ 0.21	$ (0.73)	$ (0.04)
Diluted	$ (0.06)	$ (0.73)	$ (0.04)
Weighted average shares used in computing basic earnings (loss) per share	873,517	725,129	564,188
Weighted average shares used in computing diluted earnings (loss) per share	1,007,869	725,129	564,188

See accompanying notes to the consolidated financial statements

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

	Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholder Deficit
	Shares	Par value					
Balances at January 1, 2019	**523,232**	**$ 523**	**$ 775,741**	**$ (10)**	**$ (825,385)**	**$ 1,000**	**$ (48,13**
Issuance of common stock and warrants for cash in a registered direct offering (net of $ 2.7 million warrant liability and $ 0.4 million cash offering cost)	32,708	33	4,040	—	—	—	4,07
Warrants exercised for cash	9,532	10	2,210	—	—	—	2,22
Reclassification of warrant liabilities related to warrants exercised for cash	—	—	1,759	—	—	—	1,75
Issuance of common stock and warrants for conversion of debt and accrued interest	35,480	35	9,138	—	—	—	9,17
Stock-based compensation	1,340	1	1,818	—	—	—	1,81
Cumulative effect of adopting new accounting standard	—	—	—	—	4,802	—	4,80
Issuance of common shares in connection with a settlement agreement	12,000	12	(12)	—	—	—	
Beneficial conversion feature related to amended convertible note	—	—	68	—	—	—	6
Reclass between shares payable and additional paid-in capital	—	—	138	—	—	—	13
Net loss	—	—	—	—	(20,812)	—	(20,81
Cumulative translation adjustment	—	—	—	—	—	(164)	(16
Balances at December 31, 2019	**614,292**	**614**	**794,900**	**(10)**	**(841,395)**	**836**	**(45,05**
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)	—	—	16,49
Issuance of common stock and warrants for conversion of debt and accrued interest	58,368	58	19,591	—	—	—	19,64
Warrants exercised for cash	47,511	48	13,867	—	—	—	13,91
Reclassification of warrant liabilities related to warrants exercised for cash	—	—	22,701	—	—	—	22,70
Cashless warrants exercise	7,086	7	(7)	—	—	—	
Cashless option exercise	71	—	-	—	—	—	
Reclassification of warrant liabilities related to cashless warrants exercise	—	—	9,478	—	—	—	9,47
Beneficial conversion feature related to amended convertible note	—	—	44	—	—	—	4
Issuance of common stock in connection with Flaskworks acquisition	655	1	1,132	—	—	—	1,13
Stock-based compensation	3,667	4	52,205	—	—	—	52,20
Reclassification of warrant liabilities related to sequencing policy	—	—	78,292	—	—	—	78,29
Net loss	—	—	-	—	(529,821)	—	(529,82
Cumulative translation adjustment	—	—	-	—	—	(1,984)	(1,98
Balances at December 31, 2020	**829,631**	**830**	**1,008,665**	**(79)**	**(1,371,216)**	**(1,148)**	**(362,94**
Issuance of common stock for cash	6,272	6	4,064	—	—	—	4,07
Issuance of common stock and warrants for conversion of debt and accrued interest	5,145	5	7,495	—	—	—	7,50
Warrants and stock options exercised for cash	86,910	87	19,888	—	—	—	19,97
Reclassification of warrant liabilities related to warrants exercised for cash	—	—	68,692	—	—	—	68,69
Cashless warrants and stock options exercise	20,439	20	(20)	—	—	—	
Reclassification of warrant liabilities related to cashless warrants exercise	—	—	2,369	—	—	—	2,36
Stock-based compensation	48	—	15,571	—	—	—	15,57
Reclassification of warrant liabilities based on authorized shares	—	—	(59,851)	—	—	—	(59,85
Net income	—	—	—	—	179,126	—	179,12
Cumulative translation adjustment	—	—	—	—	—	1,505	1,50
Balances at December 31, 2021	**948,445**	**$ 948**	**$ 1,066,873**	**$ (79)**	**$(1,192,090)**	**$ 357**	**$ (123,99**

See accompanying notes to the consolidated financial statements

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

	For the years ended December 31,		
	2021	**2020**	**2019**
Cash Flows from Operating Activities:			
Net income (loss)	$ 179,126	$ (529,821)	$ (20,812)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	324	87	21
Amortization of debt discount	2,301	3,013	1,430
Change in fair value of derivatives	(239,347)	435,351	(11,828)
Change in fair value of contingent liability	—	913	—
Loss from extinguishment of debt	165	1,582	1,941
Inducement expense	647	—	—
Amortization of operating lease right-of-use asset	262	338	(322)
Stock-based compensation related to warrants modification	—	—	3
Stock-based compensation for services	15,498	52,209	1,819
Non-cash interest expense	—	4,270	—
Subtotal of non-cash charges	(220,150)	497,763	(6,936)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	3,475	(2,350)	(1,226)
Other non-current assets	(179)	(31)	(11)
Accounts payable and accrued expenses	77	1,702	30
Related party accounts payable and accrued expenses	(674)	431	(3,230)
Lease liabilities	26	213	326
Net cash used in operating activities	(38,299)	(32,093)	(31,859)
Cash Flows from Investing Activities:			
Purchase of equipment and construction in progress	(6,015)	(6,610)	(360)
Acquisition of Flaskworks, net of cash	—	(1,532)	—
Net cash used in investing activities	(6,015)	(8,142)	(360)
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock and warrants in a registered direct offering, net	4,070	26,814	6,874
Proceeds from exercise of warrants and stock options	19,975	13,915	2,220
Proceeds from issuance of notes payable, net	29,665	8,557	7,000
Proceeds from warrants modification	—	4	7
Proceeds from issuance of convertible notes payable, net	—	5,115	—
Proceeds from issuance of convertible notes payable to related party	—	315	—
Investor advances	250	—	—
Repayment of notes payable	(5,828)	(1,556)	(420)
Repayment of notes payable to related parties	—	(379)	(329)
Repayment of convertible notes payable	—	(89)	—
Repayment of convertible notes payable to related parties	—	—	(5,400)
Net cash provided by financing activities	48,132	52,696	9,952
Effect of exchange rate changes on cash and cash equivalents	1,368	(2,850)	415
Net increase (decrease) in cash and cash equivalents	5,186	9,611	(21,852)
Cash and cash equivalents, beginning of the year	9,983	372	22,224
Cash and cash equivalents, end of the year	$ 15,169	$ 9,983	$ 372
Supplemental disclosure of cash flow information			
Interest payments on notes payable to related party	$ —	$ (9)	$ (177)
Interest payments on convertible notes payable	$ —	$ (11)	$ —
Interest payments on notes payable	$ (1,730)	$ —	$ (43)
Interest payments on convertible notes payable to related party	$ —	$ (19)	$ (795)

See accompanying notes to the consolidated financial statement

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

	For the years ended December 31,		
	2021	**2020**	**2019**
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	$ 20	$ 7	$ —
Reclassification of warrant liabilities related to warrants exercised for cash	$ 68,692	$ 22,701	$ 1,759
Reclassification of warrant liabilities related to cashless warrants exercise	$ 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	$ 7,487	$ 8,230	$ 7,313
Offering cost related to warrant liability	$ —	$ 4,876	$ 2,693
Deferred offering cost	$ —	$ —	$ 108
Capital expenditures included in accounts payable	$ 33	$ 1,088	$ 947
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	$ 68
Conversion of outstanding accounts payables to note payable and contingent payable	$ —	$ —	$ 8,560
Issuance of common shares in connection with a settlement agreement	$ —	$ —	$ 12
Reclass between shares payable and additional paid-in capital	$ —	$ —	$ 138

See accompanying notes to the consolidated financial statement

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 the U.K. and on April 25, 2019, the Company established a new wholly owned subsidiary Northwest Biotherapeutics B.V. in the Netherlands, where the European Medicines Agency relocated.

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 to close and automate the manufacturing of cell therapy products such as DCVax®.

2. Financial Condition, Going Concern and Management Plans

The Company has incurred annual net operating losses since its inception. The Company had loss from operations of approximately $52.7 million for the year ended December 31, 2021. The Company used approximately $38.3 million of cash in its operating activities for the year ended December 31, 2021. Management believes that the Company has access to capital resources through the sale of equity and debt financing arrangements. However, the Company has not secured any commitments for new financing for this specific purpose at this time.

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 condensed 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 continued through 2021 to impact most aspects of the activities following database lock, and have also impacted the process of analyzing the Phase III trial results and preparing to report them, especially with the successive waves of COVID-19 cases in many areas. The independent service firms have had limited capacity, and restrictions on operations. Key experts at certain specialized service providers have been unavailable for periods of time. Other experts have gone on extended leave. Clinical trial sites have not allowed personnel from the contract research organization 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 have been unavailable due to being reassigned for COVID-19, and the limited site personnel have had to work under restrictions. Committee processes and regulatory processes have been similarly focused on COVID-19 matters and delayed on other matters. Firms such as the ones storing the Phase III trial tissue samples that are needed for certain analyses, and the firms conducting the analyses have had only limited operations. Even logistical matters such as the shipping of materials have been subjected to substantial difficulties 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.

On May 14, 2018, the Company entered into a DCVax®-L Manufacturing and Services Agreement with Advent BioServices (“Advent”). For purposes of VIE determination, the Company concluded that it is not the primary beneficiary of Advent, a related party partially controlled by an Executive of the Company. However, the Company will continue to evaluate this analysis as facts and circumstances change, as applicable.

As of December 31, 2021 and 2020, 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, 2021, of the total $15.2 million in cash and cash equivalents, $0.5 million was held by foreign subsidiaries. As of December 31, 2020, of the total $10.0 million in cash and cash equivalents, $0.6 million was held by foreign subsidiaries. The Company had not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Property, Plant and Equipment

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

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

The Company 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, 2021 and 2020.

Fair Value of Financial Instruments

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

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

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

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

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

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

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

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

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

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

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

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

Debt Extinguishment

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

Sequencing

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

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.

Recently Issued Accounting Standards Not Yet Adopted

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. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or disclosures.

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, 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

		Fair value measured at December 31, 2020		
	Fair value at December 31, 2020	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 354,972	$ —	$ —	$ 354,972
Embedded conversion option	2,507	—	—	2,507
Contingent payable derivative liability	8,275	—	—	8,275
Total fair value	$ 365,754	$ —	$ —	$ 365,754

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2021 and 2020.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2021 and 2020. 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 Conversion Option	Contingent Payable Derivative Liability	Total
Balance - January 1, 2020	**$ 20,213**	**$ —**	**$ 7,261**	**$ 27,474**
Additional warrant liability	18,864	—	—	18,864
Reclassification of warrant liabilities	(110,471)	—	—	(110,471)
Extinguishment of embedded conversion option due to debt conversion and debt repayment	—	(8,271)	—	(8,271)
Additional embedded conversion option	—	2,807	—	2,807
Change in fair value	426,366	7,971	1,014	435,351
Balance – December 31, 2020	**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**

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, 2021 and 2020 is as follows:

	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 %

	As of December 31, 2020		
	Warrant Liability	Embedded Conversion Option	Contingent Payable Derivative Liability
Strike price	$ 0.28	$ 0.59	$ 1.53 *
Contractual term (years)	1.6	0.9	1.4
Volatility (annual)	116 %	106 %	126 %
Risk-free rate	0.2 %	0.1 %	0.1 %
Dividend yield (per share)	0 %	0 %	0 %

* Contingent payable derivative liability based on stock price as of December 31, 2021 and 2020.

5. Flaskworks Acquisition

On August 28, 2020, the Company completed the acquisition of Flaskworks (the "Acquisition"), whereby Flaskworks became a wholly-owned subsidiary of the Company.

The Unit Purchase Agreement was executed and closed on August 28, 2020. The Company acquired100% of the ownership units of Flaskworks. Flaskworks was previously owned by its technical founders and Corning Inc. The technical team from Flaskworks has joined the Company as part of the Acquisition. It is anticipated that the Flaskworks system will enable substantial scale-up of production volumes of DCVax products and substantial reduction of production costs. The Company's buildout of the Sawston, UK facility has been designed to proceed in phases, as modules, both for efficiency in the timing of capital costs and to allow flexibility in operations and usage. The Company anticipates that implementation of the Flaskworks system will enable certain phases of the buildout to be simplified and streamlined.

The total purchase price was approximately $4.3 million, of which $1.7 million was paid in cash at closing, up to $2.01 million was paid in stock subject to milestone-based vesting (see Note 6), and $0.7 million was paid in either cash or stock, or a combination thereof, within 120 days after the closing. Between October and December 2020, $0.5 million was paid in cash upon the seller's election.

In addition to the $0.5 million cash payment, on December 25, 2020, upon the seller's election, the Company issued 654,762 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 a component of general and administrative expense in the consolidated statement of operations.

Based on the Company's valuation, the total estimated consideration of $2.1 million has been allocated to assets acquired and liabilities assumed as of the acquisition date as follows (amount in thousands):

Cash	$	146
Current assets		135
Fixed assets, net		188
Indefinite-lived intangible asset		1,292
Security deposits		8
Total assets acquired		1,769
Accounts payable		(12)
Accrued expenses		(240)
Total liabilities assumed		(252)
Net identifiable assets acquired		**1,517**
Goodwill		626
Total estimated consideration (1)	**$**	**2,143**
Less special consideration paid in cash and stock	$	(465)
Less cash acquired		(146)
Total consideration paid, net of cash acquired	$	1,532

(1) The purchase price allocation excludes $2.01 million stock consideration, which was recorded as stock-based compensation for accounting purposes, although the treatment for tax purposes is anticipated to be different (see Note 6), and $0.2 million payable for services not related to the Acquisition in either cash or stock within 120 days after the closing.

The Acquisition was accounted for under the acquisition method of accounting in accordance with US GAAP. As such, results of operations for Flaskworks are included in the accompanying consolidated statements of operations since the Acquisition date, and the assets acquired and liabilities assumed were recorded at their fair value as of the Acquisition date.

Accordingly, goodwill has been measured as the excess of the total consideration over the amounts assigned to the identifiable assets acquired and liabilities assumed. Based on the Company's valuation, the Company recorded goodwill of approximately $0.6 million, which was primarily related to the acquisition of the assembled workforce and other indefinite-lived intangible asset of approximate $1.3 million in connection with the Acquisition. The $0.6 million of goodwill is expected to be deductible for tax purposes.

The acquired Licensed IP Agreement was identified as an intangible asset and valued separate and apart from goodwill. Specifically, the Company used the Relief-from-Royalty Method, a form of the Income Approach, to estimate the fair value of the Licensed IP Agreement based on projected sales and cash flow. In application of the Relief-from-Royalty Method, we estimate the value of the Licensed IP Agreement by capitalizing the royalties saved because the Company owns the specific technology and the owner of the technology realizes a benefit from owning the intangible asset rather than paying a rent or royalty for the use of the asset.

The royalty rate used for this Licensed IP Agreement was based on the rate and terms indicated in the license agreement that was corroborated with the Company's external research of third-party royalty rates for technology and patents in the pharma, healthcare, and medical industries. The estimation of fair value was determined based on the projected sales assuming commercialization of Flaskworks' products and the respective royalty rate, tax affected and discounted to the present using a discount rate based on Flaskworks' weighted average cost of capital.

The purchase price allocation has been finalized as of December 31, 2021. There is no adjustment to the initial valuation.

6. Stock-Based Compensation

The following table summarizes total stock-based compensation expense recognized for the years ended December 31, 2021, 2020 and 2019 (in thousands). The stock-based compensation expense during the year ended December 31, 2021 was mostly related to the applicable portion vesting during this period of stock options awards made prior to 2021.

	For the years ended December 31,		
	2021	2020	2019
Research and development	$ 7,607	$ 19,792	$ 471
General and administrative	7,964	32,163	1,350
Total stock-based compensation expense	**$ 15,571**	**$ 51,955**	**$ 1,821**

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, 2021, 2020 and 2019:

	For the years ended December 31,		
	2021	2020	2019
Exercise price	$ 0.92	$ 0.26	$ 0.20
Expected term (years)	5.3	5.2	5.6
Expected stock price volatility	97 %	98 %	86 %
Risk-free rate of interest	1 %	0 %	1 %

The total unrecognized compensation cost was approximately $2.2 million as of December 31, 2021, and will be recognized over the next 2 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").

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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 of potential equity compensation equal to twenty percent of the outstanding securities of the Company, which is on an evergreen basis as under the Prior Plan.

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

The following table summarizes stock option activity for the Company's option plans during the years ended December 31, 2021, 2020 and 2019 (amount 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, 2019	100,159	$ 0.24	9.3	$ —
Granted	4,500	0.22	10.4	—
Outstanding as of December 31, 2019	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
Options vested (3)	282,890	$ 0.32	8.0	$ 107,443

(1) The options granted during the year ended December 31, 2020 included options already approved at various times during the 3 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 2 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) Approximately 237 million options are not exercisable until at least March 31, 2022.

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 6 months, until November 1, 2020 and correspondingly extended the contractual term for 6 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 officer, on August 5, 2020, the Company cancelled 1.75 million options which were originally issued in December 2019 and issued 3 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 Acquisition

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 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, 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.

7. Property, Plant and Equipment

Property, plant and equipment consist of the following at December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020	Estimated Useful Life
Leasehold improvements	$ 13,910	$ 81	Lesser of lease term or estimated useful life
Office furniture and equipment	310	219	3-5 years
Computer and manufacturing equipment and software	1,799	1,403	3-5 years
Land in the United Kingdom	92	93	NA
	16,111	1,796	
Less: accumulated depreciation	(1,084)	(756)	
Total property, plant and equipment, net	$ 15,027	$ 1,040	
Construction in progress	$ —	$ 9,074	

Depreciation expense was approximately $324,000, $87,000 and $21,000 for the years ended December 31, 2021, 2020 and 2019, 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 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 a license for collection and processing of human cells and tissues, and a license for manufacture of cell therapy products for compassionate use at its Sawston, UK facility in December 2021. All costs associated with the facility buildout were reclassified from construction in progress to leasehold improvements effective December 2021 as a result of the receipt of the MHRA license and amortized over the estimated useful life of the facility.

8. Notes Payable

2021 Activities

The following table summarizes outstanding debt as of December 31, 2021 (amount 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 million. The Commercial Loan bears interest at 8% per annum with a 22-month term. There are no principal repayments during the first 8 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 million.

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 8 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.

2020 Activities

The following table summarize outstanding debt as of December 31, 2020 (amount in thousands):

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Embedded Conversion Option	Carrying Value
Short term convertible notes payable							
6% unsecured (1)	Due	6 %	$ 3.09	$ 135	$ —	$ —	$ 135
8% unsecured (2)(3)(4)	4/30/2021	8 %	$ 0.85	2,125	(937)	2,507	3,695
				2,260	**(937)**	**2,507**	**3,830**
Short term notes payable							
8% unsecured (5)	Various	8 %	N/A	1,785	(51)	—	1,734
10% unsecured (6)	Various	10 %	N/A	263	—	—	263
12% unsecured (7)	On Demand	12 %	N/A	440	—	—	440
				2,488	**(51)**	**—**	**2,437**
Long term notes payable							
8% unsecured (8)	Various	8 %	N/A	7,160	(496)	—	6,664
6% secured (9)	3/25/2025	6 %	N/A	1,843	—	—	1,843
				9,003	**(496)**	**—**	**8,507**
Ending balance as of December 31, 2020				**$ 13,751**	**$ (1,484)**	**$ 2,507**	**$ 14,774**

(1) This $135,000 outstanding balance as of December 31, 2021 and 2020 consists of two separate 6% notes in the amounts of $110,000 and $25,000. In regard to the $110,000 note, the Company has made ongoing attempts to locate the creditor to repay or convert this note, but has been unable to locate the creditor to date. In regard to the $25,000 note, the holder has elected to convert these notes into equity, the Company has delivered the applicable conversion documents to the holder, and the Company is waiting for the holder to execute and return the documents.

(2) In February 2020, the Company entered into multiple one-year convertible notes (the "February Notes") with multiple holders (the "Holders") for an aggregate principal amount of $1.0 million. The Notes are convertible into common shares of the Company at $0.21 per share and bear interest at the rate of 10% per annum. Upon issuance of the February Notes, the Holders also received a 2-year warrant to purchase a total of 1.4 million common shares of the Company at an exercise price of $0.35 per share. The fair value of the warrants was approximately $79,000 on the grant date.

During the year ended December 31, 2020, the Company converted the entire February Notes, including $68,000 accrued interest into approximate 5.1 million shares of the Company's common stock.

In April 2020, the Company entered into a six-month convertible note (the "April Note") with an individual investor (the "Holder") with an aggregate principal amount of $0.8 million for cash proceeds of $0.7 million. The Company also incurred approximately $69,000 placement agent costs, including both a cash fee and the fair value of common stock warrants issued to the placement agent, which was recognized as additional debt discount.

The April Note bears interest at the rate of 10% per annum and is convertible into common shares of the Company at $0.17 per share plus a warrant to purchase a number of exercise shares equal to 50% of the number of common shares issued upon conversion (the "Conversion Warrants"). The Conversion Warrants will be exercisable until April 9, 2022 beginning on November 1, 2020, with an exercise price of $0.20 per share. The conversion option within the April Note is required to be bifurcated at fair value, which was approximately $0.4 million on the issuance date, resulting in additional debt discount to the April Note.

As consideration for entering into the April Note, the Company also agreed to amend the Holder's existing outstanding warrants to purchase 5.1 million common shares of the Company. The exercise price of the warrants was amended from $0.25 per share to $0.20 per share. The incremental change in fair value resulting from the amendment was approximately $51,000, which was recognized as additional debt discount to the April Note.

On August 3, 2020, the Company converted approximately $0.8 million of outstanding principal and $26,000 of accrued interest of the April Note into approximately 5.1 million shares of common stock and 2.5 million warrants with fair value of approximately $2.4 million. The Company also extinguished $1.5 million embedded derivative liability and $0.2 million unamortized debt discount upon the conversion. The Company recorded approximately $0.3 million debt extinguishment loss.

In April 2020, the Company entered into a Note Amendment Agreement (the "Amendment") with an individual holder of a short-term convertible note, primarily to agree on the following changes:

- Reclassed $75,000 accrued interest as of amendment date to the outstanding principal amount;
- Extended the maturity date of a convertible note with approximately $0.6 million of principal outstanding, as of the amendment date, to October 18, 2020 (the "Amended Note");
- Reduced the conversion price from $0.22 to $0.181
- Issued a new 2-year warrant for up to 2.3 million shares of the Company's common stock at an exercise price of $0.25 per share valued at $115,000 on the amendment date;

The amendment was recognized as a debt extinguishment, resulting in a loss on debt extinguishment of approximately $70,000.

During the year ended December 31, 2020, the Company converted the entire Amended Note of approximately $0.6 million, including $28,000 accrued interest into approximately 3.3 million shares of common stock.

(3) In May 2020, the Company entered into a six-month convertible note (the "May Note") with an individual investor (the "Holder") with an aggregate principal amount of $0.6 million. The May Note contains an OID in the amount of $50,000.

The May Note bears interest at the rate of 8% per annum and is convertible into common shares of the Company at $0.25 plus a warrant to purchase a number of exercise shares equal to 40% of the number of common shares issued upon conversion (the "Conversion Warrants"). The Conversion Warrants will be exercisable until November 28, 2022 beginning on November 1, 2020 with exercise price of $0.25 per share. The conversion option within the May Note required bifurcation at fair value, which was approximately $0.5 million on the issuance date, resulting in additional debt discount to the May Note.

On October 1, 2020, the Company converted the entire $0.6 million of the May Note including $19,000 accrued interest, into approximately 2.3 million shares of the Company's common stock and 0.9 million warrants with fair value of approximate $3.4 million. The Company also extinguished $2.8 million embedded derivative liability upon the conversion.

In August 2020, the Company entered into another convertible note (the "August Note") with the same investor as the May Note (the "Holder") with an aggregate principal amount of $1.1 million. The August Note contains OID in the amount of $110,000.

The August Note bears interest at the rate of 8% per annum and is convertible into common shares of the Company at $0.345 plus a warrant to purchase a number of exercise shares equal to 35% of the number of common shares issued upon conversion (the "Conversion Warrants"). The Conversion Warrants will be exercisable until February 4, 2023 beginning on December 15, 2020 with exercise price of $0.34 per share. The conversion option within the August Note is required to be bifurcated at fair value, which was approximately $0.6 million on the issuance date, resulting in additional debt discount to the August Note.

On September 29, 2020, the Company converted the entire $1.1 million balance remaining on the August Note into approximately 3.3 million shares of the Company's common stock and 1.1 million warrants with fair value of approximately $3.3 million. The Company also extinguished $2.3 million embedded derivative liability and $0.5 million unamortized debt discount upon the conversion. The company recorded approximately $0.4 million debt extinguishment loss.

(4) In October 2020, the Company entered into a convertible note (the "October Note") with the same investor as the August Note (the "Holder") with an aggregate principal amount of $2.1 million. The October Note contains OID in the amount of $200,000.

The October Note bears interest at the rate of 8% per annum and is convertible into common shares of the Company at $0.85 plus a warrant to purchase a number of exercise shares equal to 30% of the number of common shares issued upon conversion (the "Conversion Warrants"). The Conversion Warrants will be exercisable until January 12, 2022 beginning on January 15, 2021 with exercise price of $2.00 per share. The conversion option within the October Note is required to be bifurcated at fair value, which was approximately $1.4 million on the issuance date, resulting in additional debt discount of $1.4 million to the October Note.

(5) During the year ended December 31, 2020, the Company converted approximately $5.8 million of outstanding principal and $0.6 million of accrued interest into approximately 29.1 million shares of the Company’s common stock with a fair value of $7.6 million. The Company recognized approximately $1.2 million in debt extinguishment loss from this conversion.

(6) In May 2020, the Company converted approximately $0.3 million of outstanding principal and accrued interest into approximately 1.3 million shares of the Company’s common stock with a fair value of $0.5 million. The Company recognized approximately $0.2 million in debt extinguishment loss from this conversion.

In August 2020, the Company extinguished approximately $1.5 million of outstanding principal and accrued interest into approximately 4.8 million shares of the Company's common stock and 1.7 million warrants. The Company also modified certain existing warrants and issued additional 6.5 million warrants consideration for certain suspension. The Company also agreed to amend the remaining outstanding $1.5 million outstanding debt. The note became convertible at a conversion price of $0.34 (the “Amended August Note”). The amendment was accounted as debt extinguishment and the Company recognized approximately $1.6 million in debt extinguishment loss from this transaction.

During the year ended December 31, 2020, the Company made $0.1 million cash payment and converted approximate $1.4 million outstanding debt, including $15,000 accrued interest, into approximately 4.1 million shares of the Company’s common stock.

During the year ended December 31, 2020, the Company entered into multiple Note Extension Agreements with multiple holders, primarily resulting in the following changes:

- Extended the maturity dates of promissory notes with outstanding principal balances aggregating approximately $3.3 million for an additional 6 to 12 months from the original maturity date;

- Issued new 2-year warrants to purchase up to 10.3 million shares of the Company’s common stock at an exercise prices ranging from $0.20 and $0.23 per share valued at approximately $0.5 million on the amendment date;

The Note Extension Agreements for approximately $2.3 million of outstanding principal of promissory notes was recognized as a debt modification, while the amendments for approximately $1.0 million of outstanding principal of promissory notes was recognized as a debt extinguishment, resulting in a loss on extinguishment of debt of approximately $0.1 million.

(7) The $440,000 balance of outstanding principal as of December 31, 2021, 2020 and 2019 consists of two separate 12% demand notes in the amounts of $300,000 and $140,000.

(8) During the year ended December 31, 2020, the Company entered into two note purchase agreements (the “Loans”) with same investor for an aggregate principal amount of approximate $7.2 million. The Loans bear interest at 8% per annum with 21-month term. There are no repayments during the first 7 months of the term. The Loans are amortized in 14 installments starting in month 8. The Loans carry an OID of $650,000 and $10,000 legal costs that were reimbursable to the investor.

(9) Cambridge Loan

On March 26, 2020, the Company entered into a Loan Agreement (the “Loan Agreement”) with Cambridge & Peterborough Combined Authority (the “Lender”) for a loan of £1.35 million (approximately $1.7 million) (the “Cambridge Loan”) for the current phase of buildout of the Sawston facility. The Company received funds on April 6, 2020. The Lender provides funding for selected economic development projects in the Cambridge region through a competitive selection process.

Under the Cambridge Loan Agreement, there were no repayments during the first year of the Cambridge Loan term, although interest accrued. Following the first anniversary, repayment of the Cambridge Loan principal and interest are taking place over 4 years, for a total term of 5 years. The interest rate on the Cambridge Loan is 6.25% per annum.

In conjunction with the Cambridge Loan, the Company agreed to enter into a Security Agreement with the Lender under which the Company granted a security interest in the Company’s 17-acre property in Sawston, U.K. to secure the Cambridge Loan. No other tangible or intangible assets of the Company or its subsidiaries are subject to any security interest. Such security interest on the 17-acre property will be released upon completion of repayment.

PPP Loan

On May 20, 2020, the Company received a loan under the Coronavirus Aid, Relief and Economic Security (“CARES”) Act’s Paycheck Protection Program (“the 2020 PPP Loan") for the amount of $0.4 million. The terms of the PPP loan was two years with a maturity date of May 20, 2022 and it contained a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the 2020 PPP Loan were deferred for the first six months of the term of the 2020 PPP Loan until November 20, 2020. The Company used the loan to make payments for payroll, health and disability insurance and rent.

The Company submitted a PPP loan forgiveness application to the Lender on October 26, 2020, with the amount which may be forgiven equal to the sum of qualifying expenses, including payroll costs, covered rent obligations, and covered utility payments incurred by the Company during the twenty-four week period beginning on May 20, 2020, calculated in accordance with the terms of the CARES Act. The forgiveness application was approved on December 7, 2020. The Company recorded approximate $0.4 million debt extinguishment gain from the forgiveness of the 2020 PPP Loan during the year ended December 31, 2020.

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.

Interest Expenses Summary

The following table summarizes total interest expenses related to outstanding debt for the years ended December 31, 2021, 2020 and 2019, respectively (in thousands):

	For the years ended December 31,		
	2021	2020	2019
Interest expenses related to outstanding notes:			
Contractual interest	$ 2,347	$ 1,231	$ 1,168
Amortization of debt discount	2,301	2,891	1,430
Total interest expenses related to outstanding notes	**4,648**	**4,122**	**2,598**
Interest expenses related to outstanding notes to related parties:			
Contractual interest	—	20	366
Amortization of debt discount	—	122	—
Total interest expenses related to outstanding notes to related parties	**—**	**142**	**366**
Interest expenses related to forbearance of debt to related parties	—	4,270	—
Interest expenses related to payables to Advent BioServices	140	—	—
Other interest expenses	223	10	11
Total interest expense	**$ 5,011**	**$ 8,544**	**$ 2,975**

The following table summarizes the principal amounts of the Company's debt obligations as of December 31, 2021 (amount 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	2,320	2,320	—	—
9% unsecured	4,232	4,232		
12% unsecured	703	703	—	—
Long term notes payable				
1% unsecured	433	—	—	433
8% unsecured	25,938	—	25,938	—
6% secured	1,482	—	—	1,482
Total	**$ 35,243**	**$ 7,390**	**$ 25,938**	**$ 1,915**

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

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

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

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The following table sets forth the computation of earnings (loss) per share for the years ended December 31, 2021, 2020 and 2019 (amounts in thousands):

	For the years ended December 31,		
	2021	2020	2019
Net earnings (loss) - basic	$ 179,126	$ (529,821)	$ (20,812)
Reversal of gain due to change in fair value of warrant liability	(239,347)	—	—
Net loss - diluted	$ (60,221)	$ (529,821)	$ (20,812)
Weighted average shares outstanding - basic	873,517	695,423	564,188
Diluted shares- Options	38,496	—	—
Diluted shares- Warrants	95,780	—	—
Convertible notes and interest	76	—	—
Weighted average shares outstanding - diluted	1,007,869	695,423	564,188

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,		
	2021	2020	2019
Common stock options	266,350	308,840	104,659
Common stock warrants	129,689	328,979	347,734
Contingently issuable warrants	—	2,774	11,739
Convertible notes and accrued interest	—	2,617	2,617
Potentially dilutive securities	**396,039**	**643,210**	**466,749**

10. Related Party Transactions

Advent BioServices Services Agreement

The Company has a Manufacturing Services Agreement with Advent BioServices ("Advent"), a related party as discussed in Note 3, for the manufacture of DCVax-L products at an existing facility in London, as previously reported. The Company also has an Ancillary Services Agreement with Advent, which establishes a structure under which Advent submits Statements of Work (“SOWs”) for activities related to the development of the Sawston facility and the compassionate use activities in the UK, as previously reported. The Ancillary Services Agreement had an original term of eight months, which ended in July 2020. During the year ended December 31, 2020, the Company extended the initial term by 12 months to July 2021, with no other changes, and during the year ended December 31, 2021 extended the term for another 12 months to July 2022.

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 2 times the 5.75 pound sterling (approximate $7.76 per square foot based on exchange rate as of December 31, 2021) rate per square foot payable under the head lease, but subject to a cap of $10 per square foot. Accordingly, the lease payments under the Sublease are set at $144,590 per year. The total lease payments paid by the Company for the facility, exterior spaces and parking under the head lease are 500,000 pounds per year. 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 will start to recognize sub-lease income starting January 1, 2022.

Related Party Expenses and Accounts Payable

The Company recognized approximately $7.4 million, $7.5 million and $5.7 million in research and development costs from Advent for the years ended December 31, 2021, 2020 and 2019, respectively.

Additionally, the Company capitalized $3.2 million and $3.6 million costs related to the Sawston buildout as of December 31, 2021 and 2020, respectively. The buildout contractors and process were overseen by Advent, and buildout costs were reviewed and invoiced by Advent. Some of these amounts have been paid and some have not been paid for the year ended December 31, 2021, and 2020, respectively.

The following table summarizes outstanding unpaid accounts payable and accrued expenses held by related parties as of December 31, 2021 and 2020 (amount in thousands). These unpaid amounts include part of the expenses reported in the above section and also certain expenses incurred in prior periods:

	December 31, 2021	December 31, 2020
Advent BioServices – amount invoiced	$ 3,046	$ 3,734
Advent BioServices – amount accrued	—	1,629
Accounts payable and accrued expenses to Advent BioServices	$ 3,046	$ 5,363

As of December 31, 2021, there were approximately $0.8 million unpaid board compensation and [$0.1 million accrued for estimated expense reimbursements owed to an executive] that were also included in the accounts payable to related party on the consolidated balance sheets.

Related Parties Loans

Linda F. Powers - Demand Loans

Between February 2018 and April 2018, the Company's Chief Executive Officer, Linda Powers, loaned the Company aggregate funding of $5.4 million pursuant to convertible Notes. The Notes were 15-day demand notes, for loans provided as short-term bridge loans. However, repayment was not completed for nearly 1-1/2 years.

During the year ended December 31, 2019, the Company repaid the $5.4 million principal and approximately $0.8 million interest to Ms. Powers.

Loan from Advent BioServices

Advent BioServices, a related party as discussed in Note 3, 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 7 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, 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.

11. Stockholders' Deficit

2021 Activities

Common Stock

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 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.

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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 million (the "August Financing"). The financings were comprised of:

- Approximately $7 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 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 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, see Note 8 for further details.

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.

2019 Activities

Registered Direct Offering

During the year ended December 31, 2019, the Company issued an aggregate of 32.7 million shares of its common stock at a purchase price between $0.19 and $0.23 per share to certain institutional investors in multiple registered direct offerings (the "Offering"). Included with the Offering were 1.3 million shares of common stock which were issued from the conversion of an existing loan and the related accrued interest totaling $306,000. The net proceeds from the Offering were approximately $6.9 million, after deducting offering costs of $0.3 million paid by the Company.

In connection with the Offering, the Company did not issue any additional warrants for the new investment by the investors, but the Company, in effect, agreed to modify certain existing warrants already held by some of those investors. The Company extended the expiration date for additional 12 to 18 months after the original expiration date and the weighted average exercise price of warrants was reduced by an amount ranging from 2 to 8 cents as well. The Company recorded an incremental change of $2.5 million on the fair value of warrants due to the modification and recorded it as part of offering cost during the year ended December 31, 2019.

Debt Conversion

During the year ended December 31, 2019, the Company converted debt of approximately $6.8 million of principal and $0.7 million of accrued interest into approximately 35.5 million shares of the Company's common stock at a fair value of $9.2 million. The Company recorded approximately $1.7 million of debt extinguishment loss from the conversion.

Warrants Exercised for Cash

During the year ended December 31, 2019, the Company issued 9.5 million shares of its common stock from warrants exercised for cash. The Company received $2.2 million in cash.

Shares Settlement

On May 28, 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 the settlement agreement, the number of shares of the Company's common stock which the Company was to issue to Cognate was substantially reduced: 52 million shares of the Company's common stock which the Company had previously agreed to issue to Cognate were reduced to 12 million shares. The Company considers the reduction in shares owed to Cognate a modification. Because the 52 million shares were never issued and the modification, which resulted in a decrease in fair value, is not a forfeiture, previously recognized expense related to services performed by Cognate is not reversed in connection with this modification. During the year ended December 31, 2019, the Company recorded $12,000 in its common stock par and reduced same amount in additional paid-in capital.

Stock Purchase Warrants

The following is a summary of warrant activity for the years ended December 31, 2021, 2020 and 2019 (dollars in thousands, except per share data):

	Number of Warrants	Weighted Average Exercise Price	Remaining Contractual Term
Outstanding as of January 1, 2019	**372,153**	**$ 0.29**	**1.97**
Warrants granted	8,067	0.23	
Warrants exercised for cash	(9,532)	0.23	
Warrants expired and cancellation	(11,215)	0.62	
Outstanding as of December 31, 2019	**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**

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 after March 31, 2022.

At December 31, 2021, a total of approximately 240 million options and 102 million warrants were under block or suspension agreements.

At March 1, 2022, a total of approximately 237 million options and 121 million warrants were under block or suspension until between March 31, 2022 and May 15, 2022.

12. Commitments and Contingencies

Operating Lease- Lessee Arrangements

The Company adopted ASC Topic 842 - Leases as of January 1, 2019, using the transition method per ASU No. 2018-11 issued on July 2018 wherein entities were allowed to initially apply the new leases standard at adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Accordingly, all periods prior to January 1, 2019 were presented in accordance with the previous ASC Topic 840, Leases, and no retrospective adjustments were made to the comparative periods presented. Adoption of ASC 842 resulted in an increase to total assets and liabilities due to the recording of operating lease right-of-use assets ("ROU") and operating lease liabilities of approximately $4.3 million, as of January 1, 2019. On March 4, 2019, the Company recognized additional $0.6 million ROU and lease liabilities to its amended office lease in the U.S. The adoption did not materially impact the Company's consolidated statements of operations or cash flows.

The Company has operating leases for corporate offices in the U.S., U.K., and for manufacturing facilities in the U.K. 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 renewal options have not been included in the calculation of the lease liabilities and ROU as the Company is not reasonably certain 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.

On March 8, 2021, the Company extended its office lease in the U.S for additionalthree years and five months under an amended agreement. The extension included a waiver of any rent payment for the initial five-month extension period as well as insignificant change to monthly rent costs for the remainder of the lease. The Company recognized additional $0.7 million ROU assets and lease liabilities for its amended office lease in the U.S.

Operating Lease- Lessor Arrangements

On December 31, 2021, the Company entered into a Sub-lease Agreement (the "Agreement") with Advent BioServices, Ltd ("Advent"), a related party as discussed in Note 3. 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 2 times the 5.75 pound sterling (approximate $7.76 per square foot based on exchange rate as of December 31, 2021) 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 $144,590 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 will start to recognize sub-lease income starting January 1, 2022.

At December 31, 2021, the Company had operating lease liabilities of approximately $5.5 million in aggregate 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 of approximately $4.9 million for the Sawston lease and US office lease, which were included in the consolidated balance sheet.

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

	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 %	

	For the Year ended December 31, 2019		
	U.K	U.S	Total
Lease cost			
Operating lease cost	$ 607	$ 247	$ 854
Short-term lease cost	50	81	131
Variable lease cost	—	15	15
Total	$ 657	$ 343	$ 1,000
Other information			
Operating cash flows from operating leases	$ —	$ (244)	$ (244)
Weighted-average remaining lease term – operating leases	10.0	0.9	
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, 2021, 2020 and 2019.

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

Year ended December 31, 2022	$ 966
Year ended December 31, 2023	975
Year ended December 31, 2024	881
Year ended December 31, 2025	676
Year ended December 31, 2026	676
Thereafter	8,086
Total	12,260
Less present value discount	(6,717)
Operating lease liabilities included in the Consolidated Balance Sheet at December 31, 2021	$ 5,543

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

Year ended December 31, 2022	$ 145
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	$ 2,465

Manufacturing Services Agreements

The Company has a manufacturing services agreement with Advent BioServices in the U.K., a related party as discussed in Note 3.

Advent BioServices

On May 14, 2018, the Company entered into a DCVax®-L Manufacturing and Services Agreement (“MSA”) with Advent BioServices, a related party which was formerly part of Cognate BioServices and was spun off separately as part of an institutional financing of Cognate. The Advent Agreement provides for manufacturing of DCVax-L products at an existing facility in London. The Agreement is structured in the same manner as the Company’s prior agreements with Cognate BioServices. The Advent Agreement provided for a program initiation payment of approximately $1.0 million (which was fully paid in 2018), in connection with technology transfer and operations to the U.K. from Germany, development of new Standard Operating Procedures (SOPs) for the London facility, selection of new suppliers and auditing for GMP compliance, and other preparatory activities. The Advent Agreement 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. Either party may terminate the MSA on twelve months’ notice, to allow for transition arrangements by both parties.

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 may also cover agreement by the parties and SOWs for operational milestones and related payments. The Ancillary Services Agreement had an original term of eight months, which ended in July 2020. The Company extended the term by 12 months to July 2021, with no other changes, and recently extended it for another 12 months to July 2022.

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 (approximately $595,000) 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. The Company recently received tax bills for the 2016-2019 tax years that totaled €208,000. The Company is awaiting a decision on the appeal of the late charges prior to making any additional tax payments and determining next steps. Accruals have been made for the invoices received for the 2016-2019 tax years, but payment may be contingent on the outcome of our appeal. The Company has not accrued for the appealed late charges, as we believe this new bill is not consistent with the settlement that was reached with the federal and city officials earlier this year. Based on the Company's current operating state in Germany and the negotiations, the Company concluded based on its evaluation under ASC 740, the Company believes 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.

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, 2021 and 2020 are comprised of the following (in thousands):

	As of December 31, 2021	As of December 31, 2020
Deferred tax asset		
Net operating loss carryforward	$ 193,605	$ 185,308
Research and development credit carry forwards	17,982	18,580
Stock based compensation and other	23,637	22,997
Total deferred tax assets	235,224	226,885
Valuation Allowance	(235,224)	(226,885)
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, 2021, are approximately $682.9 million. Unused NOL carryforwards from years prior to 2018 of $537.1 million will begin to expire in 2021 through 2037. NOL incurred in 2018 and later amount to $145.7 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. 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, 2021 are $32.4 million. NOL in the United Kingdom and Germany of $15.5 million and $16.6 million respectively do not expire over time. NOL in the Netherlands of $0.3 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, 2021 and 2020.

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, 2021	As of December 31, 2020
Statutory federal income tax rate	21.0 %	21.0 %
State taxes, net of federal tax benefit	(2.0)%	1.1 %
Tax rate differential on foreign income	0.1 %	(0.0)%
Derivative gain or loss	(28.0)%	(17.3)%
Expiration of net operating losses	3.9 %	(1.5)%
Other permanent items and true ups	0.1 %	(0.1)%
R&D Credit	0.3 %	0.3 %
Change in valuation allowance	4.6 %	(3.5)%
Income tax provision (benefit)	0.0 %	0.0 %

	As of December 31, 2021	As of December 31, 2020
Federal		
Current	$ —	$ —
Deferred	(5,765)	(15,539)
State		
Current	—	—
Deferred	(1,975)	(4,327)
Foreign		
Current		
Deferred	(599)	670
Change in valuation allowance	8,339	19,196
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, 2021, 2020, and 2019, 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, 2021, 2020 and 2019. 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

In total, the Company received $5.4 million from exercises of warrants, issuance of notes and common stock between January 1, 2022 and February 25, 2022.

During January and February 2022, 8.0 million shares of common stock were issued upon warrant exercises for proceeds of approximately $2.4 million.

During January and February 2022, the Company received $2.4 million from issuance of 3.6 million shares of common stock to various investors.

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During February 2022, the Company issued approximately 26,000 shares of common stock upon 56,000 warrant cashless exercises.

During January 2022, the Company entered into multiple four-month note agreements (the "Notes") with various individual lenders (the "Holders") with an aggregate principal amount of $0.63 million for net proceeds of $0.6 million. The Notes contain a conditional piggy-back right to independently purchase shares from the Company, which provides a right for the Holders, contingent on the release of clinical trial data and the next private placement offering ("Next Offering") after this release, to (a) purchase shares from the Company within seven days following such Next Offering at a 12% discount from the share price of the Next Offering for a variable number of shares equal to an amount up to 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, within seven days after the Next Offering at a 12% discount, resulting in a reduced cash amount repayable under the loan agreement.

On February 28, 2022, the Company further extended the suspension of the exercise rights of approximately 295.7 million warrants and options held by certain of the Company's officers and board of directors until at least March 31, 2022. Additionally, certain investors also agreed to suspend exercise rights of approximately 18.6 million warrants until May 15, 2022.